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QIAstat-Dx® BCID GN Plus AMR Panel Instructions for Use

IVD For In Vitro Diagnostic Use

For use with QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

	Σ	REF	Version
QIAstat-Dx BCID GPF Plus AMR Panel	6	691814	Version 1

CE 0197

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Sample to Insight

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1. Intended Use

The QIAstat-Dx® BCID GN Plus AMR Panel is an automated qualitative multiplexed real-time PCR-based in vitro diagnostic test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial targets and selected genetic determinants associated with antimicrobial resistance.

The following gram-negative bacteria are identified and differentiated using the QIAstat-Dx BCID GN Plus AMR Panel:

- *Acinetobacter calcoaceticus-baumannii* complex
- *Bacteroides fragilis*
- *Enterobacter* spp.
- *Escherichia coli*
- *Haemophilus influenzae*
- *Klebsiella* spp.
- *Neisseria meningitidis* (Encapsulated)
- *Proteus* spp.
- *Pseudomonas aeruginosa*
- *Salmonella* spp.
- *Serratia* spp.
- *Stenotrophomonas maltophilia*
- Pan *Enterobacterales*

The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of the following genetic determinants of resistance:

- *aac(6')-Ib*
- *ampC* (CMY/LAT/DHA/FOX)
- *armA*
- CTX-M
- GES
- IMP
- KPC

- NDM
- OXA-23
- OXA-24/40
- OXA-48-like
- OXA-58
- PER
- SHV
- SPM
- TEM
- VEB
- VIM

The QIAstat-Dx BCID GN Plus AMR Panel is intended for use in patients suspected of having gram-negative bacterial infections identified as such via Gram stain in the following sample types:

Positive blood culture samples

The test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain.

The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens of bloodstream infection and select determinants of anti-microbial resistance. Results should be used in conjunction with additional laboratory testing, e.g. sub-culturing of positive blood cultures for identification of organisms not detected by QIAstat-Dx BCID GN Plus AMR Panel and susceptibility testing and clinical presentation must be taken into consideration for patient management decisions.

Negative results do not preclude the presence of pathogens that are not detected by this test. Positive QIAstat-Dx BCID GN Plus AMR Panel results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GN Plus AMR Panel.

Negative AMR results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure.

Pure colonies

The test is performed on pure colonies of gram-negative bacteria.

The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens isolated in culture plates and to aid clinicians in determining appropriate therapeutic strategies for known or suspected non-susceptible bacterial infections.

Negative results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure.

The QIAstat-Dx BCID GN Plus AMR Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional and is not intended for self-testing.

2. Intended User

The QIAstat-Dx BCID GN Plus AMR Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional and is not intended for self-testing.

3. Description and Principle

3.1. Summary and explanation

Bloodstream infections (BSIs) are serious, life-threatening conditions defined by the presence of viable microorganisms in the bloodstream that trigger a systemic inflammatory response. The majority of BSIs are bacterial in origin, while approximately 10% are caused by fungal pathogens. Diagnosis is typically confirmed through positive blood cultures (1).

Like other infections, BSIs can progress to sepsis which is a dysregulated host response to infection resulting in life-threatening organ dysfunction. Both BSIs and sepsis carry a substantial public health burden and are associated with high rates of morbidity and mortality (1,2). Exacerbating this challenge is the ongoing rise in antimicrobial resistance (AMR) among causative pathogens. With resistant infections projected to significantly impact global mortality in the coming decades, there is an urgent need for an innovative approach to prevention, diagnosis, and treatment (1,3).

The QIAstat-Dx BCID GN Plus AMR Panel offers rapid multiplex detection of gram-negative bacteria and key AMR genetic markers commonly associated with gram-negative organisms - all within a single cartridge. When integrated with antimicrobial stewardship programs, rapid diagnostic tools for blood cultures can support timely and targeted antimicrobial therapy. This approach has the potential to reduce mortality, shorten hospital stays, and decrease healthcare costs for patients with BSIs and sepsis.

3.2. Pathogen information

***Acinetobacter calcoaceticus-baumannii* complex** (ACB complex) comprises closely related gram-negative, non-fermenting coccobacilli that are major nosocomial pathogens worldwide. Species within this complex include *A. baumannii, A. calcoaceticus, A. dijkshoorniae, A. nosocomialis, A. pittii,* and *A. seifertii,* with *A. baumannii* as the most common cause of human infections. Unfortunately, *Acinetobacter* isolates at the species level are not easily identified due to phenotypic and genotypic similarities. Molecular tests are often necessary for correct identification (4). BSIs due to the ACB complex frequently occur in critically ill patients with invasive devices or prolonged hospitalization and are associated with significant morbidity, mortality, and healthcare burden. *A. baumannii* has a remarkable ability to acquire multidrug-resistance through diverse mechanisms, leading to limited therapeutic options. The prevalence of carbapenem-resistant strains further complicates treatment and

underscores the clinical importance of accurate detection and management of these infections (5).

Bacteroides fragilis is a gram-negative obligate anaerobe and a predominant member of the human gut microbiota (6). Although normally commensal, it becomes an important opportunistic pathogen when the intestinal barrier is disrupted, such as after abdominal surgery, trauma, or inflammation, allowing translocation into sterile sites and the bloodstream (7). It is the most frequently isolated anaerobe in bacteremia, often occurring in the context of intra-abdominal infections and polymicrobial sepsis. BSIs with *B. fragilis* are associated with significant morbidity and mortality, with reported crude mortality rates around 20–30% in hospitalized patients. The species possesses virulence factors, including capsular polysaccharides that promote abscess formation, and may exhibit antimicrobial resistance which complicates therapy. Appropriate antimicrobial treatment and source control are critical for favorable outcomes in *B. fragilis* BSI (6).

Enterobacterales **(Pan)** is an order of gram-negative, facultatively anaerobic bacilli that includes common pathogens such as *Escherichia coli, Klebsiella pneumoniae, Enterobacter* spp., *Proteus* spp., and others (8). These organisms are among the most frequent causes of BSIs worldwide, accounting for a substantial proportion of gram-negative bacteremia in both community and healthcare settings (9). *Enterobacterales* BSIs are associated with significant morbidity and mortality, particularly when caused by multidrug-resistant strains such as extended-spectrum β-lactamase (ESBL) or carbapenem-resistant *Enterobacterales* (CRE), which limit effective treatment options and worsen clinical outcomes. Their clinical significance makes *Enterobacterales* a primary focus of sepsis management and antimicrobial stewardship efforts (10,11).

Enterobacter **spp.** are gram-negative, facultatively anaerobic bacilli within the *Enterobacterales* order, commonly found in the human gastrointestinal tract and the environment. *E. cloacae* and *E. hormaechei* represent the most frequently isolated species described in clinical infections, especially in immunocompromised patients and those hospitalized in an intensive care unit (ICU). *Enterobacter* spp. contributes significantly to nosocomial bacteremia, often complicated by multidrug resistance mechanisms (12).

Escherichia coli is a gram-negative, facultatively anaerobic bacillus that commonly inhabits the human gut but also stands out as the most frequent cause of bacterial BSIs worldwide (13,14). It accounts for a large proportion of both community- and healthcare-associated bacteremia, often originating from urinary tract, abdominal, or other focal infections (13). These infections carry substantial morbidity and mortality, and outcomes worsen with antimicrobial resistance, including ESBL production (15).

***Klebsiella* spp**. are gram-negative, facultatively anaerobic bacilli within the *Enterobacterales* order, with *Klebsiella pneumoniae* being the most clinically significant species (16). These organisms are major causes of BSIs in both healthcare and community settings, particularly among patients with comorbidities, invasive devices, or prolonged hospital stays. The clinical impact of *Klebsiella* spp. BSIs has been amplified by the global spread of multidrug-resistant strains, including ESBL producers and carbapenem-resistant *Klebsiella pneumoniae* (CRKP), which limit therapeutic options and worsen outcomes (16,17).

***Proteus* spp.** are gram-negative, facultatively anaerobic bacilli within the *Enterobacterales* order and are part of the normal human intestinal microbiota (18). Among them, *Proteus mirabilis* is the species most frequently associated with human disease (19). *Proteus* spp. are well-recognized causes of BSIs, and infections often arise secondary to urinary tract infections, especially in individuals with urinary catheters or structural abnormalities (18,19). Clinical management may be complicated by intrinsic and acquired antimicrobial resistance, including reduced susceptibility to multiple β-lactams (19).

***Salmonella* spp.** are gram-negative, facultatively anaerobic bacilli belonging to the *Enterobacterales* order and are important human pathogens worldwide. *Salmonella* serovars are classified into typhoidal and nontyphoidal. In industrialized countries, nontyphoidal *Salmonella* is transmitted predominantly by commercially produced food contaminated by animal feces, and it usually causes a self-limited gastroenteritis (20). Approximately 5% of individuals with gastrointestinal illness caused by nontyphoidal *Salmonella* will develop bacteremia, especially in immunocompromised patients (21). Typhoidal *Salmonella* is an invasive disease characterized by BSI, and transmitted predominantly through water or food contaminated with human feces. Enteric fever in high-income countries is usually acquired abroad and is associated with travel to areas of endemicity (20).

***Serratia* spp**. are gram-negative, facultatively anaerobic bacilli belonging to the *Enterobacterales* order, widely distributed in the environment (22). Among them, *Serratia marcescens* is the species most commonly associated with human disease (23). *Serratia* spp. are recognized causes of healthcare-associated BSIs, particularly in critically ill patients and those with invasive devices such as central venous catheters (24). Clinical management is often complicated by intrinsic and inducible antimicrobial resistance, including chromosomal AmpC β-lactamase production, which can limit therapeutic options (22,23).

Haemophilus influenzae is a gram-negative, facultatively anaerobic coccobacillus that colonizes the human upper respiratory tract (25). It is an important cause of invasive disease, including BSIs, particularly in young children, older adults, and immunocompromised individuals. Historically, encapsulated *H. influenzae* type b (Hib) was a leading cause of

bacteremia and sepsis in children; although Hib vaccination has dramatically reduced incidence. However, non-typeable *H. influenzae* strains have become more prevalent and are now a leading cause of invasive infections (26). Antimicrobial resistance, including β-lactamase production and altered penicillin-binding proteins, can complicate treatment, underscoring the importance of prompt detection and appropriate antimicrobial therapy (27).

***Neisseria meningitidis* (encapsulated)** is a gram-negative, aerobic diplococcus that colonizes the human nasopharynx and is an important cause of invasive meningococcal disease, including BSIs (28,29). Of the 13 different polysaccharide capsular types, only 6 commonly cause disease globally: A, B, C, W-135, X, and Y, although substantial rates of serogroup X disease are restricted to parts of sub-Saharan Africa. Serogroup A *N. meningitidis* occurs primarily in the meningitis belt of sub-Saharan Africa and is responsible for the largest and most devastating meningococcal epidemics (29). Although disease incidence is relatively low compared with other bacterial BSIs, *N. meningitidis* infections are associated with high morbidity and mortality, particularly in children, adolescents, and young adults. Rapid diagnosis and prompt antimicrobial therapy are critical, as the clinical course can deteriorate quickly. Vaccination programs have substantially reduced disease burden, but meningococcal BSIs remain a serious public health concern (28).

Pseudomonas aeruginosa is a gram-negative, aerobic, non-fermenting bacillus widely distributed in the environment and a prominent opportunistic pathogen in healthcare settings. It is an important cause of BSIs, particularly among critically ill, immunocompromised patients and those with invasive devices, burns, or prolonged hospitalization (30). *P. aeruginosa* BSIs are associated with high morbidity and mortality, partly due to the organism's intrinsic resistance to multiple antimicrobial classes and its ability to rapidly acquire additional resistance mechanisms (30–32). Delayed appropriate antimicrobial therapy is strongly associated with worse outcomes, highlighting the importance of rapid detection and susceptibility-guided treatment (32).

Stenotrophomonas maltophilia is a gram-negative, obligate aerobic, non-fermenting bacillus widely distributed in aqueous environments and increasingly recognized as an opportunistic pathogen in healthcare settings. It is an important cause of BSIs, particularly among immunocompromised patients, those with malignancy, prolonged hospitalization, or indwelling intravascular devices. Clinical management is challenging because the organism exhibits intrinsic resistance to many broad-spectrum antibiotics, including most β-lactams and carbapenems. BSIs often originate from catheter-related sources or respiratory infections (33).

3.3. Antimicrobial Resistance Genes

3.3.1. Ambler Class A β-lactamases (serine β-lactamases)

CTX-M β-lactamases are a family of ESBLs that confer resistance to extended-spectrum cephalosporins (such as cefotaxime, ceftriaxone, ceftazidime, or cefepime) and monobactams (aztreonam), and are among the most prevalent ESBLs worldwide. Genes encoding CTX-M enzymes (bla_{CTX-M}) are typically plasmid-mediated, facilitating rapid dissemination among *Enterobacterales,* particularly *E. coli* and *K. pneumoniae*. Within the CTX-M enzymes, the CTX-M-15 and CTX-M-14 are by far the most important ones, virtually invading all human and animal compartments as well as the environment all over the world (34).

GES β-lactamases (Guiana extended-spectrum β-lactamases) are a heterogeneous family of enzymes that confer resistance to extended-spectrum cephalosporins (including GES-1) and, in some variants, carbapenems (including GES-2, GES-4, GES-5, GES-6, and GES-14). However, GES enzymes do not hydrolyze aztreonam. Genes encoding GES enzymes (bla_{GES}) are typically carried on integrons and plasmids, facilitating dissemination among gram-negative bacteria, including *K. pneumoniae, P. aeruginosa,* and other *Enterobacterales* (35,36). Although still rare, according to scattered reports, GES enzymes have been identified worldwide (36).

KPC (*Klebsiella pneumoniae* carbapenemase) is a class A serine β-lactamase that confers resistance to carbapenems, penicillins, cephalosporins, and aztreonam. Genes encoding KPC enzymes (bla_{KPC}) are typically plasmid-mediated and have disseminated widely among *Enterobacterales,* particularly *K. pneumoniae,* but also *E. coli* and *Enterobacter* spp. (36,37). KPC-producing organisms are a major cause of BSIs associated with high morbidity and mortality, largely due to delayed effective therapy and limited treatment options. KPC enzymes are endemic in several regions, including parts of the United States, southern Europe, South America, and Asia, and are frequently associated with healthcare-associated outbreaks (36). KPC variants vary with geographic location, being KPC-2 and KPC-3 the most predominant (37).

PER β-lactamases are class A ESBLs that confer resistance to penicillins and extended-spectrum cephalosporins, and may reduce susceptibility to aztreonam (38). Genes encoding PER enzymes (bla_{PER}) are often located on plasmids or integrons, facilitating dissemination among gram-negative pathogens, particularly *P. aeruginosa, Acinetobacter* spp., and *Enterobacterales* (39,40). From an epidemiological perspective, PER enzymes remain relatively uncommon globally but are endemic or sporadically reported in specific regions,

including the mediterranean basin, the Middle East, and South America. PER-1 is the most prevalent and widely distributed variant, while PER-2 has been reported mainly in South America (39,41).

SHV β-lactamases are class A enzymes that were initially described as narrow-spectrum β-lactamases intrinsic to *K. pneumoniae,* but later evolved into important ESBLs through point mutations. Genes encoding SHV enzymes (bla_{SHV}) are frequently plasmid-borne, enabling dissemination among *Enterobacterales*. Epidemiologically, SHV enzymes have a global distribution, although they have been partly displaced by CTX-M enzymes in many regions. The most prevalent ESBL variants include SHV-2, SHV-5, and SHV-12, which confer resistance to extended-spectrum cephalosporins and aztreonam. Among the non-ESBL variants, SHV-11 represents one of the most reported worldwide together with SHV-1 (42).

TEM β-lactamases are class A enzymes and among the earliest and most widespread β-lactamases described in gram-negative bacteria. Initially identified as narrow-spectrum enzymes conferring resistance to penicillins, TEM variants subsequently evolved into important ESBLs through point mutations. Genes encoding TEM enzymes (bla_{TEM}) are commonly plasmid-mediated and widely disseminated among *Enterobacterales,* particularly *E. coli* and *K. pneumoniae*. Although TEM-type ESBLs have been largely overtaken epidemiologically by CTX-M enzymes, variants such as TEM-3 and TEM-10 remain clinically relevant in certain regions (43).

VEB β-lactamases (vietnamese extended-spectrum β-lactamases) are class A ESBLs that confer resistance to extended-spectrum cephalosporins and aztreonam (44). Genes encoding VEB enzymes (bla_{VEB}) are typically located on integrons and plasmids, facilitating horizontal dissemination among gram-negative bacteria, particularly *P. aeruginosa, Acinetobacter* spp., and *Enterobacterales* (43). Epidemiologically, VEB enzymes have a limited but global distribution, with higher prevalence reported in Southeast Asia, the Middle East, and parts of Europe. VEB-1 is by far the most prevalent and clinically significant variant (45).

3.3.2. Ambler Class B β-lactamases (metallo β-lactamases)

Metallo-β-lactamases (MBLs) are zinc-dependent carbapenemases that hydrolyze most β-lactam antibiotics, including carbapenems. Unlike other β-lactams, aztreonam is generally not hydrolyzed by MBLs, although susceptibility may be affected by co-produced β-lactamases:

IMP metallo-β-lactamases (MBLs) are class B carbapenemases that confer resistance to carbapenems and most other β-lactams, with the exception of aztreonam (46). Genes

encoding IMP enzymes (*bla*$_{IMP}$) are typically carried on integrons and plasmids, facilitating horizontal spread among gram-negative bacteria, particularly *P. aeruginosa, Acinetobacter* spp., and *Enterobacterales*. Epidemiologically, IMP enzymes were among the first carbapenemases described and remain endemic in parts of Asia-Pacific regions, while sporadic cases and outbreaks occur worldwide (36). The most prevalent variants include IMP-1 and IMP-4 (46).

NDM (New Delhi metallo-β-lactamase) enzymes are class B MBLs that confer resistance to carbapenems and nearly all other β-lactams, with the exception of aztreonam. Genes encoding NDM enzymes (*bla*$_{NDM}$) are typically plasmid-mediated and frequently associated with additional resistance determinants, resulting in multidrug- or extensively drug-resistant phenotypes. *K. pneumoniae* and *E. coli* are important NDM-producing organisms. Epidemiologically, NDM enzymes emerged in the late 2000s and have since spread globally, with high prevalence reported in South Asia, the Middle East, and parts of Europe. NDM-1 is the most prevalent variant worldwide (36).

SPM (São Paulo metallo-β-lactamase) is a class B MBL that confers resistance to carbapenems and most other β-lactams, except aztreonam. The gene encoding SPM (*bla*$_{SPM}$) is typically chromosomally located within mobile genetic elements and has been predominantly associated with *P. aeruginosa* (47). Epidemiologically, SPM shows a highly restricted geographic distribution, being largely confined to Brazil, where it has caused persistent endemicity and hospital outbreaks since its first description. SPM-1 is the only widely recognized and clinically significant variant (48).

VIM (Verona integron-encoded metallo-β-lactamase) enzymes are class B MBLs that confer resistance to carbapenems and most β-lactams, while aztreonam typically remains active unless additional mechanisms are present (36). VIM-producing organisms include mainly *P. aeruginosa, K. pneumoniae,* and other *Enterobacterales*. Epidemiologically, VIM enzymes have a broad global distribution, with endemicity reported in southern Europe, the Mediterranean basin, and parts of Asia, and sporadic spread worldwide. The most prevalent variant is VIM-2 (47).

3.3.3. Ambler Class C β-lactamases (serine cephalosporinases - ampC)

***ampC* (CMY/LAT/DHA/FOX)** β-lactamases are class C enzymes that confer resistance to most penicillins, narrow- and broad-spectrum cephalosporins, cephamycins (e.g. cefoxitin), and aztreonam and are not inhibited by classical β-lactamase inhibitors (49). Cefepime and carbapenems generally retain activity against *ampC*-producing organisms, although resistance may occur when additional mechanisms are present (50). In addition to

chromosomal *ampC* (e.g. in *Enterobacter, Citrobacter, Serratia* spp.), plasmid-mediated *ampC* variants play an important role in *E. coli* (49). Minor differences in amino acid sequence have given rise to families, such as CMY, LAT, DHA, and FOX, with CMY-2 being the most prevalent variant globally (50).

3.3.4. Ambler Class D β-lactamases (serine oxacillinases)

OXA-23 is a class D carbapenem-hydrolyzing β-lactamase predominantly associated with *A. baumannii*. The gene bla_{OXA-23} is usually located on plasmids or within transposons, facilitating rapid dissemination. Epidemiologically, OXA-23 is the most widespread carbapenemase in *A. baumannii,* with global distribution and endemicity in many hospitals worldwide, particularly in ICUs. Within the OXA-23-like group, OXA-23 itself remains by far the most prevalent and clinically significant (51).

OXA-24/40 β-lactamases are class D carbapenem-hydrolyzing enzymes primarily associated with *Acinetobacter baumannii* (51). Epidemiologically, OXA-24/40 enzymes have a global distribution, with higher prevalence reported in Europe, the United States, and parts of Asia. Within the OXA-24/40-like group, OXA-24/40 is the most prevalent variant (52).

OXA-48-like β-lactamases are class D carbapenemases that confer resistance primarily to penicillins and carbapenems and may reduce susceptibility to temocillin, while often sparing extended-spectrum cephalosporins, which can complicate phenotypic detection. Apart from the previous OXA families mostly described in *Acinetobacter,* OXA-48-like enzymes are particularly associated with *Enterobacteriaceae*. Genes encoding OXA-48-like enzymes ($bla_{OXA-48-like}$) are usually plasmid-mediated and highly transmissible among *Enterobacterales,* particularly *K. pneumoniae*. Epidemiologically, OXA-48-like enzymes have a wide global distribution, with endemicity in North Africa, the Middle East, and Europe, and increasing spread worldwide (51).

OXA-58 is a class D carbapenem-hydrolyzing β-lactamase predominantly associated with *A. baumannii* (51). The gene bla_{OXA-58} is usually plasmid-borne and frequently linked to insertion sequences that enhance expression, contributing to carbapenem dissemination. Epidemiologically, OXA-58 shows a global but heterogeneous distribution, with higher prevalence historically reported in Europe, the Mediterranean region, and parts of Asia (51,52).

3.3.5. Aminoglycoside resistance

armA encodes a 16S rRNA methyltransferase that confers high-level resistance to all clinically relevant aminoglycosides. The gene *armA* is typically plasmid-mediated and frequently associated with other resistance determinants, resulting in extensively drug-resistant phenotypes, particularly in *Enterobacterales, A. baumannii,* and *P. aeruginosa*. Unlike β-lactamases, *armA* shows minimal sequence diversity. Epidemiologically, *armA* is globally distributed, with higher prevalence reported in Asia and Europe (53).

aac(6')-Ib encodes an aminoglycoside 6'-N-acetyltransferase that confers resistance to several aminoglycosides, including amikacin, tobramycin, and kanamycin. The gene *aac(6')-Ib* is typically plasmid-mediated and widely disseminated among *Enterobacterales*. Epidemiologically, *aac(6')-Ib* is one of the most prevalent aminoglycoside resistance genes worldwide. The most clinically important variant is *aac(6')-Ib-cr,* which additionally reduces susceptibility to fluoroquinolones, enhancing its clinical and epidemiological significance in BSIs (54,55).

3.4. Principle of the procedure

The QIAstat-Dx BCID GN Plus AMR Panel Cartridge is a single-use, fully automated molecular testing device designed to detect Gram-negative bacteriaand antimicrobial resistance markers from positive blood culture samples. Key features include:

- **Pre-loaded, self-contained reagents** for complete test execution
- **Hermetically sealed design** for safe handling and disposal
- **Walk-away operation**, with all steps performed inside the cartridge
- **Microfluidic pneumatic system** ensures reagent movement without direct contact
- **Environmental safeguards** via filtered air handling in QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0

The cartridge enables automation of all testing steps, enhancing safety, efficiency, and ease of use.

After the QIAstat-Dx BCID GN Plus AMR Panel Cartridge containing the sample is introduced into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, the following assay steps occur automatically:

- Resuspension of Internal Control
- Cell lysis using mechanical and/or chemical means
- Membrane-based nucleic acid purification
- Mixing of the purified nucleic acid with lyophilized master mix reagents
- Transfer of defined aliquots of eluate/master mix to different reaction chambers
- Performance of multiplex real-time PCR testing within each reaction chamber

Note: An increase in fluorescence, indicating detection of the target analyte, is detected directly within each reaction chamber.

The layout and features of QIAstat-Dx BCID GN Plus AMR Panel Cartridge is shown in Figure 1.

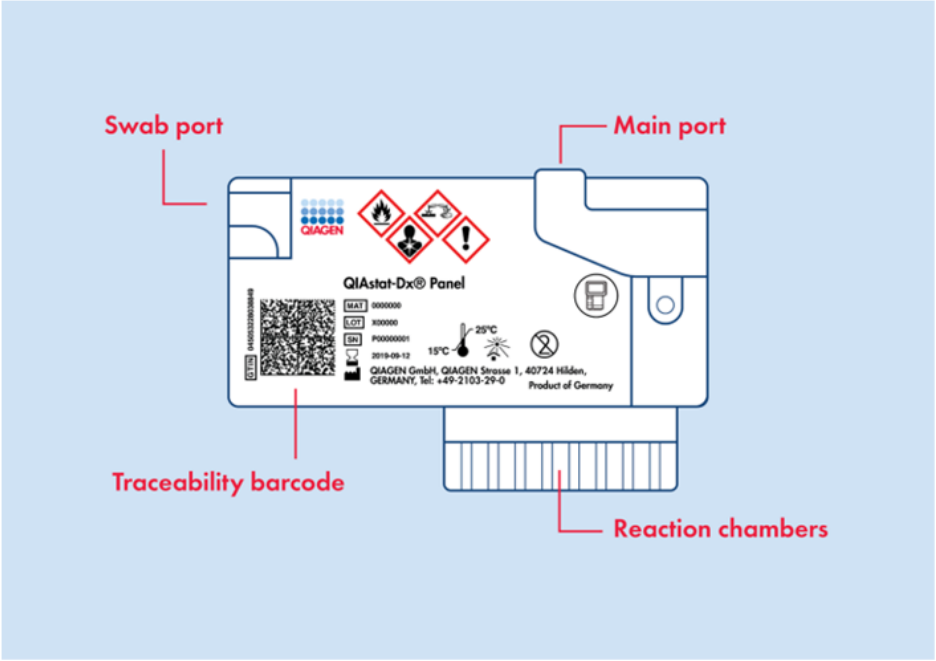


Figure 1. Layout of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge and its features.

Note: The swab port is not used for the QIAstat-Dx BCID GN Plus AMR Panel assay.

4. Materials Provided

4.1. Kit contents

QIAstat-Dx BCID GN Plus AMR Panel	
Catalog no.	**691814**
Number of preps	**6**
QIAstat-Dx BCID GN Plus AMR Panel Cartridge*	6
Transfer pipettes†	6

* 6 individually packaged cartridges containing all reagents needed for sample preparation and multiplex real-time RT-PCR, plus Internal Control.

† 6 individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx BCID GN Plus AMR Panel Cartridge.

4.2. Active ingredients

Reagent	Critical/Active ingredient	Concentration/range
QIAstat-Dx BCID GN Plus AMR Panel	Internal Control	40,000–60,000 CFU/cartridge
	Proteinase K	≥0.1% to <1%
	Reverse Transcriptase	20–100 U/cartridge
	dNTP	1–5 mM
	DNA polymerase	10–100 U/cartridge
	Target specific primers	100–1000 µM
	Target specific fluorophore labelled detection probe	100–1000 µM

5. Materials Required but not Provided

5.1. Platform and software

Important: Prior to use, ensure that the instrument has been checked and calibrated according to the manufacturer's recommendations.

The QIAstat-Dx BCID GN Plus AMR Panel is designed for use with QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0. Before beginning a test, ensure that the following are available:

- For QIAstat-Dx Analyzer 1.0*
  - at least one Operational Module and one Analytical Module must be installed with software version 1.5†

    Note: Application software version 1.6 or later cannot be installed on QIAstat-Dx Analyzer 1.0.
  - *QIAstat-Dx Analyzer 1.0 User Manual* (for use with software version 1.5)
- For QIAstat-Dx Analyzer 2.0:
  - at least one Operational Module PRO and one Analytical Module with software version 1.6 or later
  - *QIAstat-Dx Analyzer 2.0 User Manual* (for use with software version 1.6 or later)
- QIAstat-Dx latest Assay Definition File software for the QIAstat-Dx BCID GN Plus AMR Panel installed in the Operational module or Operational Module PRO

Note: QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 have dedicated ADFs to ensure proper functionalities on each instrument. Each dedicated ADF is properly indicated in the QIAGEN webpage.

*QIAstat-Dx Analyzer 1.0 is no longer commercially available.

† DiagCORE® Analyzer instruments running QIAstat-Dx software version 1.5 can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

6. Warnings and Precautions

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

- The QIAstat-Dx BCID GN Plus AMR Panel is for in vitro diagnostic use.
- The QIAstat-Dx BCID GN Plus AMR Panel is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

6.1. Safety information

- When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF at **www.qiagen.com/safety** where you can find, view, and print the SDS for each QIAGEN kit and kit component.
- Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the Biosafety in Microbiological and Biomedical Laboratories from the Centers for Disease Control and Prevention and the National Institutes of Health (**https://www.cdc.gov/labs/BMBL.html**).
- Specimens and samples are potentially infectious. Discard sample and assay waste according to your local safety procedures.
- Always wear appropriate personal protective equipment and follow your laboratory's safety procedures for handling biological samples. Handle all samples, cartridges, and transfer pipettes as if they are capable of transmitting infectious agents.
- Always observe safety precautions as outlined in relevant guidelines, such as the *Clinical and Laboratory Standards Institute® (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections*; Approved Guideline (M29), or other appropriate documents provided by local authorities.
- The QIAstat-Dx BCID GN Plus AMR Panel Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0. Do not use a QIAstat-Dx BCID GN Plus AMR Panel Cartridge that is past its expiration date, appears damaged, or leaks fluid.

- Dispose of samples, used or damaged cartridges, and transfer pipettes in accordance with all national, state, and local health and safety regulations and laws.
- In the event of cartridge leakage, follow the *QIAstat-Dx Analyzer 1.0 User Manual* or *QIAstat-Dx Analyzer 2.0 User Manual*, decontaminate the external surfaces accordingly, and contact Technical Service at the appropriate regional number or email for internal decontamination assistance.

6.1.1. Emergency information

CHEMTREC

Outside USA & Canada +1 703-527-3887

6.2. Precautions

The following hazard and precautionary statements apply to components of the QIAstat-Dx BCID GN Plus AMR Panel.

Contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t- Octylphenoxypolyethoxyethanol. Danger! Highly flammable liquid and vapor. Harmful if swallowed or if inhaled. May be harmful in contact with skin. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor. Rinse mouth. Do NOT induce vomiting. Remove person to fresh air and keep comfortable for breathing. Wash contaminated clothing before reuse. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/ container to an approved facility in accordance with local, regional, national and international regulations.

To guard against possible contamination of the specimen and work area, standard laboratory safety and cleaning procedures must be performed, including the following precautions:

- Samples should be processed in a biosafety cabinet or a similar clean surface ensuring the user's protection. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield must be used.
- *QIAstat-Dx BCID GN Plus AMR Panel Instructions for Use* should be used as a guide when preparing samples.
- For sample preparation and cartridge loading, do not use a biosafety cabinet that is used for performing pathogen testing (e.g. culture).
- Prior to processing samples, thoroughly clean the work area using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue buildup and potential damage to the specimen or interference from disinfectants, wipe disinfected surfaces with water.
- Samples and cartridges should be handled one at a time.

- Use clean gloves to remove materials from bulk packaging bags and reseal bulk packaging bags when not in use.
- Change gloves and clean the work area between each sample.
- Discard used cartridges in an appropriate biohazard container immediately after the run has been completed.
- Avoid excessive handling or shaking of the cartridges before and after test runs.
- Avoid damaging the cartridge.

6.3. Precautions related to public health reporting

National, state and local public health authorities have published guidelines for notification of reportable diseases in their jurisdictions to determine necessary measures for verification of results to identify and trace outbreaks and for epidemiological investigations. E.g. following the Official Journal of the European Union 6.7.2018 L 170/1 (56), the list includes *Haemophilus influenzae, Neisseria meningitidis,* and *Salmonella* spp., of the pathogens included in the QIAstat-Dx BCID GN Plus AMR Panel.

Several initiatives are also in place worldwide to track AMR (antimicrobial resistance), such as the EARS-Net in the EU.

Laboratories are responsible for following their state or local regulations for submission of clinical material or isolates on positive specimens to their state public health laboratories.

7. Disposal

- Dispose of hazardous waste in compliance with local and national regulations. This also applies to unused products. In case of damaged cartridge, please refer to the "Safety information" on page 20.
- Follow recommendations in the Safety Data Sheet (SDS).

8. Storage and Handling

8.1. Cartridge storage and handling

Store the QIAstat-Dx BCID GN Plus AMR Panel Cartridges in a dry, clean storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx BCID GN Plus AMR Panel Cartridges or the transfer pipettes from their individual packaging until use. Once the cartridge is removed from the pouch, it should be protected from direct sunlight and used according to In-use stability conditions. Under these conditions, the QIAstat-Dx BCID GN Plus AMR Panel Cartridges can be stored until the expiration date printed on the individual packaging. The expiration date is also included in the QIAstat-Dx BCID GN Plus AMR Panel Cartridge barcode and is read by QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 when the cartridge is scanned prior to running a test.

Attention should be paid to the expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components.

In the event of cartridge damage, please refer to "Safety information" on page 20.

8.1.1. In-use stability

After the cartridge package is opened, the sample should be introduced into the QIAstat-Dx BCID GN Plus AMR Panel Cartridge within 30 minutes. Sample-loaded cartridges should be loaded into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 within 90 minutes.

Do not use if stored outside the specifications, if the packaging has been damaged, or if other signs of deterioration or malfunction are visible.

8.2. Specimen storage and handling

The QIAstat-Dx BCID GN Plus AMR Panel is for use with positive blood culture samples. All samples should be treated as potentially hazardous. Discard sample and assay waste according to your local safety procedures.

8.2.1. Specimen collection, transport, and storage

Blood culture samples should be collected and handled according to the manufacturer's recommended procedures.

Store the positive blood culture samples according to these recommended storage conditions:

- Room temperature (15–25°C) up to 24 hours, after initial blood culture bottle positivity
- In the blood culture system for up to 24 hours after positivity

Pure Colony suspensions in saline should be generated and handled as per Standard of Care (SoC) protocol and guidelines.

Follow these recommended storage conditions for pure colonies (suspended in saline) samples:

- Room temperature (15–25°C) for up to 2 days after suspension.
- Refrigerated (4–8°C) for up to 2 days after suspension

9. Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx BCID GN Plus AMR Panel is tested against predetermined specifications to ensure consistent product quality.

9.1. External control information

All external quality control requirements and testing should be performed in accordance with local, state, and federal regulations or accreditation organizations and should follow the user's laboratory standard quality control procedures.

Blank controls are not applicable to the device because it is a single test disposable cartridge. Regular testing of negative and positive external controls is not necessary but can be used. Controls are not provided with the QIAstat-Dx BCID GN Plus AMR Panel.

10. Protocol

10.1. Blood culture samples

Important points before starting

- Sample container, consumables, and lab areas and equipment used should be cleaned with 10% bleach or a similar disinfectant followed by a water rinse.

  Note: Avoid contact of bleach with blood culture samples as it can cause sample degradation, leading to potential false negative results.
- Samples should be processed in a Microbiological Safety cabinet.
- Change gloves when processing a different sample to reduce risk of cross-contamination.
- Collect blood culture samples from positive blood culture bottles according to the manufacturer's recommended procedures.
- Blood culture samples identified as positive by a continuous monitoring blood culture system should be removed from the equipment as soon as possible, or within 24 hours of ringing positive.
- Bottle and sterile laboratory consumables (i.e. sub-culture unit, syringe, tube, etc.) should be transferred in a clean Microbiological Safety cabinet and specimens must be collected and handled according to the institution's safety procedures.

Procedure

1. Gently invert the positive blood culture bottle 3 times to ensure mixing of the contents.
2. Allow the bottle to sit for 10 seconds to allow any resin which may be present to settle at the bottom.
3. Wipe the septum of the blood culture bottle with a 70% IPA wipe (or equivalent) and allow to air dry prior to collecting sample.
4. Draw >300 µL of blood culture sample through the bottle septum slowly, using a syringe or a subculture device, as per manufacturer's recommended procedures, taking care to avoid the formation of bubbles. Draw back on the syringe to clear the nozzle of sample to reduce the risk of contamination. Carefully remove the syringe.

   Note: Minimum volume of positive blood culture matrix required is 300 µL.

   Note: Ensure that no resin is collected when drawing the blood culture sample from the bottle.

5. Dispense the contents to a sterile secondary container with a lid, e.g. 1.5 mL microcentrifuge tube. Ensure that no part of the syringe/subculture device touches the secondary container.
6. Close the lid of the tube until ready to proceed with loading the sample into the QIAstat-Dx BCID GN Plus AMR Panel Cartridge.

Note: Transfer pipettes for loading the QIAstat-Dx BCID GN Plus AMR Panel Cartridge provided in the kit are single use. In case transfer pipettes are dropped or contaminated due to user error, use any other commercially available pipette with a minimum volume of 100 µL.

Note: Thermo Scientific™ VersaTrek™ bottles do not require diluting.

Note: Samples grown in bioMérieux and Becton Dickinson bottles must be diluted in saline prior to loading in the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, as per the procedure described in Section 10.3 "Loading a sample into the QIAstat-Dx BCID GN Plus AMR Panel Cartridge" on the next page.

10.2. Pure colony suspended in saline samples

Important point before starting

- Pathogen colonies isolated from culture plates and suspended in saline can be used as a sample type.

Procedure

1. In a clear test tube, prepare a 1.0 McFarland Standard suspension in saline using growth observed in the culture plate, as per relevant guidelines or laboratory protocols (total volume required >0.1mL).

   Note: Minimum volume required for testing is 100 µL of pure colony 1.0 McFarland Standard suspension.

   Note: McFarland reference standard: 1.0 McFarland reference standard.
2. Ensure the collection of a representative sample of isolated colonies off the relevant enrichment plate with a loop (or relevant lab consumable), i.e selected isolated colonies from multiple regions of the plates.

Important: For polymicrobial cultures, each distinct colony type identified on the culture plate shall be treated individually. Produce 1.0 McFarland suspensions from each colony type separately.

Note: Avoid the transfer of agar when collecting colonies from the enrichment plate.

Note: More colonies can be picked or extra saline can be added as necessary to adjust the suspension to 1.0 McFarland Standard suspension.

3. Ensure a homogenous organism suspension has been prepared.
4. Dispose of materials used as per regulations.

Note: Pure Colony 1.0 McFarland Standard suspensions in saline should be stored as per standard protocol and guidelines, to avoid contamination, until testing is performed.

10.3. Loading a sample into the QIAstat-Dx BCID GN Plus AMR Panel Cartridge

1. Thoroughly decontaminate the consumables and lab areas used to load a QIAstat-Dx BCID GN Plus AMR Panel Cartridge with 10% bleach or similar disinfectant followed by a water rinse (or equivalent).

   Important: Avoid contact of bleach with blood culture samples as it can cause sample degradation, leading to potential false negative results.
2. Open the package of a QIAstat-Dx BCID GN Plus AMR Panel Cartridge using the tear notches on the sides of the packaging (Figure 2).

   Important: After the cartridge package is opened, sample should be introduced inside the QIAstat-Dx BCID GN Plus AMR Panel Cartridge and loaded into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 within 120 minutes (30 minutes since the cartridge package is opened and 90 minutes once the sample is loaded into the cartridge).

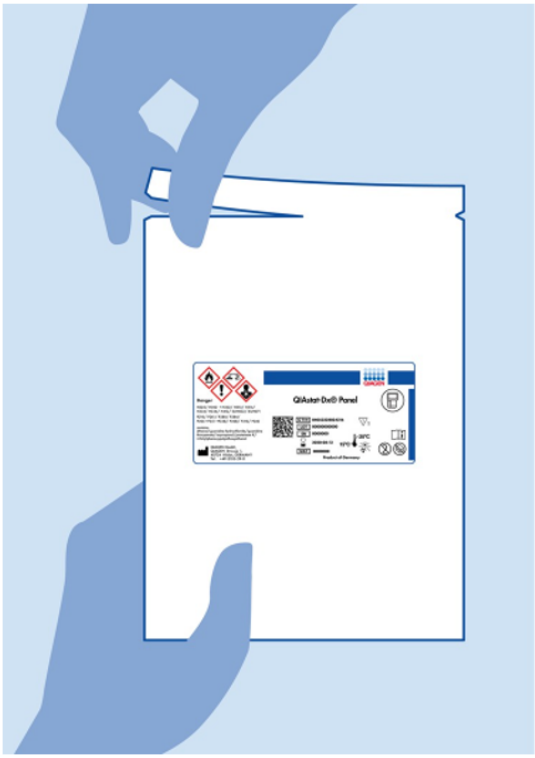


Figure 2. Opening the QIAstat-Dx BCID GN Plus AMR Panel Cartridge.

3. Remove the QIAstat-Dx BCID GN Plus AMR Panel Cartridge from the packaging and position it so that the QR code on the label is facing forward.
4. Manually record the sample information or place a sample information label on top of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge. Ensure that the label is properly positioned and does not block the lid opening (Figure 3).

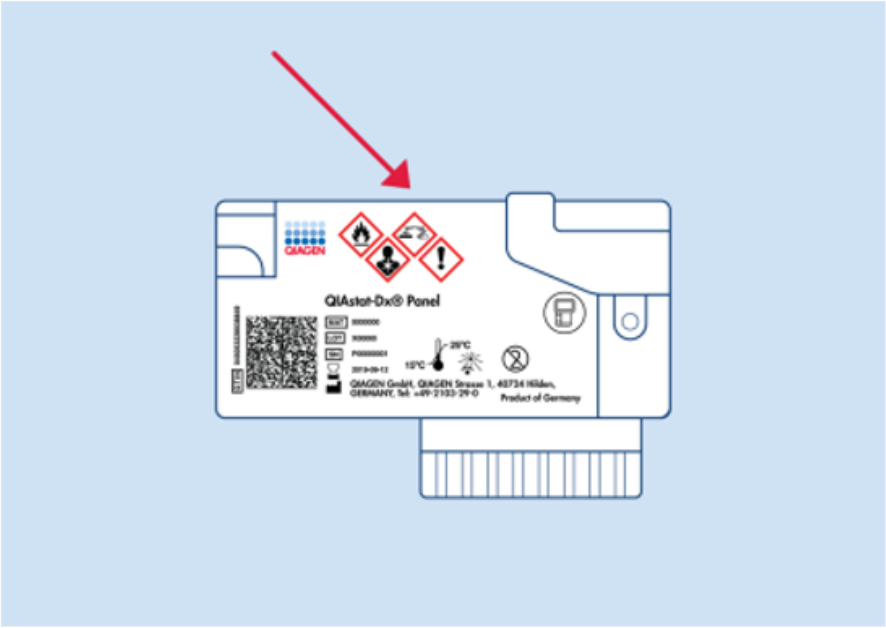


Figure 3. Sample information placement on top of QIAstat-Dx BCID GN Plus AMR Panel Cartridge.

5. Place the QIAstat-Dx BCID GN Plus AMR Panel Cartridge flat on the clean work surface so that the barcode on the label faces upwards.
6. Open the sample lid of the main port in front of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge (Figure 4).

   Important: Do not flip the QIAstat-Dx BCID GN Plus AMR Panel Cartridge or agitate it while the main port lid is open. The main port contains silica beads used in the sample disruption. The silica beads could fall out of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge if it is agitated while the lid is open.

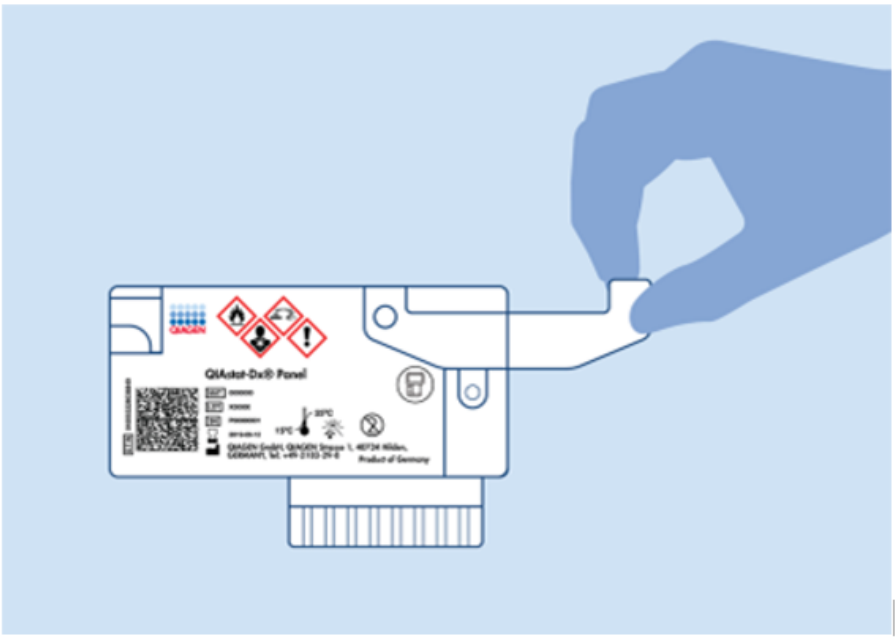


Figure 4. Opening the sample lid of main port.

7. To ensure that the sample to be tested is thoroughly mixed, invert the tube at least 5 times before processing. (See Section 10.1 "Blood culture samples" on page 28).
8. Open the tube with the sample to be tested. Use the supplied transfer pipette to draw up fluid to the first fill line on the pipette (100 µL) (Figure 5).

   Note: Thermo Scientific VersaTrek bottles do not require diluting.

   Note: Samples grown in bioMérieux and Becton Dickinson bottles must be diluted in saline prior to loading in the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, as per the following procedure.

   a. Measure 300 µL of 0.45% saline into a microcentrifuge tube (e.g. 1.5 mL) with the transfer pipette using the third line up from the tip of the pipette. Always pipet the saline prior to pipetting the 300 µL positive blood culture sample.

      Note: This step may be performed using a micropipette.

   b. Close the lid of the tube. Then, invert the tube at least 5 times to mix the diluted sample.

c. Load 100 µL of the diluted sample into the cartridge immediately.

d. Dispose of materials used as per regulations.

Note: Take care to avoid drawing air into the pipette.

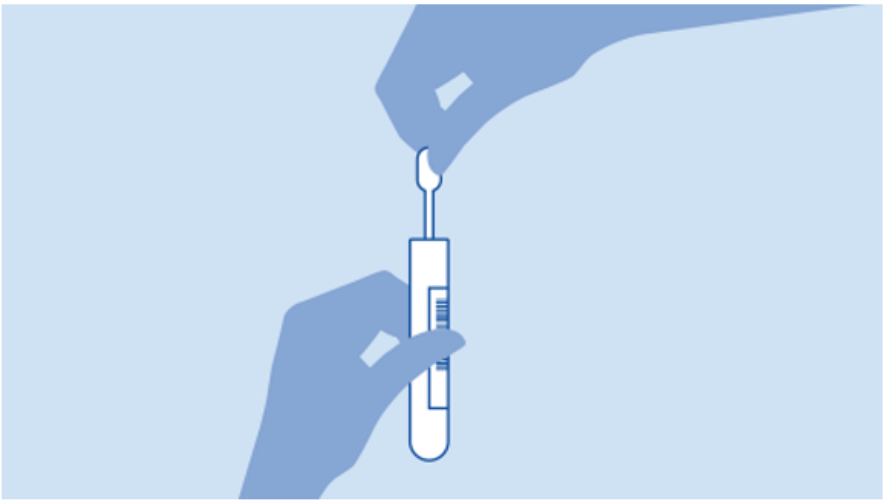


Figure 5. Drawing sample into the supplied transfer pipette.

9. Carefully transfer 100 µL of sample volume into the main port of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge using the supplied single-use transfer pipette (Figure 6).

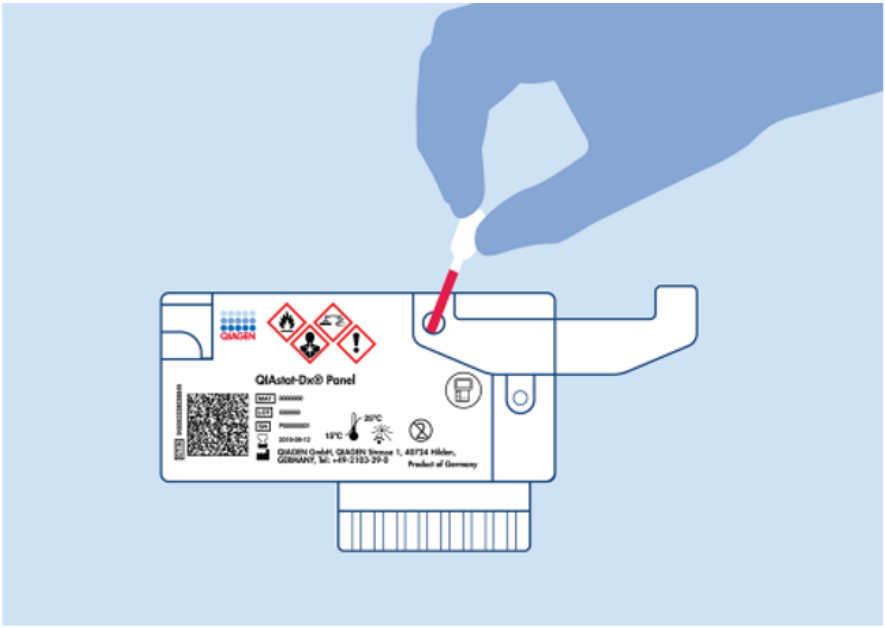


Figure 6. Transferring sample to main port of QIAstat-Dx BCID GN Plus AMR Panel Cartridge.

10. Firmly close the sample lid of the main port until it clicks (Figure 7).

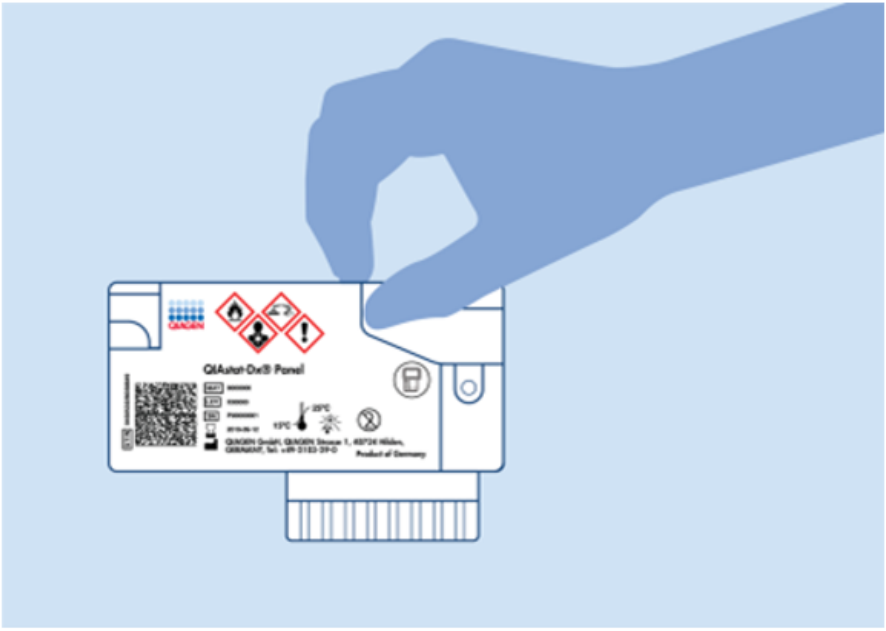


Figure 7. Closing the lid of the main port.

11. To visually confirm that the sample has been loaded, check the sample inspection window of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge (Figure 8).

    Important: After the sample is placed inside the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, the cartridge must be loaded into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 within 90 minutes.

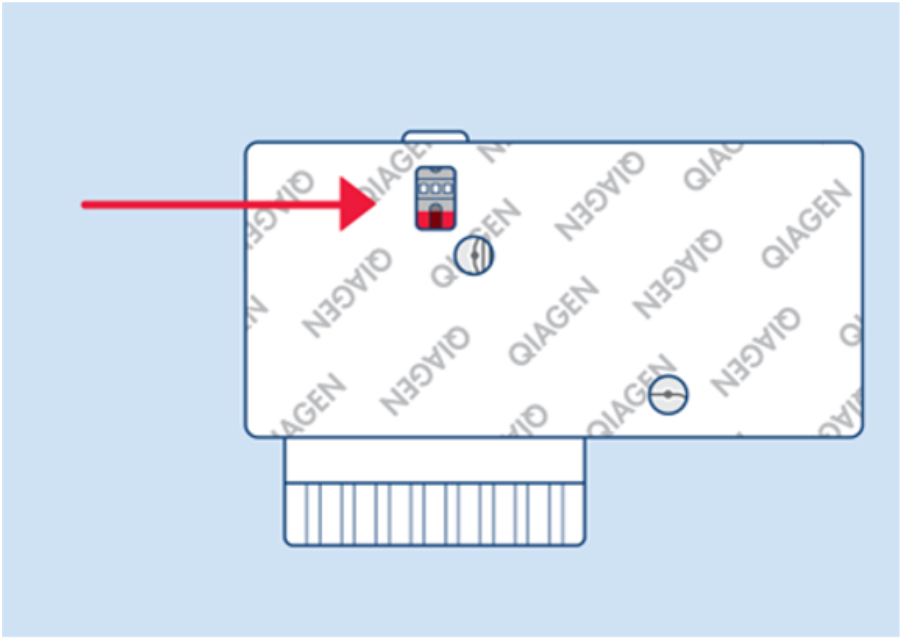


Figure 8. Sample inspection window (red arrow).

10.4. Starting QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

1. To power on the instrument, press the **On/Off** button in front of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

   Note: The power switch on the back of the Analytical Module must be set in the "I" position. QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 status indicators will turn blue.
2. Wait until the Main screen appears and QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 status indicators turn green and stop blinking.
3. Enter the username and password to log in.

   Note: The Login screen appears if **User Access Control** is activated. If **User Access Control** is disabled, username/password is not required and the Main screen will appear.
4. If the Assay Definition File software is not installed in QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, follow the installation instructions prior to running the test (Section 18.1

"Appendix A: Installing the Assay Definition File" on page 214 for additional information).

10.5. Running a test

1. Select **Run Test** located in the top-right corner of the touchscreen of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.
2. When prompted, scan the sample ID barcode on the tube containing the sample, or scan the specimen information barcode located on top of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge (see step 3) using the integrated front barcode reader of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 (Figure 9).

   Note: To enter the sample ID using the virtual keyboard of the touchscreen, select the **Sample ID** field.

   Note: Depending on the selected system configuration, entering the patient ID may also be required at this point.

   Note: Instructions from QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 appear in the Instructions Bar located at the bottom of the touchscreen.

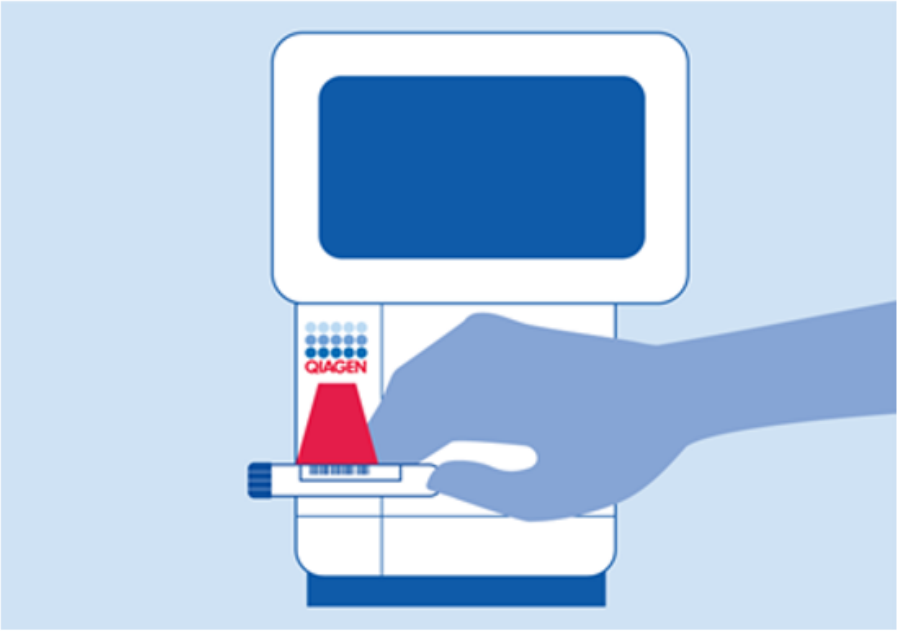


Figure 9. Scanning sample ID barcode.

3. When prompted, scan the barcode of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge to be used (Figure 10). QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 enable automatic recognition of the assay to be run based on the cartridge barcode.

   Note: QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 are designed to reject QIAstat-Dx BCID GN Plus AMR Panel Cartridges with lapsed expiration dates, previously used cartridges, or cartridges for assays that have not been installed on the unit. An error message is displayed in these cases, and the QIAstat-Dx BCID GN Plus AMR Panel Cartridge will be rejected. Refer to the *QIAstat-Dx Analyzer 1.0 User Manual* or *QIAstat-Dx Analyzer 2.0 User Manual* for further details about how to install assays.

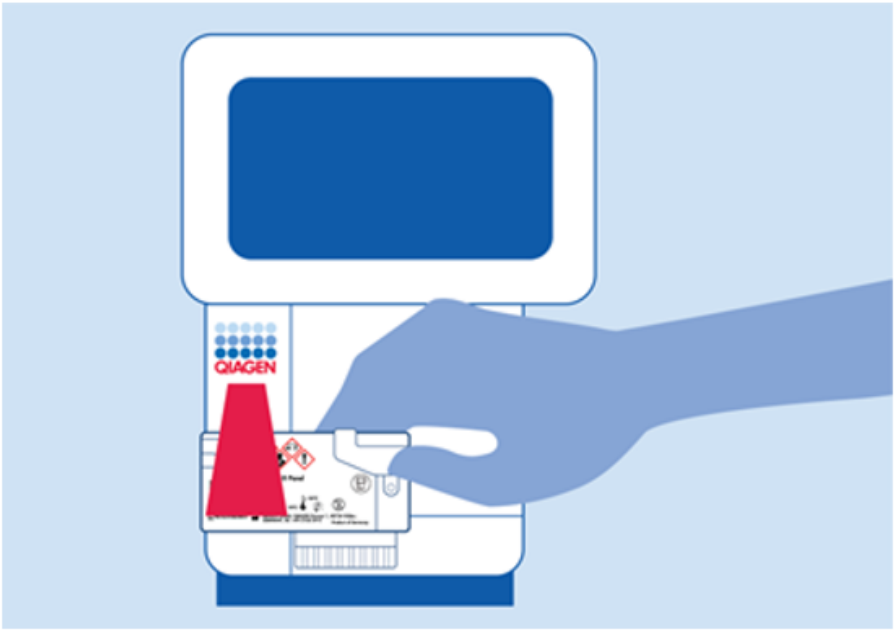


Figure 10. Scanning QIAstat-Dx BCID GN Plus AMR Panel Cartridge barcode.

4. The Sample Type screen will appear (Figure 11). Select the correct sample type from the **Sample Type** list depending on the tested sample.

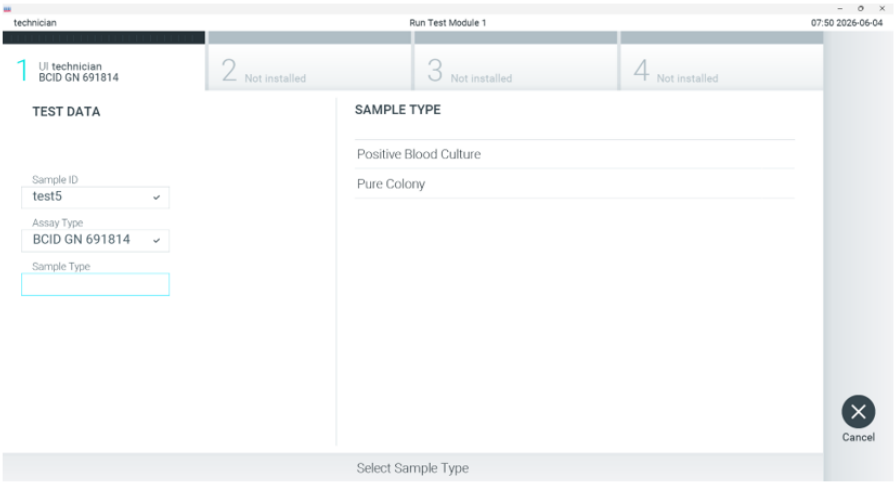


Figure 11. Selecting sample type.

5. In the Confirm screen, review the entered data. To make any necessary changes, select the relevant fields on the touchscreen and edit the information. To cancel the test, press **Cancel**.
6. After confirming that all displayed data are correct, press **Confirm** (Figure 12).

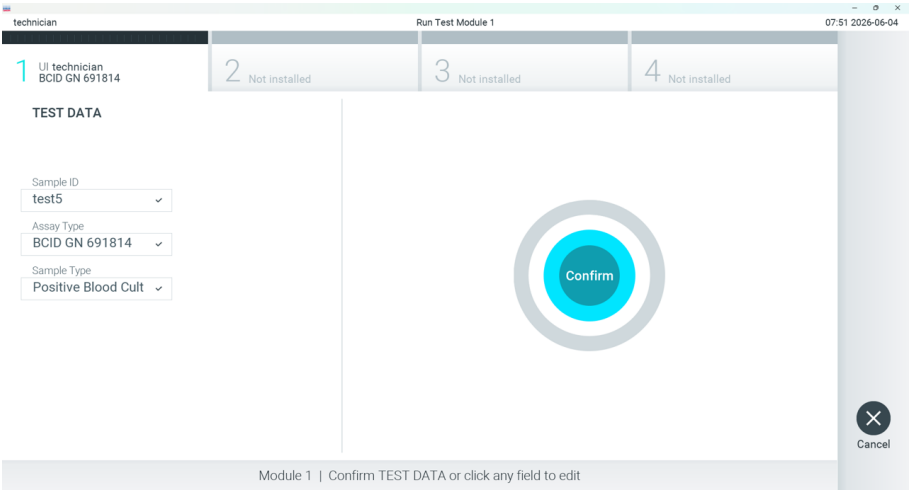


Figure 12. Confirming data entry.

7. Ensure that both sample lids of the swab port and main port of the QIAstat-Dx BCID GN Plus AMR Panel Cartridge are firmly closed. When the cartridge entrance port on the top of QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx BCID GN Plus AMR Panel Cartridge with the cartridge barcode facing to the left and the reaction chambers facing down (Figure 13).

   Note: Do not push the QIAstat-Dx BCID GN Plus AMR Panel Cartridge into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0. Position it correctly into the cartridge entrance port and QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 will automatically position the cartridge into the Analytical Module.

   Note: The swab port is not used for the QIAstat-Dx BCID GN Plus AMR Panel assay.

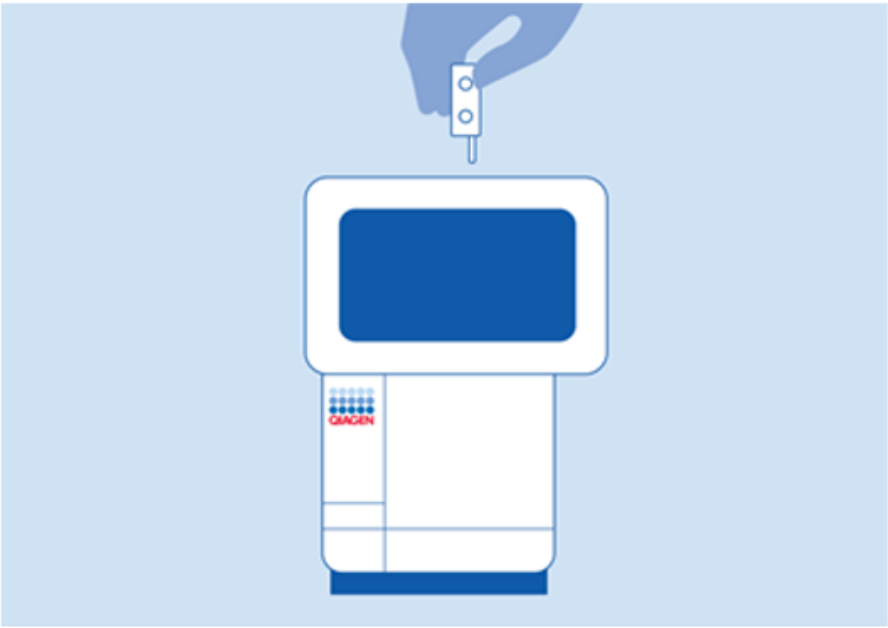


Figure 13. Inserting QIAstat-Dx BCID GN Plus AMR Panel Cartridge into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

8. Upon detecting the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 enable the automatic closing of the lid of the cartridge entrance port and immediately start the test run.

   Note: Depending on the system configuration, the operator may be required to re-enter their user password to start the test run. Otherwise, no further action is required from the operator to start the run.

   Note: QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 are designed to reject a QIAstat-Dx BCID GN Plus AMR Panel Cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated and the cartridge will be automatically ejected.

   Note: Up to this point, a test run can be canceled by selecting **Cancel** in the bottom right corner of the touchscreen.

   Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx BCID GN Plus AMR Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 1.

9. While the test is running, the remaining run time is displayed on the touchscreen.
10. After the test run is completed, the Eject screen will appear (Figure 14) and the Module status bar will display the test result as one of the following options:
    - **TEST COMPLETED**: The test was completed successfully.
    - **TEST FAILED**: An error occurred during the test.
    - **TEST CANCELED**: The user canceled the test.

    Important: If Test Failed is displayed, contact QIAGEN Technical Service.

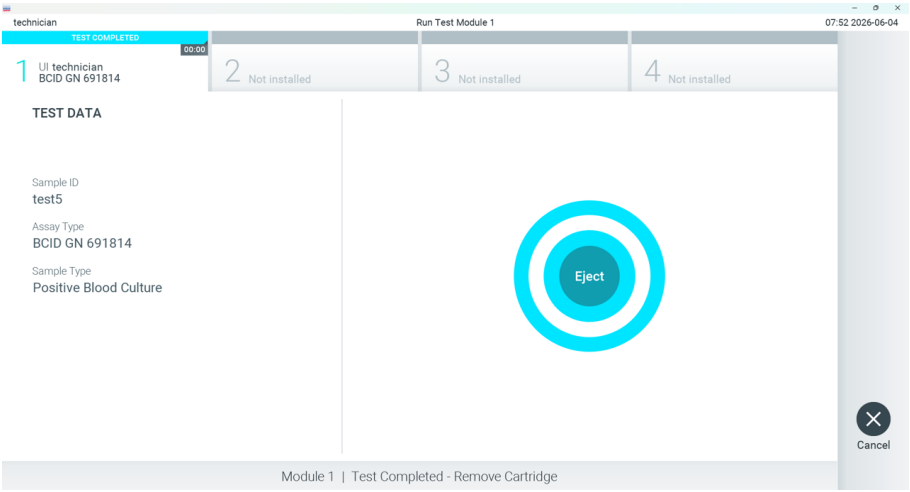


Figure 14. Eject screen display.

11. Press **Eject** on the touchscreen to remove the QIAstat-Dx BCID GN Plus AMR Panel Cartridge and dispose of it as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws.

    The QIAstat-Dx BCID GN Plus AMR Panel Cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, and the cartridge entrance port lid will close. If this occurs, press **Eject** to reopen the lid of the cartridge entrance port and remove the cartridge.

    Important: Used QIAstat-Dx BCID GN Plus AMR Panel Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

12. After the QIAstat-Dx BCID GN Plus AMR Panel Cartridge has been ejected, the Results Summary screen will appear. To begin the process for running another test, press **Run Test**.

11. Interpretation of Results

11.1. Internal Control interpretation

The QIAstat-Dx BCID GN Plus AMR Panel Cartridge includes a full process Internal Control, which is titered *Schizosaccharomyces pombe,* a yeast (fungi) that is included in the cartridge in dried form and is rehydrated upon sample loading. This Internal Control material verifies all steps of the analysis process, including sample homogenization, lysis of cellular structures (by means of chemical and mechanical disruption), nucleic acid purification, and real-time PCR.

A positive signal for the Internal Control or any other target in the Internal Control Amplification Chamber indicates that all processing steps performed by the QIAstat-Dx BCID GN Plus AMR Panel Cartridge were successful.

A negative signal of all the targets in the Internal Control Amplification chamber does not negate any positive results for detected and identified targets, but it does invalidate all negative results in the analysis. Therefore, Negative tests should be repeated if the Internal Control or any other target in the Internal Control Chamber signals are negative.

Internal Control results are to be interpreted according to Table 1.

Table 1. Interpretation of Internal Control chamber results

Control result	Explanation	Action
Passed	The Internal Control or any other target in the Internal Control Reaction Chamber amplified successfully.	The run was completed with success. All results are valid and can be reported. Detected pathogens are reported as positive and undetected pathogens are reported as negative.
Failed	The Internal Control or any other target in the Internal Control Reaction Chamber failed to amplify.	Positively detected pathogen(s) are reported, but all negative results (tested but not detected pathogen[s]) are invalid. Repeat the testing using a new QIAstat-Dx BCID GN Plus AMR Panel Cartridge.

11.2. Sample result interpretation

11.2.1. Pathogen assay result interpretation

A result for a QIAstat-Dx BCID GN Plus AMR Panel is interpreted as "Positive" when the corresponding PCR assay is positive for the pathogen targets. For Antimicrobial Resistance Results, see Section 11.2.2 "Antimicrobial Resistance (AMR) assay result interpretation" on the next page.

An overall test result is provided as well as a result for individual targets. Possible results for each organism include Detected/Positive, Detected/Positive with warning, Not Detected/Negative, and Invalid (Table 2).

If the Internal Control reaction chamber has failed and no positive signal was detected, or if there is an instrument error, there will be no pathogen/AMR determinants results provided.

Table 2. Description of pathogen results as displayed on Summary Result screen and the Result printout

Result	Symbol	Explanation	Action
Positive/Detected		A positive signal was detected for this target. Control Result is passed.	None. Report results.
Positive/Detected with Warning	 pos!*	A positive signal was detected for this target, but the Control result failed.	Repeat the test using a new cartridge. Accept the results of the repeat testing. If the Invalid result persists, contact QIAGEN Technical Service for further instructions.
Negative/Not detected		No signal was detected for this target. Control Result passed.	None. Report results.
Invalid		No signal was detected for this target and the Control Result is failed (but other pathogens have been detected).	Repeat the test using a new cartridge. Accept the results of the repeat testing. If the Invalid result persists, contact QIAGEN Technical Service for further instructions.

11.2.2. Antimicrobial Resistance (AMR) assay result interpretation

The QIAstat-Dx BCID GN Plus AMR Panel reports antimicrobial resistance markers only when the corresponding pathogen is detected, as outlined in the association matrix, see Table 3. This table illustrates the logical structure implemented in the assay software and reflects possible combinations of pathogens with antimicrobial resistance markers based on current literature and best clinical practices. A "No" entry does not imply that such combination cannot occur or is not allowed; however, the AMR will not be reported in those cases.

For AMR results, the reporting follows the same logic described in Table 3 for pathogens, with one exception: if none of the microorganisms associated with a specific AMR marker are detected, the AMR result will not be displayed on the screen (neither as "Detected" nor as "Not detected").

Table 3. Pathogens & genetic determinants of resistance of QIAstat-Dx BCID GN Plus AMR Panel

	AMR																	
Pathogen	***ampC***	**CTX-M**	**IMP**	**KPC**	**NDM**	**OXA-23**	**OXA-48-like**	**OXA-24/40**	**OXA-58**	**SHV**	**TEM**	**VIM**	**PER**	***armA***	***aac(6')-Ib***	**VEB**	**GES**	**SPM**
Enterobacter spp.	YES	YES	YES	YES	YES	NO	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO
Escherichia coli	YES	YES	YES	YES	YES	NO	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO
Klebsiella spp.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO
Proteus spp.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO	NO
Salmonella spp	NO	YES	YES	YES	YES	NO	YES	NO	NO	YES	YES	YES	YES	YES	YES	YES	NO	NO
Serratia spp	YES	YES	YES	YES	YES	NO	YES	NO	NO	YES	YES	YES	NO	YES	YES	NO	YES	NO
Pseudomonas aeruginosa	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Neisseria meningitidis	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO
Haemophilus influenzae	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO
Acinetobacter calcoaceticus-baumannii complex	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES
Bacteroides fragilis	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO

Table 3. Pathogens & genetic determinants of resistance of QIAstat-Dx BCID GN Plus AMR Panel (continued)

	AMR																	
Pathogen	***ampC***	**CTX-M**	**IMP**	**KPC**	**NDM**	**OXA-23**	**OXA-48-like**	**OXA-24/40**	**OXA-58**	**SHV**	**TEM**	**VIM**	**PER**	***armA***	***aac(6')-Ib***	**VEB**	**GES**	**SPM**
Stenotrophomonas maltophilia	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Pan *Enterobacterales*	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO

Note: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the QIAstat-Dx BCID GN Plus AMR Panel antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. A Detected result for an antimicrobial resistance gene cannot be definitely linked to the pathogen detected. Subculturing and standard susceptibility testing of isolates are required to determine antimicrobial susceptibility.

11.2.3. Pan *Enterobacterales* assay result interpretation

The QIAstat-Dx BCID GN Plus AMR Panel includes a broad-range 'Pan *Enterobacterales*' target to detect a wide range of *Enterobacterales* species, including but not limited to those belonging to the following genera: *Cedecea, Citrobacter, Cronobacter, Enterobacter* (including *E. ludwigii*), *Escherichia, Erwinia, Hafnia, Klebsiella, Kluyvera, Kosakonia, Leclercia, Lelliottia, Morganella, Phytobacter, Pluralibacter, Proteus, Providencia, Pseudoescherichia, Rahnella, Raoultella, Salmonella, Serratia* (including *S. odorifera* and *S. rubidaea*), *Sodalis, Shigella, Tatumella, Yersinia, Yokenella, Brenneria, Chania, Dickeya, Edwardsiella, Gibbsiella, Izhakiella, Limnobaculum, Lonsdalea, Metakosakonia, Nissabacter, Obesumbacterium, Pectobacterium, Pragia, Scandinavium, Shimwellia,* and *Xenorhabdus*.

The 'Pan *Enterobacterales*' result can be triggered through 2 complementary mechanisms:

- Direct detection by the broad-range Pan *Enterobacterales* assay, based on dedicated primers and probes; and
- Indirect detection through the result interpretation algorithm, whereby detection of any of the 6 individually reported *Enterobacterales* targets (*Escherichia coli, Salmonella* spp., *Enterobacter* spp., *Proteus* spp., *Klebsiella* spp., and *Serratia* spp.) automatically contributes to a Detected 'Pan *Enterobacterales*' result.

A negative/Not Detected 'Pan *Enterobacterales*' result indicates that no *Enterobacterales* were detected in the sample, including the ones targeted by the broad *Enterobacterales* assay and the 6 organisms reported as individual targets in the panel (i.e. *Escherichia coli, Salmonella* spp., *Enterobacter* spp., *Proteus* spp., *Klebsiella* spp. and *Serratia* spp.).

A positive/ Detected 'Pan *Enterobacterales*' result indicates that one or more *Enterobacterales* have been detected. This includes detection of any of the 6 *Enterobacterales* reported as individual targets in the panel, as well as any *Enterobacterales* belonging to genera included in the broad 'Pan *Enterobacterales*' inclusivity.

Additional testing for organism identification is recommended in case of Detected Pan *Enterobacterales* target, and no other *Enterobacterales* single target is detected.

Refer to Table 4 for 'Pan *Enterobacterales*' result interpretation. The actions to be taken follow the same logic as in Table 2.

Table 4. QIAstat-Dx BCID GN Plus AMR Panel Pan *Enterobacterales* result interpretation

Pan *Enterobacterales* result*	Description†
Detected	At least one positive signal was detected from the following assays: *Escherichia coli*, *Salmonella* spp., *Enterobacter* spp., *Proteus* spp., *Klebsiella* spp., *Serratia* spp., and the broad *Enterobacterales* assay. Control Result is passed. Additional testing for organism identification is recommended in case of Detected Pan *Enterobacterales* target, and no other *Enterobacterales* single target is detected.
Not detected	No signal for any of the assays included in the 'Pan *Enterobacterales*' target detected in the sample. Control Result is passed.

* For the complete interpretation of results, including positive/detected with warning and invalid results with warnings, refer to Table 2.

† The full list of species predicted to be detected based on in silico analysis can be found in Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95.

11.2.4. Group- and genus- assay result interpretation

The QIAstat-Dx BCID GN Plus AMR Panel includes targets designed to detect, but not differentiate, species within the following group and genus level assays:

- *Acinetobacter baumannii-calcoaceticus* complex
- *Enterobacter* spp.
- *Klebsiella* spp.
- *Proteus* spp.
- *Salmonella* spp.
- *Serratia* spp.

When a group or genus level target is detected, the result indicates that one or more organisms belonging to the corresponding group or genus have been detected. Additional testing for organism identification is recommended in case of a Detected target.

See Table 5 for organisms detected by each assay.

Table 5. QIAstat-Dx BCID GN Plus AMR Panel group- and genus-assay result

QIAstat-Dx BCID GN Plus AMR target	Result*	Description†
Acinetobacter calcoaceticus-baumannii complex	Detected	One or more *Acinetobacter calcoaceticus-baumannii* complex organisms have been detected, including but not limited to: *Acinetobacter baumannii, Acinetobacter calcoaceticus, Acinetobacter nosocomialis, Acinetobacter pittii*. Additional testing for organism identification is recommended.
	Not Detected	None of the *Acinetobacter calcoaceticus-baumannii* complex species detected.
Enterobacter spp.	Detected	One or more *Enterobacter* spp. organisms have been detected, including but not limited to: *Enterobacter amnigenus, Enterobacter ludwigii, Enterobacter asburiae, Enterobacter cancerogenus, Enterobacter cloacae, Enterobacter hormaechei* (including subsp. *xiangfangensis, hoffmannii, steigerwaltii, oharae*), *Enterobacter kobei, Enterobacter bugandensis, Enterobacter roggenkampii, Enterobacter gergoviae, Enterobacter cloacae* subsp. *dissolvens, Lelliottia nimipressuralis*. Additional testing for organism identification is recommended.
	Not Detected	None of the *Enterobacter* spp. detected.
Klebsiella spp.	Detected	One or more *Klebsiella* spp. organisms have been detected, including but not limited to: *Klebsiella aerogenes, Klebsiella pneumoniae, Klebsiella variicola, Klebsiella oxytoca*. Additional testing for organism identification is recommended.
	Not Detected	None of the *Acinetobacter calcoaceticus-baumannii* complex group species detected.
Proteus spp.	Detected	One or more *Proteus* spp. organisms have been detected, including but not limited to: *Proteus mirabilis, Proteus vulgaris, Proteus terrae, Proteus cibarius, Proteus hauseri* Additional testing for organism identification is recommended.
	Not Detected	None of the *Proteus* spp. detected.

Table 5. QIAstat-Dx BCID GN Plus AMR Panel group- and genus-assay result (continued)

QIAstat-Dx BCID GN Plus AMR target	Result*	Description†
Salmonella spp.	Detected	One or more *Salmonella* spp. organisms have been detected, including but not limited to: *Salmonella bongori, Salmonella enterica* (including subsp. *enterica serotype Westhampton, subsp. gallinarum*, subsp. *seftenberg*), *Salmonella typhimurium*. Additional testing for organism identification is recommended.
	Not Detected	None of the *Salmonella* spp. detected.
Serratia spp.	Detected	One or more *Serratia* spp. organisms have been detected, including but not limited to: *Serratia ficaria, Serratia fonticola, Serratia liquefaciens, Serratia marcescens, Serratia plymuthica, Serratia odorifera* Additional testing for organism identification is recommended.
	Not Detected	None of the *Serratia* spp. detected.

* For the complete interpretation of results, including positive/detected with warning and invalid results with warnings, refer to Table 2.

† The full list of species predicted to be detected based on in silico analysis can be found in Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95.

11.3. Viewing results

QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 enable the automatic interpretation and saving of test results. After ejecting the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, the Results Summary screen is automatically displayed (Figure 15).

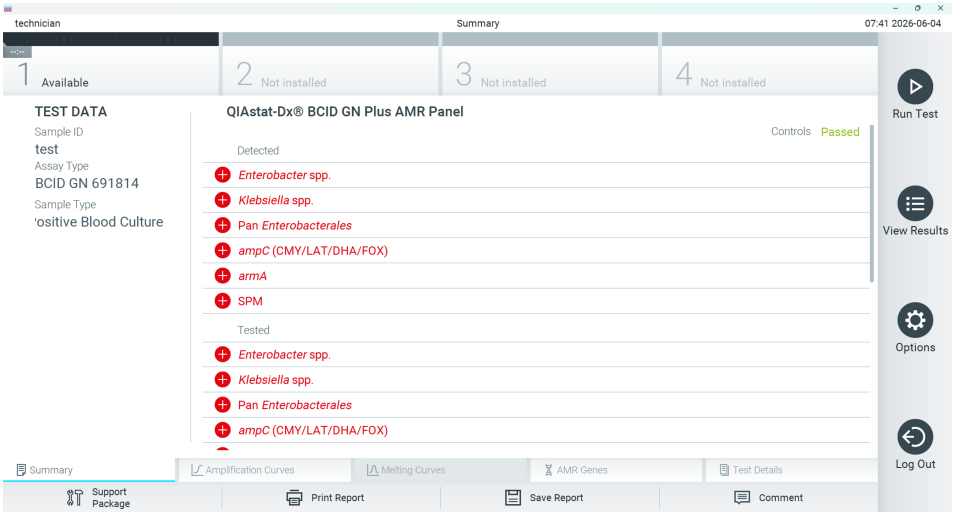


Figure 15. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel.

From this screen, other tabs with more information are available. These are explained in succeeding sections:

- Amplification Curves
- Melting curves (This tab is disabled for QIAstat-Dx BCID GN Plus AMR Panel)
- AMR Genes (enabled only in QIAstat-Dx Analyzer 2.0)
- Test Details

The main part of the screen displays the following lists and uses color-coding and symbols to indicate the results:

- The first list, under the heading Detected, includes all pathogens and AMRs detected and identified in the sample, which are preceded by a ⊕ sign and are colored red.
- The second list, under the heading Tested, includes all pathogens and AMRs tested in the sample. Pathogens and AMRs detected and identified in the sample are preceded by a ⊕ sign and are colored red. Pathogens and AMRs that were tested but not detected are preceded by a ⊖ sign and are colored green. Invalid pathogens are also displayed in this list and preceded by a ⊗ sign.

Note: Pathogens and AMRs detected and identified in the sample are displayed in both the Detected and Tested lists.

If the test failed to complete successfully, a message will indicate Failed followed by the specific Error Code.

The following Test Data is displayed on the left side of the screen:

- Sample ID
- Patient ID (if available)
- Assay Type
- Sample Type

Depending on the operator's access rights, further data about the assay is available through the tabs at the bottom of the screen (e.g., amplification plots and test details).

A report with the assay data can be exported to an external USB storage device. Insert the USB storage device into one of the USB ports of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 and select **Save Report** located in the bottom bar of the screen. This report can be exported later at any time by selecting the test from the View Result list.

To print the report, select **Print Report** located in the bottom bar of the screen.

11.3.1. Viewing amplification curves

To view test amplification curves of pathogens detected, press the **Amplification Curves** tab (Figure 16).

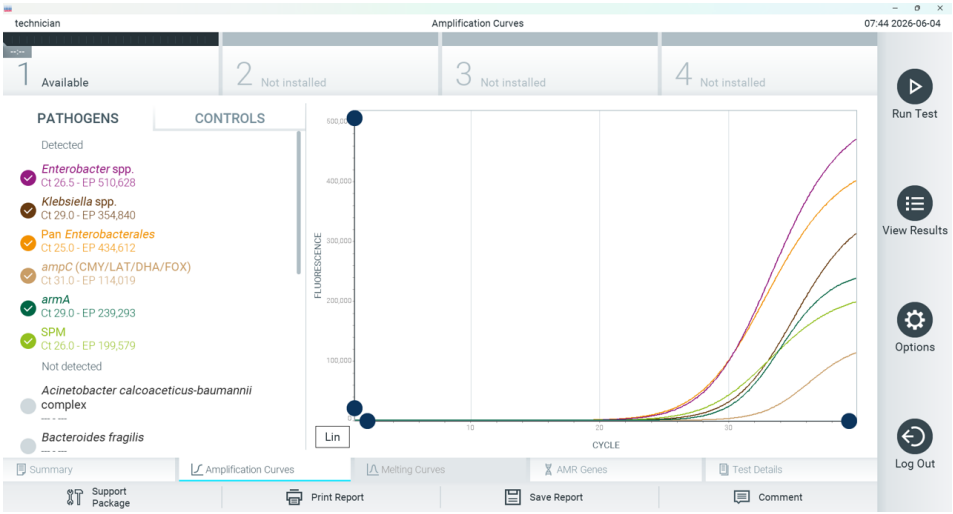


Figure 16. Amplification Curves screen (PATHOGENS tab).

Details about the tested pathogens and controls are displayed on the left and the amplification curves are displayed in the center.

Note: If **User Access Control** is enabled on QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, the Amplification Curves screen is only available for operators with access rights.

Select the **PATHOGENS** tab on the left side of the screen to display the plots corresponding to the tested pathogens. Select the pathogen name to specify which pathogens are displayed in the amplification plot. You can select single, multiple, or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with the pathogen. Unselected pathogens will be displayed in gray .

The corresponding Ct and endpoint fluorescence (EP) values are displayed below each pathogen name.

Note: The results provided by the QIAstat-Dx BCID GN Plus AMR Panel are qualitative and do not include any quantitative measurements. The intended sample type is cultured, and therefore, the Ct values obtained depend on the growth characteristics of each bacterium or fungus present in the sample. For AMR targets, Ct values are influenced by both the growth characteristics of the harboring organism and the gene copy number. Consequently, Ct values

cannot be used to infer pathogen load or establish any association between a pathogen and antimicrobial resistance.

Select the **CONTROLS** tab on the left side of the screen to view the controls in the amplification plot. Select the circle next to the control name to select or deselect it (Figure 17).

Note: If any other target in the Internal Control chamber amplifies successfully, the following screen (Figure 17) will not display an amplification curve, but the message on the left side of the screen will read: "`Failed control – None`".

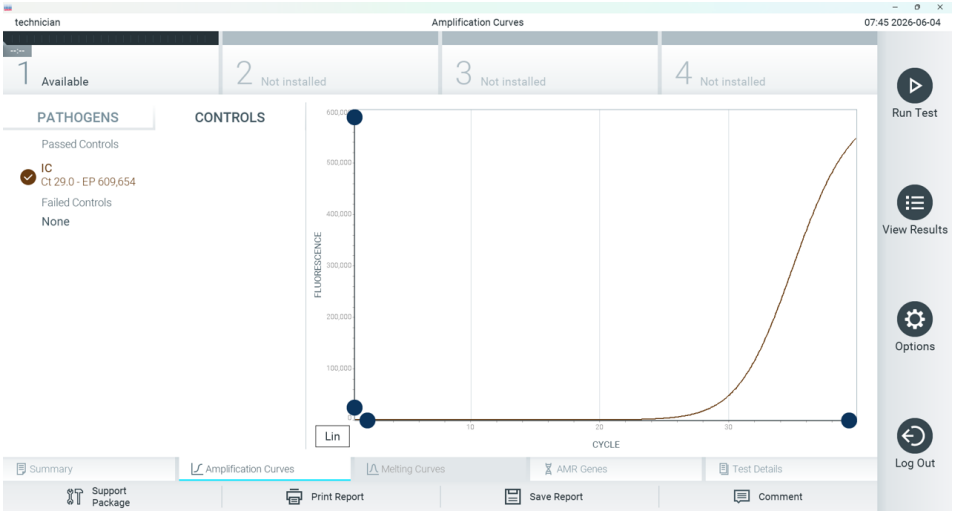


Figure 17. Amplification Curves screen (CONTROLS tab).

The amplification plot displays the data curve for the selected pathogens or controls. To alternate between logarithmic or linear scale for the Y-axis, press **Lin** or **Log** at the bottom left corner of the plot.

The scale of the X-axis and Y-axis can be adjusted using the blue pickers on each axis. Press and hold a blue picker and then move it to the desired location on the axis. Move a blue picker to the axis origin to return to the default values.

11.3.2. Viewing test details

Press **Test Details** in the Tab Menu bar at the bottom of the touchscreen to review the results in more detail. Scroll down to see the complete report.

The following Test Details are displayed in the center of the screen (Figure 18):

- User ID
- Cartridge SN (serial number)
- Cartridge Expiration Date
- Module SN
- Test Status (Completed, Failed, or Canceled by operator)
- Error Code (if applicable)
- Test Start Date and Time
- Test Execution Time
- Assay Name
- Test ID
- Test Result
  - **Positive** (if at least one BCID GN pathogen is detected/identified)
  - **Positive with warning** (if at least one BCID GN pathogen is detected, but the Internal Control Failed)
  - **Negative** (if no BCID GN pathogen is detected)
  - **Failed** (an error occurred or the test was canceled by the user)
- List of analytes tested in the assay, with Ct and endpoint fluorescence in the event of a positive signal
- Internal Control, with Ct and endpoint fluorescence

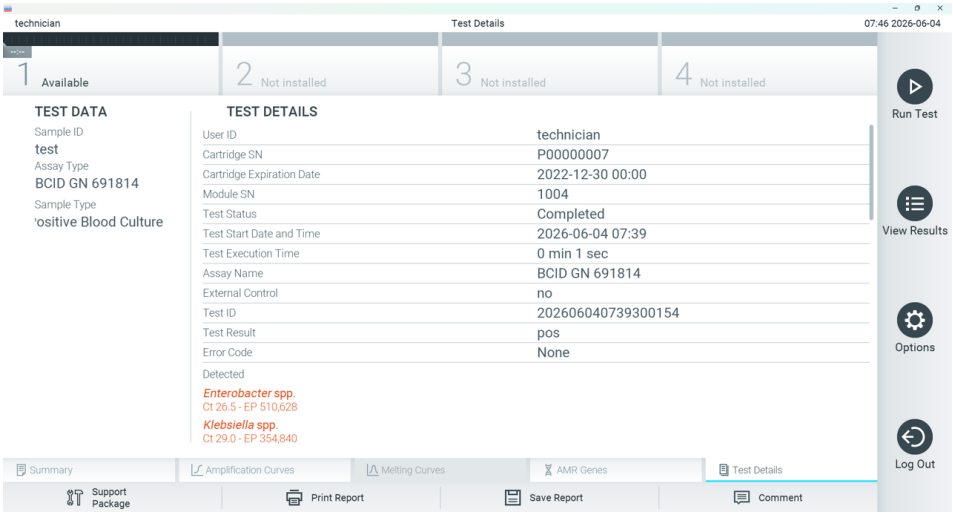


Figure 18. Example screen showing Test Data on the left panel and Test Details in the main panel.

11.3.3. Viewing AMR genes with QIAstat-Dx Analyzer 2.0

Press **AMR Genes** in the Tab Menu bar at the bottom of the touchscreen to review the AMR genes association. This screen (Figure 19) displays the AMR genes detected and all relevant bacterial targets linked by the assay software logic presented in Table 3, Section 11.2.2 "Antimicrobial Resistance (AMR) assay result interpretation" on page 48. A Not Detected result for a resistance gene does not indicate susceptibility to the associated antibiotic classes. Gram-negative bacteria may be resistant to specific antibiotics by mechanisms of resistance not targeted by the QIAstat-Dx BCID GN Plus AMR Panel. Selecting each AMR gene name provides a list of detected and not detected linked bacterial pathogens to that specific AMR gene.

Note: The results for the antimicrobial resistance gene assays do not specifically link the resistance gene to the associated organism. In mixed growth, the QIAstat-Dx BCID GN Plus AMR Panel does not specifically attribute antibiotic resistance genes to a specific organism.

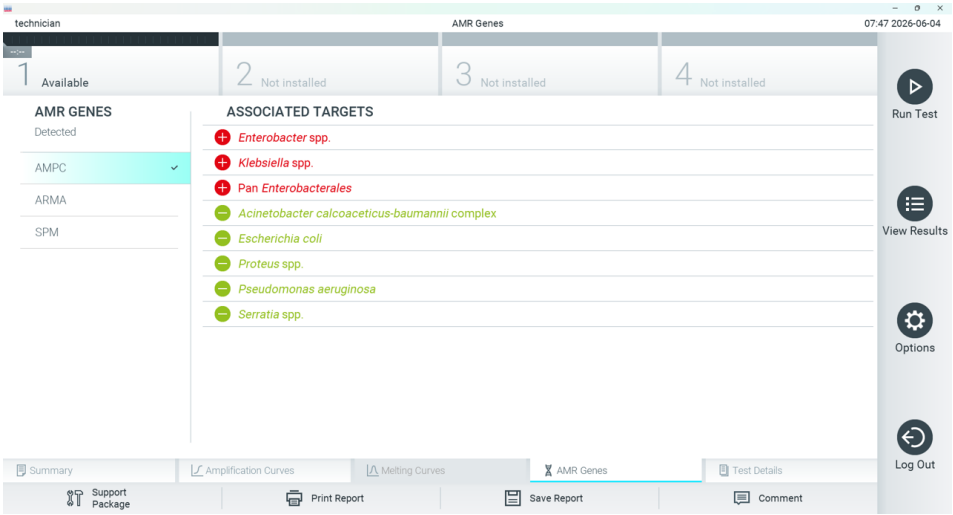


Figure 19. Example screen showing AMR Genes on the left and Associated Targets on the right (when operating with QIAstat-Dx Analyzer 2.0).

11.3.4. Browsing results from previous tests

To view results from previous tests that are stored in the results repository, press **View Results** on the Main Menu bar (Figure 20).

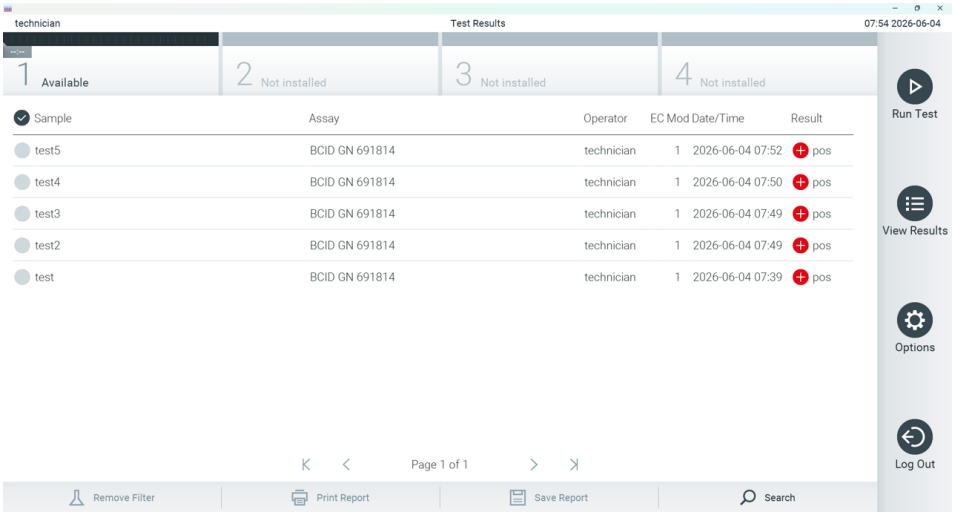


Figure 20. Example View Results screen.

The following information is available for every executed test (Figure 18):

- Sample ID
- Assay (name of test assay which is BCID GN Plus AMR Panel)
- Operator ID
- Mod (Analytical Module on which the test was executed)
- Date/Time (date and time when the test was finished)
- Result (outcome of the test: positive [pos] , positive with warning [pos*], negative [neg], failed [fail], or successful [suc])

Note: If **User Access Control** is enabled on QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, the data for which user has no access rights will be hidden with asterisks.

To select one or more test results, press the gray circle to the left of the sample ID. A checkmark will appear next to selected results. To deselect the results, press the checkmark. To select the entire list of results, press the checkmark in the top row (Figure 21).

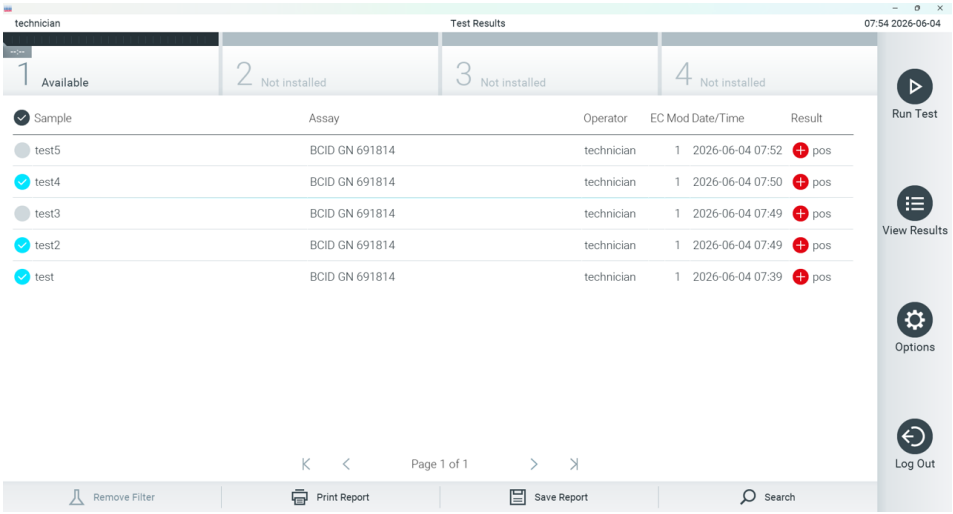


Figure 21. Example of selecting Test Results in the View Results screen.

Select anywhere in the test row to view the result for a particular test.

Select a column headline (e.g., Sample ID) to sort the list in ascending or descending order. The list can be sorted according to only one column at a time.

The Result column shows the outcome of each test (Table 6).

Table 6. Descriptions of the test results in View Results screen

Outcome	Result	Description	Action
Positive	pos	At least one pathogen is positive	Refer to the Summary Result Screen or Result Printout for pathogen specific results.
Positive with Warning	!pos	At least one pathogen is positive, but the Control failed	Refer to the Summary Result Screen or Result Printout for pathogen specific results.
Negative	neg	No analytes were detected	Refer to the Summary Result Screen or Result Printout for pathogen specific results.

Table 6. Descriptions of the test results in View Results screen (continued)

Outcome	Result	Description	Action
Failed	 fail	The test failed because either an error occurred, the test was canceled by the user, or no pathogens were detected and the Control failed.	Repeat the test using a new cartridge. Accept the results of the repeat testing. If the error persists, contact QIAGEN Technical Service for further instructions.
Successful	 Suc	The test is either positive or negative, but the user does not have the access rights to view the test results.	Log in from a user profile with rights to view the results.

Press **Save Report** to save the report(s) for the selected result(s) in PDF to an external USB storage device.

11.4. Selecting report type

The following report types are available for QIAstat-Dx BCID GN Plus AMR Panel:

- List of Tests
- Test Reports

Select **Search** to search the test results by Sample ID, Assay, and Operator ID. Enter the search string using the virtual keyboard and press **Enter** to start the search. Only the records containing the searched text will be displayed in the search results.

If the results list has been filtered, the search will only apply to the filtered list.

Press and hold a column headline to apply a filter based on that parameter. For some parameters, such as Sample ID, the virtual keyboard will appear so the search string for the filter can be entered.

For other parameters such as Assay, a dialog box will open with a list of assays stored in the repository. Select one or more assays to filter only the tests that were performed with the selected assays.

The T symbol to the left of a column headline indicates that the column's filter is active.

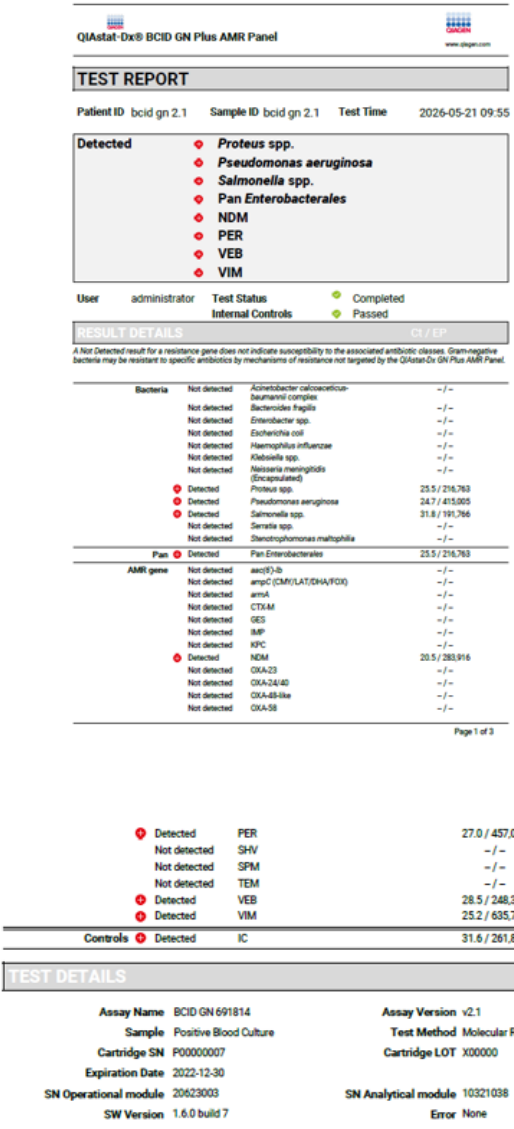
To remove a filter, press **Remove Filter** in the Submenu bar.

11.4.1. Exporting reports to a USB storage device

From any tab of the View Results screen, select **Save Report** to export and save a copy of the test results in PDF (Figure 22 and Figure 23) to a USB storage device. The USB port is located on the front of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0. Table 7 lists the interpretation of results in the PDF file.

Table 7. Interpretation of test results on PDF reports

	Outcome	Symbol	Description
Pathogen result	Detected		Pathogen detected
	Not Detected	No symbol	Pathogen not detected
	Invalid	No symbol	The Internal Control failed and there is not valid result for this target and the sample should be retested
Test status	Completed		The test was completed and the Internal Control and/or one or more targets were detected
	Failed		The test failed
Internal controls	Passed		The Internal Control or any target in the Internal Control reaction chamber passed
	Failed		The Internal Control or any target in the Internal Control reaction chamber failed



QIAstat-Dx® BCID GN Plus AMR Panel

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TEST REPORT

Patient ID bcid gn 2.1 **Sample ID** bcid gn 2.1 **Test Time** 2026-05-21 09:55

Detected

- ***Proteus* spp.**
- ***Pseudomonas aeruginosa***
- ***Salmonella* spp.**
- **Pan *Enterobacterales***
- **NDM**
- **PER**
- **VEB**
- **VIM**

User administrator **Test Status** Completed

Internal Controls Passed

RESULT DETAILS

Ct / EP

A Not Detected result for a resistance gene does not indicate susceptibility to the associated antibiotic classes. Gram-negative bacteria may be resistant to specific antibiotics by mechanisms of resistance not targeted by the QIAstat-Dx GN Plus AMR Panel.

Bacteria	Not detected	*Acinetobacter calcoaceticus-baumannii complex*	– / –
	Not detected	*Bacteroides fragilis*	– / –
	Not detected	*Enterobacter spp.*	– / –
	Not detected	*Escherichia coli*	– / –
	Not detected	*Haemophilus influenzae*	– / –
	Not detected	*Klebsiella spp.*	– / –
	Not detected	*Neisseria meningitidis (Encapsulated)*	– / –
	Detected	*Proteus spp.*	25.5 / 216,763
	Detected	*Pseudomonas aeruginosa*	24.7 / 415,005
	Detected	*Salmonella spp.*	31.8 / 191,766
	Not detected	*Serratia spp.*	– / –
	Not detected	*Stenotrophomonas maltophilia*	– / –
Pan	Detected	Pan Enterobacterales	25.5 / 216,763
AMR gene	Not detected	aac(6')-Ib	– / –
	Not detected	ampC (CMY/LAT/DHA/FOX)	– / –
	Not detected	armA	– / –
	Not detected	CTX-M	– / –
	Not detected	GES	– / –
	Not detected	IMP	– / –
	Not detected	KPC	– / –
	Detected	NDM	20.5 / 283,916
	Not detected	OXA-23	– / –
	Not detected	OXA-24/40	– / –
	Not detected	OXA-48-like	– / –
	Not detected	OXA-58	– / –

Page 1 of 3

	Detected	PER	27.0 / 457,050
	Not detected	SHV	– / –
	Not detected	SPM	– / –
	Not detected	TEM	– / –
	Detected	VEB	28.5 / 248,337
	Detected	VIM	25.2 / 635,753
Controls	Detected	IC	31.6 / 261,886

TEST DETAILS

Assay Name	BCID GN 691814	**Assay Version**	v2.1
Sample	Positive Blood Culture	**Test Method**	Molecular RT-PCR testing
Cartridge SN	P00000007	**Cartridge LOT**	X00000
Expiration Date	2022-12-30		
SN Operational module	20623003	**SN Analytical module**	10321038
SW Version	1.6.0 build 7	**Error**	None

Figure 22. Sample test report.

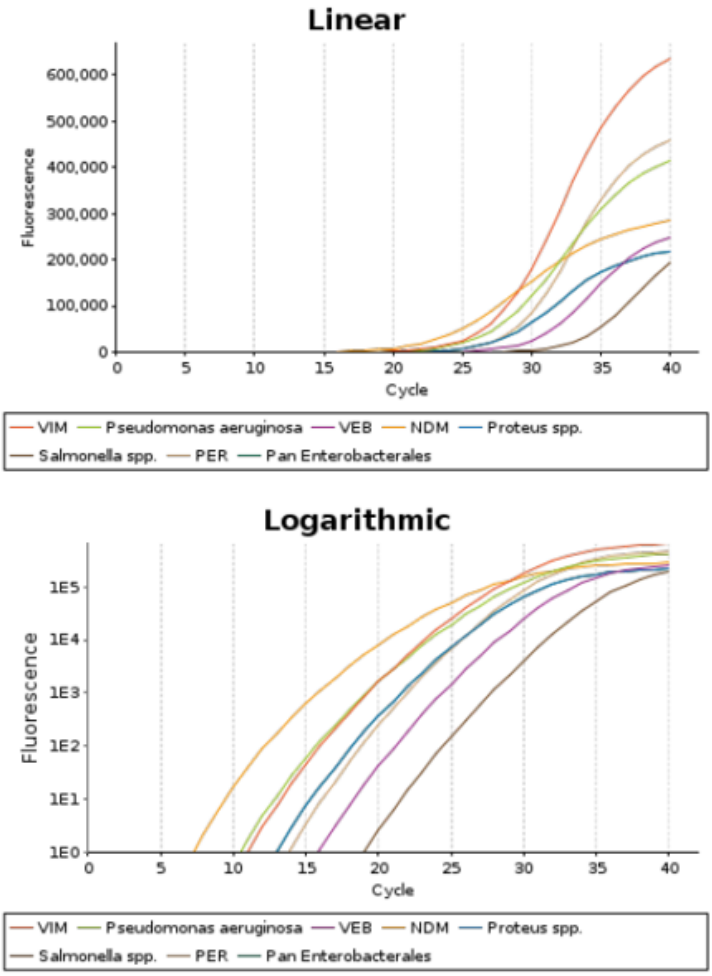

Figure 23. Sample test report showing assay data.

11.5. Printing results

Ensure that a printer is connected to QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 and that an appropriate driver is installed. Press **Print Report** to send a copy of the PDF test results to the printer.

Note: When using the ADF in a QIAstat-Dx Analyzer 1.0, the reports from an EC run will return an error. This feature is not supported for QIAstat-Dx Analyzer 1.0.

12. Limitations

- The QIAstat-Dx BCID GN Plus AMR Panel is not intended for testing of samples other than blood culture samples identified as positive by a continuously monitoring blood culture system and pure colony suspended in saline samples.
- The QIAstat-Dx BCID GN Plus AMR Panel is indicated for use with positive blood culture samples identified via Gram stain to contain gram-negative bacteria.
- All pathogen identification results from the QIAstat-Dx BCID GN Plus AMR Panel should be interpreted in conjunction with the Gram stain findings from the positive blood culture. Gram stain characteristics, including cellular morphology (e.g. Gram-negative rods (bacilli), coccobacilli or diplococci), should be carefully analyzed.
- The QIAstat-Dx BCID GN Plus AMR Panel is intended to be used in conjunction with standard of care culture for organism recovery, identification, and/or antimicrobial susceptibility testing where applicable.
- The QIAstat-Dx BCID GN Plus AMR Panel provides qualitative results and does not provide quantitative values for detected organisms.
- The performance of this test has not been established for monitoring response to treatment for any of the panel organisms.
- Results from the QIAstat-Dx BCID GN Plus AMR Panel must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory, and epidemiological findings.
- The QIAstat-Dx BCID GN Plus AMR Panel can be used with QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0.
- This assay cannot be run on positive blood culture bottles containing charcoal resins.
- Positive samples from bioMérieux and Becton Dickinson blood culture bottles require dilution prior to loading into the cartridge.
- The performance of this test has primarily been evaluated with the BD BACTEC™ (Lytic Anaerobic, Plus Aerobic, Plus Anaerobic, and PedPlus), bioMérieux BACT/ALERT® (FA Plus, FN Plus, and PF Plus) and Thermo Scientific VersaTREK (REDOX 1 EZ Draw and REDOX 2 EZ Draw) blood culture bottles. Other media have been assessed analytically for interference with the detection of organisms at positive blood culture levels (see Section 13.1.3 "Bottle equivalency" on page 76).
- A false negative result may originate from several factors and/or combinations, including improper specimen collection, improper culture techniques, handling or storage, technical error, sample mix-up, variation in the nucleic acid sequences targeted by the assay,

infection by organisms not included in the assay, target organism levels that are below the limit of detection of the assay, or use of certain medications, therapies, or agents by the patient.

- Organism and amplicon contamination may produce erroneous results for this test. Particular attention should be given to the Laboratory Precautions noted under Section 6.2 "Precautions" on page 21.
- The effect of interfering substances has only been evaluated for those listed in the labeling at their indicated amount or concentration. Interference by substances other than those described in Section 13.1.8 "Interfering substances (Positive Blood Culture samples)" on page 146 can lead to erroneous results.
- A detected result does not rule out co-infection with organisms not included (off-panel) in the QIAstat-Dx BCID GN Plus AMR Panel.
- A detected result does not imply that the microorganism detected is the definitive cause of the disease.
- Negative results for targeted microorganisms does not preclude the presence of pathogens that are not detected by this test.
- A negative result with the QIAstat-Dx BCID GN Plus AMR Panel does not exclude the infectious nature of the syndrome and should not be used as the sole basis for diagnosis, treatment, or patient management decisions.
- QIAstat-Dx BCID GN Plus AMR Panel detects bacterial nucleic acids and does not differentiate between viable and non-viable organisms. Bacterial nucleic acids may persist in vivo, even if the organism is not viable or infectious, leading to false positive results.
- Bacteria detected by the QIAstat-Dx BCID GN Plus AMR Panel may not be culturable if the patient has been on antimicrobial therapy prior to or at the time of blood culture collection.
- In specimens containing multiple organisms and/or multiple detectable antimicrobial resistance targets, the assay may not identify all detectable targets present in the specimen, depending upon the concentration of each target and the growth characteristics of organisms within the sample.
- Competitive inhibition has been observed for certain pathogens and AMRs in mixed cultures (see Section 13.1.9 "Competitive inhibition" on page 148) for combinations tested in Competitive Inhibition).
- Isolation on solid media is needed to differentiate mixed growth with other microorganisms and to identify possible blood cultures yielding a negative result.
- The QIAstat-Dx BCID GN Plus AMR Panel contains targets designed to detect different species within a genus or organism group but not differentiate certain species.

- Mixed cultures with species belonging to the same genus or organism group cannot be differentiated in a specimen (e.g. *Klebsiella pneumoniae* and *Klebsiella oxytoca,* or *Proteus mirabilis* and *Proteus hauseri*). Refer to Section 11.2.4 "Group- and genus- assay result interpretation" on page 52 for details.
- The genus level and group assays included as a part of the QIAstat-Dx BCID GN Plus AMR Panel (*Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Salmonella* spp., *Serratia* spp. and Pan *Enterobacterales*), are designed to detect a broad range of species but will not necessarily detect all species within a genus or group or may have reduced sensitivity for some species. For species detected by these assays, including those not detected or detected with reduced sensitivity, refer to Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95.
- Inclusivity testing demonstrated that the QIAstat-Dx BCID GN Plus AMR Panel may have reduced sensitivity for some pathogen strains and may not be detected at concentration normally observed at the time of bottle positivity, but can be detected at higher concentrations. Refer to Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95 for further details.
- There is a risk of false not-detected results due to the presence of strains with sequence variability in the target regions of the oligonucleotides design. Refer to Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95 for additional information.
- Only encapsulated strains of *Neisseria meningitidis* will be detected by the QIAstat-Dx BCID GN Plus AMR Panel.
- There is a risk of false positive results due to cross-reactivity with target organisms as well as cross-contamination by their nucleic acids, or the amplified product, or from non-specific signals in the assay.
- Cross-reactivity with bloodstream infection organisms not evaluated in Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95 may occur and may generate erroneous results.
- In silico analyses used to predict detection and cross-reactivity of organisms and antimicrobial resistance genes were based on sequence comparisons between the CARD (McMaster University) and GenBank (NCBI) databases and the QIAstat-Dx BCID GN Plus AMR Panel primers. These analyses were conducted in September 2025; sequences added after this date were not evaluated, and additional limitations may arise as new sequence data or novel variants emerge.
- Cross-reactivity was identified for certain assays based on in silico and/or in vitro analyses and a comprehensive list is shown in Section 13.1.6 "Exclusivity (Analytical Specificity)"

on page 90. As a result, these assays may produce false detected results in the presence of cross-reacting organisms.

- Results generated by the QIAstat-Dx BCID GN Plus AMR Panel do not replace antimicrobial susceptibility testing (AST). Subculturing and standard susceptibility testing of isolates are required to determine final antimicrobial susceptibility.
- Antimicrobial resistance (AMR) can occur via multiple mechanisms. A Not Detected result for AMR targets on the QIAstat-Dx BCID GN Plus AMR Panel does not indicate antimicrobial susceptibility as other off-panel AMR determinants conferring resistance to certain antibiotics can be present in the organism.
- A detected AMR result does not preclude phenotypic resistance nor the presence of other off-panel AMR determinants and therefore may not correlate with final phenotypic results. A detected AMR also cannot predict the level of resistance to a certain antibiotic as other cellular and molecular mechanisms can influence the expression and/or inhibition of AMR genes. Subculturing and standard susceptibility testing of isolates are required to determine final antimicrobial susceptibility.
- Molecular AMR gene detection should be interpreted together with organism identification, Gram stain findings, culture results, phenotypic susceptibility testing, local epidemiology, antimicrobial stewardship guidance, and the patient's clinical context.
- A detected AMR result cannot be definitely associated to the microorganism(s) detected by the QIAstat-Dx BCID GN Plus AMR Panel.
- For the AMR targets listed in Section 13.1.6 "Exclusivity (Analytical Specificity)" on page 90, cross reactivity was identified by in silico analysis and was not evaluated in vitro; therefore, these AMR assays could potentially generate false detected signals for the reported target(s).
- Some resistance markers (e.g., TEM, SHV) include variants with different activity against multiple antibiotic classes. The primer sets used in the QIAstat-Dx BCID GN Plus AMR Panel therefore detect but do not differentiate a broad range of TEM and SHV genes, including penicillinases, cephalosporinases, and extended spectrum beta-lactamase (ESBL) variants.
- Inclusivity testing demonstrated that the QIAstat-Dx BCID GN Plus AMR Panel may have reduced sensitivity or not be inclusive for some AMR variants and thus, they may not be detected at concentration normally observed at the time of bottle positivity, while no negative effect on the detectability of the associated pathogen is observed. The presence of a pathogen in a sample does not therefore exclude the possibility of a false negative result for the associated AMR(s). Refer to Section 13.1.7 "Inclusivity (Analytical Reactivity)" on page 95 for further details.

13. Performance Characteristics

13.1. Analytical performance

The analytical performance shown below was demonstrated using QIAstat-Dx Analyzer 1.0. QIAstat-Dx Analyzer 2.0 uses the same Analytical Module as QIAstat-Dx Analyzer 1.0; therefore, the performance is transferrable to QIAstat-Dx Analyzer 2.0.

13.1.1. Growth and detection

The expected organism concentration in incubated blood cultures at bottle positivity was determined for each organism on the QIAstat-Dx BCID GN Plus AMR Panel. Each bacterium in the QIAstat-Dx BCID GN Plus AMR Panel was represented by at least one strain, which was mixed with negative human whole blood and seeded directly into a blood culture bottle, typically at ≤300 CFU/bottle. The bottle was then incubated in a continuous monitoring blood culture system until it was indicated as positive for growth (also known as the “bottle ring”) and 27 hours after "bottle ring". At this point, the bottles were removed, and the organism concentration was determined in CFU/mL using a standard plate count procedure.

The system was then used to test the blood culture sample following the QIAstat-Dx BCID GN Plus AMR Panel procedure.

Each representative strain was grown in at least 3 independent blood culture bottles, and each bottle was tested on the QIAstat-Dx system in triplicate, at least.

Mean CFU/mL across the 3 bottles for each condition and pathogen, and results for the detection of the organism at the bottle-positive concentration and plus 27 hours are reported in Table 8. The concentrations listed below indicate approximate levels that may typically occur in a clinical setting.

Table 8. Growth and detection results summary

Organism	Source ID	Organism target [AMR target]	Concentration at bottle positivity (CFU/mL)	Concentration at bottle positivity + 27h (CFU/mL)
Acinetobacter baumannii	ATCC BAA-2801	*Acinetobacter calcoaceticus-baumannii* complex [OXA-23, PER, TEM]	1.65E+08	2.54E+08
Klebsiella pneumoniae	CCUG 68728	*Klebsiella* spp., Pan *Enterobacterales* [CTX-M, *armA*, *ampC* (CMY/LAT/DHA/FOX), SHV, NDM, TEM, *aac(6')-Ib*]	7.70E+07	2.70E+09
Proteus mirabilis	ATCC BAA-2792	*Proteus* spp., Pan *Enterobacterales* [VIM, *aac(6')-Ib*, *ampC* (CMY/LAT/DHA/FOX), TEM]	1.91E+08	6.39E+09
Salmonella enterica	ATCC 6962	*Salmonella* spp., Pan *Enterobacterales*	4.32E+08	3.69E+09
Stenotrophomonas maltophilia	NCTC 10259	*Stenotrophomonas maltophilia*	1.57E+07	3.13E+08
Serratia marcescens	ATCC 14041	*Serratia* spp., Pan *Enterobacterales*	3.83E+08	4.79E+08
Acinetobacter baumannii	ATCC BAA-2890	*Acinetobacter calcoaceticus-baumannii* complex [OXA-58]	4.03E+07	9.18E+07
Escherichia coli	NCTC 14320	*Escherichia coli*, Pan *Enterobacterales*, [IMP, *aac(6')-Ib*, KPC, TEM, OXA-48-like]	1.36E+08	4.30E+09
Acinetobacter baumannii	CCUG 57249	*Acinetobacter calcoaceticus-baumannii* complex [OXA-24/40]	6.47E+07	1.71E+09
Enterobacter asburiae	ATCC 35955	*Enterobacter* spp., Pan *Enterobacterales*	3.25E+08	2.66E+09

Table 8. Growth and detection results summary (continued)

Organism	Source ID	Organism target [AMR target]	Concentration at bottle positivity (CFU/mL)	Concentration at bottle positivity + 27h (CFU/mL)
Escherichia coli	NCTC 13919	*Escherichia coli*,Pan *Enterobacterales* [CTX-M, GES, *aac(6')-Ib*]	9.23E+07	2.75E+09
Pseudomonas aeruginosa	MRSN 12914	*Pseudomonas aeruginosa* [VEB]	2.21E+08	2.18E+09
Citrobacter freundii	CCUG 418T	Pan *Enterobacterales* [*ampC* (CMY/LAT/DHA/FOX)]	4.79E+07	4.16E+09
Acinetobacter baumannii	NCTC 13302	*Acinetobacter calcoaceticus-baumannii* complex, [OXA-24/40]	2.11E+08	2.21E+08
Pseudomonas aeruginosa	NCTC 13921	*Pseudomonas aeruginosa*, [*aac(6')-Ib*, SPM]	3.46E+07	3.78E+09
Neisseria meningitidis	ATCC 13077	*Neisseria meningitidis*	1.94E+08	8.50E+07
Bacteroides fragilis	CCUG 4856T	*Bacteroides fragilis*	5.78E+08	1.53E+10
Haemophilus influenzae	CCUG 33775	*Haemophilus influenzae*	7.68E+07	1.00E+09

13.1.2. Pure colony detection

The Pure colony detection study was executed to verify that the QIAstat-Dx BCID GN Plus AMR Panel can detect each target at the concentration generated when following the defined procedure of colony suspension following terminal subculture of samples grown to bottle positivity.

Representative strains (similar as the ones chosen for the bottle positivity detection) were selected to cover all analytes present in the QIAstat-Dx BCID GN Plus AMR Panel. Using positive blood culture samples, 100 µL of each bottle-positive blood sample was terminally sub-cultured on a tryptone soy agar plate (or other relevant agar) and incubated at the appropriate temperature for approximately 48–72 hours. One plate was generated per bottle lot for each pathogen, therefore, a total of 3 separate terminal subculture (TSC) plates per pathogen. For each plate, 1 pure colony suspension was manufactured to 1.0 McFarland standard, thus creating 3 separate lots of pure colony suspensions per pathogen.

Each pathogen was tested for 9 replicates on QIAstat-Dx BCID GN Plus AMR Panel (3 replicates per pure colony suspension lot) within 2 hours of sample generation. All expected targets were detected within each of the pure colony samples tested with at least 9/9 (100%) replicates positive.

13.1.3. Bottle equivalency

The performance of various blood culture media bottle types was assessed using the QIAstat-Dx BCID GN Plus AMR Panel to demonstrate that it can detect targets at positive bottle concentrations across different bottle types.

Thirteen blood culture bottles, both aerobic and anaerobic, were included in this study. Samples containing a representative organism for each target were prepared at the point of bottle positivity for BD BACTEC™ and BioMérieux BACT/ALERT blood culture media bottles by incubating them in a continuous monitoring blood culture system (CMBCI). For VersaTREK bottles, which lacked an appropriate CMBCI, samples were prepared at a similar concentration to bottle positivity by spiking them with representative target microorganisms. Additionally, one negative blood culture matrix (NBCM) sample was generated and tested on the QIAstat-Dx BCID GN Plus AMR Panel for each bottle type.

A summary of the bottle types assessed, including the proportion of positive calls by bottle type, is found in Table 9.

Table 9. Bottle equivalency results summary

			Proportion of positive calls	
Blood culture bottle information	**Hits**	**N**	**Percentage (%) (2-sided 95% Confidence Interval)**	**Study outcome (%)**
BD BACTEC Plus Aerobic	480	480	100.0 (99.2–100)	100.0 correct calls
BD BACTEC Plus Anaerobic	129	129	100.0 (97.2–100)	100.0 correct calls
BD BACTEC Standard Aerobic	153	153	100.0 (97.6–100)	100.0 correct calls

Table 9. Bottle equivalency results summary (continued)

			Proportion of positive calls	
Blood culture bottle information	**Hits**	**N**	**Percentage (%) (2-sided 95% Confidence Interval)**	**Study outcome (%)**
BD BACTEC Standard Anaerobic	119	119	100.0 (96.9–100)	100.0 correct calls
BD BACTEC Peds Plus	162	162	100.0 (97.8–100)	100.0 correct calls
BD BACTEC Lytic Anaerobic	119	121	98.3 (94.2–99.8)	98.3 correct calls False negative results observed for TEM (in Acinetobacter baumannii) (2)
BioMérieux BACT/ALERT SA Standard Aerobic	150	150	100.0 (97.6–100)	100.0 correct calls
BioMérieux BACT/ALERT SN Standard Anaerobic	151	151	100.0 (97.6–100)	100.0 correct calls
BioMérieux BACT/ALERT FA PLUS Aerobic	153	153	100.0 (97.6–100)	100.0 correct calls
BioMérieux BACT/ALERT FN PLUS Anaerobic	107	107	100.0 (96.6–100)	100.0 correct calls
BioMérieux BACT/ALERT PF PLUS Peds	149	149	100.0 (97.6–100)	100.0 correct calls
Thermo Scientific Versatrek Redox 1	156	156	100.0 (97.7–100)	100.0 correct calls
Thermo Scientific Versatrek Redox 2 EZ Draw Anaerobic	158	158	100.0 (97.7–100)	100.0 correct calls
Overall	2186	2188	99.9	
Overall BD BACTEC	1162	1164	99.8	

Table 9. Bottle equivalency results summary (continued)

			Proportion of positive calls	
Blood culture bottle information	**Hits**	**N**	**Percentage (%) (2-sided 95% Confidence Interval)**	**Study outcome (%)**
Overall BioMérieux BACT/ALERT	710	710	100.0	
Overall Thermo Scientific Versatrek	314	314	100.0	

13.1.4. Agar equivalency and interference

The QIAstat-Dx BCID GN Plus AMR Panel was evaluated to confirm that assay performance is not impacted by residual agar material from colony samples. Representative isolates for each panel target were cultured on different types of agar plates. For each agar type, 3 plates per pathogen were prepared; 1 sample was taken from each plate and tested in triplicate on the panel. Results and agar types used for each target are summarized in Table 10.

Additionally, a small agar fragment was intentionally introduced into the cartridge in a saline matrix to simulate potential mechanical interference. All negative control cartridges (saline and agar-spiked) completed runs without failures. Internal controls met validity criteria, and no false-positive results were observed. These findings demonstrate that neither saline nor agar carryover interferes with QIAstat-Dx BCID GN Plus AMR Panel performance.

Table 10. Agar equivalency results summary

		Percentage hit rate summary (%)				
Pathogen	**Target(s)**	**Columbia blood agar**	**MacConkey agar**	**TSA II agar**	**Chocolate agar with 1% PolyVitex**	**Fastidious anaerobe agar with 5% DSB**
Acinetobacter baumannii (ATCC BAA-2801)	*Acinetobacter calcoaceticus-baumannii* complex	100	100	100	N/A	N/A
	OXA-23					
	PER					
	TEM					
Klebsiella pneumoniae (CCUG 68728)	*Klebsiella* spp.	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
	CTX-M					
	armA					
	ampC (CMY/LAT/DHA/FOX)					
	aac(6')-Ib					
	SHV					
	NDM					
	TEM					
Proteus mirabilis (ATCC BAA-2792)	*Proteus* spp.	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
	VIM					
	aac(6')-Ib					
	ampC (CMY/LAT/DHA/FOX)					
	TEM					

Table 10. Agar equivalency results summary (continued)

		Percentage hit rate summary (%)				
Pathogen	**Target(s)**	**Columbia blood agar**	**MacConkey agar**	**TSA II agar**	**Chocolate agar with 1% PolyVitex**	**Fastidious anaerobe agar with 5% DSB**
Salmonella enterica (ATCC 6962)	*Salmonella* spp.	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
Stenotrophomonas maltophilia (NCTC 10259)	*Stenotrophomonas maltophilia*	100	100	100	N/A	N/A
Serratia marcescens (ATCC 14041)	*Serratia* spp.	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
Acinetobacter baumannii (ATCC BAA-2890)	*Acinetobacter calcoaceticus-baumannii* complex	100	100	100	N/A	N/A
	OXA-58					
Escherichia coli (NCTC 14320)	*Escherichia coli*	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
	IMP					
	aac(6')-Ib					
	KPC					
	OXA-48 like					
	TEM					
Acinetobacter baumannii (CCUG 57249)	*Acinetobacter calcoaceticus-baumannii* complex	100	100	100	N/A	N/A
	OXA-24/40					

Table 10. Agar equivalency results summary (continued)

		Percentage hit rate summary (%)				
Pathogen	**Target(s)**	**Columbia blood agar**	**MacConkey agar**	**TSA II agar**	**Chocolate agar with 1% PolyVitex**	**Fastidious anaerobe agar with 5% DSB**
Enterobacter cloacae (NCTC 14326)	*Enterobacter* spp.	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
	aac(6')-Ib					
	VIM					
Escherichia coli (NCTC 13919)	*Escherichia coli*	100	100	100	N/A	N/A
	Pan *Enterobacterales*					
	CTX-M					
	GES					
	aac(6')-Ib					
Pseudomonas aeruginosa (MRSN 12914)	*Pseudomonas aeruginosa*	100	100	100	N/A	N/A
	VEB					
Citrobacter freundii (CCUG 418T)	Pan *Enterobacterales*	100	100	100	N/A	N/A
	ampC (CMY/LAT/DHA/FOX)					
Pseudomonas aeruginosa (NCTC 13921)	*Pseudomonas aeruginosa*	100	100	100	N/A	N/A
	aac(6')-Ib					
	SPM					
Neisseria meningitidis (ATCC 13077)	*Neisseria meningitidis* (Encapsulated)	N/A	N/A	N/A	100	N/A
Bacteroides fragilis (CCUG 4856T)	*Bacteroides fragilis*	100	N/A	N/A	N/A	100

Table 10. Agar equivalency results summary (continued)

		Percentage hit rate summary (%)				
Pathogen	**Target(s)**	**Columbia blood agar**	**MacConkey agar**	**TSA II agar**	**Chocolate agar with 1% PolyVitex**	**Fastidious anaerobe agar with 5% DSB**
Haemophilus influenzae (CCUG 33775)	*Haemophilus influenzae*	N/A	N/A	N/A	100	N/A

13.1.5. Limit of Detection

The Limit of Detection (LoD) is defined as the lowest concentration at which ≥95% of the tested samples generate a positive call.

The LoD for each of the QIAstat-Dx BCID GN Plus AMR Panel targets was assessed, using a total of 55 pathogen strains and one synthetic DNA fragment, by analyzing serial dilutions of analytical samples prepared from culture isolates from commercial suppliers (e.g., ATCC, NCTC, CCUG).

The limit of detection of each organism was evaluated in both sample types. For the positive blood culture matrix (PBCM) sample type, each sample tested was prepared in negative blood culture matrix, which consists of screened negative whole blood added into blood culture bottles, then incubated in a blood culture instrument for 5–7 days. A lack of a positive ring at the end of incubation confirmed that the blood was negative. For the pure colony (PC) suspension sample type, each sample was manufactured by combining pathogenic strains at 1.0 McFarland into saline.

The confirmed LoD was established by testing 20 replicates at the concentration determined from the preliminary LoD for each strain. The LoD for each strain was confirmed if ≥95% of the replicates were positive. To further confirm the LoD, at least one dilution below the LoD was tested for each strain and was required to result in less than 95% positivity.

Individual LoD values for each QIAstat-Dx BCID GN Plus AMR Panel target are shown in Table 11.

Note: The reported concentrations refer to values established in direct positive blood cultures for VersaTREK media or in positive blood cultures that underwent a 1:1 dilution for other media types (BD BACTEC and BACT/ALERT).

Table 11. Limit of Detection results summary

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
		Microorganism		
Acinetobacter calcoaceticus-baumannii complex	*Acinetobacter baumannii*	NCTC 13305	3.50E+04	3.50E+04
	Acinetobacter baumannii	ATCC BAA-2803	1.78E+04	1.68E+05
	Acinetobacter baumannii	CCUG 57249	1.78E+04	6.00E+04
	Acinetobacter baumannii	ATCC BAA-2801	4.14E+04	7.00E+05
	Acinetobacter baumannii	ATCC BAA-2890	3.50E+03	N/A
	Acinetobacter pitti	CCUG 72793	N/A	6.73E+04
	Acinetobacter baumannii	ATCC BAA-1605	N/A	1.00E+05
Bacteroides fragilis	*Bacteroides fragilis*	NCTC 11625	1.30E+04	7.50E+03
	Bacteroides fragilis	NCTC 8560	1.30E+04	N/A
	Bacteroides fragilis	CCUG 4586T	N/A	4.13E+03
Enterobacter spp.	*Enterobacter asburiae*	ATCC 35955	3.40E+05	6.00E+07
	Enterobacter cloacae	NCTC 14326	2.70E+06	8.00E+06
Escherichia coli	*Escherichia coli*	CCUG 67180	3.14E+05	3.00E+05
	Escherichia coli	NCTC 14325	1.35E+05	8.00E+05
	Escherichia coli	NCTC 14321	2.30E+05	N/A
	Escherichia coli	ATCC BAA-2340	N/A	7.50E+05

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
Haemophilus influenzae	*Haemophilus influenzae*	CCUG 23946	9.00E+03 (9.05E+04 copies/mL)	N/A
	Haemophilus influenzae	CCUG 33775	1.87E+04 (copies/mL)	N/A
	Haemophilus influenzae	CCUG 26214	N/A	9.00E+03
Klebsiella spp.	*Klebsiella pneumoniae*	ATCC BAA-3077	3.00E+04	1.00E+05
	Klebsiella pneumoniae	NCTC 14334	3.00E+04	1.26E+05
	Klebsiella pneumoniae	ATCC BAA-1705	3.00E+05	1.08E+05
	Klebsiella pneumoniae	CCUG 68728	3.38E+04	N/A
	Klebsiella pneumoniae	ATCC-BAA-1144	N/A	1.26E+05
	Klebsiella oxytoca	ATCC BAA-3059	N/A	7.50E+04
	Klebsiella pneumoniae	ATCC BAA-2524	N/A	1.26E+05
Neisseria meningitidis (Encapsulated)	*Neisseria meningitidis*	ATCC 13090	1.00E+03	N/A
	Neisseria meningitidis	ATCC 13077	1.00E+04	N/A
	Neisseria meningitidis	CCUG 27650	N/A	1.00E+04
Pan *Enterobacterales*	*Hafnia paralvei*	CCUG 59411	1.26E+07	7.50E+07
	Citrobacter freundii	CCUG 418T	1.60E+05	N/A
	Citrobacter freundii	ATCC 6879	N/A	1.00E+07

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
Proteus spp.	*Proteus vulgaris*	ATCC 6380	3.00E+05	3.21E+05
	Proteus mirabilis	ATCC BAA-2792	3.00E+04	N/A
	Proteus mirabilis	ATCC 43071	N/A	1.00E+05
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	MRSN 12914	3.22E+07	5.15E+05
	Pseudomonas aeruginosa	NCTC 13437	1.00E+06	N/A
	Pseudomonas aeruginosa	JMI 378769	9.60E+05	N/A
	Pseudomonas aeruginosa	NCTC 13921	8.40E+05	N/A
	Pseudomonas aeruginosa	ATCC BAA-2794	1.00E+06	1.00E+06
	Pseudomonas aeruginosa	ATCC BAA-2796	N/A	3.00E+04
Salmonella spp.	*Salmonella enterica*	ATCC 6962	1.00E+04	1.00E+05
	Salmonella enterica	NCTC 13954	5.00E+03	N/A
Serratia spp.	*Serratia marcenses*	ATCC 14041	7.00E+06	N/A
	Serratia liquefaciens	ATCC 27592	7.50E+04	7.50E+05
	Serratia marcenses	NCTC 10211	N/A	7.50E+05
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	NCTC 10499	1.63E+08	6.00E+07
	Stenotrophomonas maltophilia	NCTC 10258	6.50E+06	8.18E+06

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
		AMR		
aac(6')-Ib	*Klebsiella pneumoniae*	ATCC BAA-3077	3.00E+04	1.00E+05
	Pseudomonas aeruginosa	ATCC BAA-2799	1.00E+05	5.15E+05
	Escherichia coli	NCTC 14325	1.35E+04	8.00E+04
	Klebsiella pneumoniae	CCUG 68728	3.38E+04	N/A
	Pseudomonas aeruginosa	NCTC 13921	8.40E+05	N/A
	Pseudomonas aeruginosa	ATCC BAA-2794	1.00E+05	1.00E+06
	Proteus mirabilis	ATCC BAA-2792	3.00E+05	N/A
	Klebsiella pneumoniae	NCTC 14334	3.00E+04	1.26E+05
	Klebsiella pneumoniae	ATCC BAA-1705	3.00E+05	1.08E+05
	Klebsiella pneumoniae	ATCC BAA-1144	N/A	1.26E+05
	Acinetobacter baumannii	ATCC BAA-2803	N/A	1.68E+05
	Enterobacter cloacae	NCTC 14326	N/A	8.00E+04

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
ampC (CMY/LAT/DHA/FOX)	*Klebsiella pneumoniae*	CCUG 68728	3.38E+05	N/A
	Proteus mirabilis	ATCC BAA-2792	3.00E+05	N/A
	Citrobacter freundii	CCUG 418	1.60E+05	N/A
	Klebsiella pneumoniae	ATCC BAA-1144	N/A	1.26E+05
	Citrobacter freundii	ATCC 6879	N/A	1.00E+06
	Morganella morganii	ATCC 25829	N/A	7.50E+05
armA	*Acinetobacter baumannii*	ATCC BAA-2803	1.78E+04	1.68E+05
	Klebsiella pneumoniae	CCUG 68728	3.38E+04	N/A
	Klebsiella oxytoca	ATCC BAA-3059	N/A	7.50E+04
CTX-M	*Klebsiella pneumoniae*	ATCC BAA-3077	3.00E+04	1.00E+05
	Escherichia coli	NCTC 14325	1.35E+05	8.00E+04
	Klebsiella pneumoniae	CCUG 68728	3.38E+04	N/A
	Klebsiella oxytoca	ATCC BAA-3059	N/A	7.50E+04
GES	*Klebsiella pneumoniae*	ATCC BAA-3077	3.00E+04	1.00E+05
	Pseudomonas aeruginosa	ATCC BAA-2794	1.00E+06	1.00E+06
IMP	*Escherichia coli*	CCUG 67180	3.14E+05	3.00E+05
	Klebsiella pneumoniae	NCTC 14334	3.00E+04	1.26E+05

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
KPC	*Escherichia coli*	NCTC 14321	2.30E+05	N/A
	Klebsiella pneumoniae	ATCC BAA-1705	3.00E+05	1.08E+05
	Escherichia coli	ATCC BAA-2340	N/A	7.50E+05
NDM	*Escherichia coli*	NCTC 14325	1.35E+05	8.00E+05
	Klebsiella pneumoniae	CCUG 68728	3.38E+06	N/A
	Pseudomonas aeruginosa	ATCC BAA-2796	N/A	3.00E+05
OXA-23	*Acinetobacter baumannii*	ATCC BAA-2803	1.78E+04	1.68E+05
	Acinetobacter baumannii	ATCC BAA-2801	4.14E+04	7.00E+05
	Acinetobacter baumannii	ATCC BAA-1605	N/A	1.00E+05
OXA-24/40	*Acinetobacter baumannii*	CCUG 57249	1.78E+04	6.00E+04
	Acinetobacter baumannii	ATCC BAA-2881	5.73E+04	6.00E+04
OXA-48-like	*Escherichia coli*	NCTC 14321	2.30E+05	N/A
	Salmonella enterica	NCTC 13954	5.00E+03	N/A
	Klebsiella pneumoniae	ATCC BAA-2524	N/A	1.26E+05
OXA-58	*Acinetobacter baumannii*	NCTC 13305	3.50E+04	3.50E+04
	Acinetobacter baumannii	ATCC BAA-2890	3.50E+03	3.50E+04

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
PER	*Acinetobacter baumannii*	ATCC BAA-2801	4.14E+05	7.00E+05
	Pseudomonas aeruginosa	ATCC BAA-2799	1.00E+05	5.15E+05
SHV	*Klebsiella pneumoniae*	ATCC BAA-3077	3.00E+04	1.00E+05
	Klebsiella pneumoniae	ATCC BAA-1705	3.00E+05	1.08E+05
	Klebsiella pneumoniae	CCUG 68728	3.38E+04	N/A
	Klebsiella pneumoniae	NCTC 14334	3.00E+05	1.26E+05
	Klebsiella pneumoniae	ATCC BAA-1144	N/A	1.26E+05
	Klebsiella pneumoniae	ATCC BAA-2524	N/A	1.26E+05
SPM	*Pseudomonas aeruginosa*	JMI 378769	9.60E+06	N/A
	Pseudomonas aeruginosa	NCTC 13921	8.40E+05	5.15E+05
	N/A - gBlock SPM-1	gBlock SPM-1_ AJ492820.1	N/A	1.06E+02 (copies/mL)

Table 11. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
TEM	*Klebsiella pneumoniae*	ATCC BAA-3077	3.00E+05	N/A
	Escherichia coli	CCUG 67180	3.14E+05	N/A
	Klebsiella pneumoniae	CCUG 68728	3.38E+06	N/A
	Proteus mirabilis	ATCC BAA-2792	3.00E+06	N/A
	Klebsiella pneumoniae	ATCC BAA-1705	N/A	1.08E+07
	Klebsiella oxytoca	ATCC BAA-3059	N/A	7.50E+05
	Klebsiella pneumoniae	NCTC 14334	N/A	1.26E+06
	Acinetobacter baumannii	ATCC BAA-2801	N/A	3.00E+08
VEB	*Pseudomonas aeruginosa*	MRSN 12914	3.22E+07	5.15E+05
	Pseudomonas aeruginosa	NCTC 13437	1.00E+06	N/A
	Pseudomonas aeruginosa	ATCC BAA 2796	N/A	3.00E+04
VIM	*Pseudomonas aeruginosa*	NCTC 13437	1.00E+06	N/A
	Pseudomonas aeruginosa	ATCC BAA-2799	1.00E+05	5.15E+05
	Enterobacter cloacae	NCTC 14326	2.70E+05	8.00E+04
	Proteus mirabilis	ATCC BAA-2792	3.00E+04	N/A

13.1.6. Exclusivity (Analytical Specificity)

The analytical specificity study was carried out by in vitro testing and in silico analysis to assess the potential cross-reactivity and exclusivity of the QIAstat-Dx BCID GN Plus AMR

Panel. On-panel organisms were tested to assess the potential for intra-panel cross-reactivity, and off-panel organisms were tested to evaluate cross-reactivity with organisms not covered by the panel content. Each off-panel organism was tested in triplicate with bacteria tested at a concentration of >1.5E+08 CFU/mL and fungi tested at a concentration of >1.5E+06 CFU/mL. Six organisms were tested below the intended starting concentration due to limitations in achievable growth in positive blood culture matrix: *Corynebacterium jeikeium* (1.92E+07 CFU/mL), *Fusarium solani* (3.70E+03 CFU/mL), *Mucor velutinosus* (1.00E+05 CFU/mL), *Staphylococcus capitis* (7.70E+07 CFU/mL), *Staphylococcus lugdunensis* (9.00E+07 CFU/mL), and *Trichosporon asteroides* (2.08E+05 CFU/mL). No cross-reactivity was predicted for these organisms in the in silico analysis.

Several off-panel microorganisms showed cross-reactivity with *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter* spp., *Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Klebsiella* spp., and *Escherichia coli* assays. The off-panel organisms tested are shown in Table 12 (see footnotes for further information regarding cross-reactions).

Table 12. List of off-panel targets tested for cross-reactivity in-vitro analysis

Pathogen	Source ID	Pathogen	Source ID
Acinetobacter haemolyticus	CCUG 888	*Haemophilus haemolyticus*	CCUG 12834
*Acinetobacter junii**	CCUG 889	*Haemophilus parainfluenzae*	CCUG 12836T
Acinetobacter lwoffii	NCTC 5866	*Lactobacillus acidophilus*	CCUG 5917
Acinetobacter nosocomialis (*genomospecies anitratus*)	CCUG 26488	*Lactobacillus casei*	CCUG 21451
Acremonium kiliense	NCPF 2901	*Lactobacillus crispatus*	LMG 12004
Aeromonas hydrophila	CCUG 67305	*Lactobacillus paracasei*	CCUG 34678
Aeromonas salmonicida	LMG 3780	*Lactobacillus rhamnosus*	CCUG 18011
Aeromonas sobria	CCUG 14550	*Legionella pneumophila*	CCUG 9568
Aggregatibacter aprhophilus	NCTC 5906	*Listeria monocytogenes*	CCUG 74245
Bacillus cereus	NCTC 8035	*Listeria innocua*	CCUG 15531
Bacteroides ovatus	CCUG 4943	*Malassezia furfur*	CBS 7019
Bacteroides caccae	CCUG 38735	*Micrococcus luteus*	NCTC 7011
Bacteroides distasonis	CCUG 4941	*Mucor velutinosus*	CBS 204.68

Table 12. List of off-panel targets tested for cross-reactivity in-vitro analysis (continued)

Pathogen	Source ID	Pathogen	Source ID
Bacteroides eggerthii	CCUG 9559	*Neisseria flavescens*	CCUG 17913
Bacteroides merdae	CCUG 38734	*Neisseria gonorrhoeae*	CCUG 26876
Bacteroides thetaiotaomicron	CCUG 10774	*Neisseria sicca*	CCUG 23929
Bacteroides ureolyticus	CCUG 7319T	*Neisseria perflava*	CCUG 66328
Bacteroides vulgatus	CCUG 4940	*Pasteurella aerogenes*	CCUG 12761
Burkholderia cepacia	NCTC 10743	*Pasteurella multocida* subsp. *Multocide*	NCTC 10322
Burkholderia glumae	CCUG 20835T	*Penicillium marneffei* (gDNA ONLY HG3)	CBS 549.77
Candida albicans	NCPF 8672	*Prevotella corporis*	CCUG 15404
Candida auris	NCPF 8971	*Prevotella intermedia*	CCUG 24041
Candida glabrata	NCPF 8018	*Prevotella nigrescens*	CCUG 9560
Candida tropicalis	NCPF 8760	*Propionibacterium/Cutibacterium acnes*	NCTC 737
Candida dublinensis	CCUG 69485	*Pseudomonas alcaligenes*	CCUG 1425
Candida famata	NCPF 8744	*Pseudomonas fluorescens*	NCTC 10038
Candida guilliermondii	NCPF 3896	*Pseudomonas putida*	NCTC 10936
Candida kefyr	NCPF 8343	*Pseudomonas mendocina*†	CCUG 1781
Candida krusei	CCUG 35869	*Pseudomonas stutzeri*	CCUG 58289
Candida lusitaniae	CCUG 37495	*Ralstonia insidiosa*	CCUG 46789
Candida metapsilosis	NCPF 8791	*Ralstonia pickettii*	CCUG 3318
Candida norvegensis	CBS 1922	*Rhizobium pusense*‡	LMG 25623
Candida orthopsilosis	NCPF 8804	*Rhodotorula minuta*	NCPF 8736
Candida parapsilosis	NCPF 3207	*Staphylococcus aureus*	CCUG 67181
Corynebacterium diphtheriae	CCUG 33629	*Staphylococcus capitis*	CCUG 42761
Corynebacterium striatum	ATCC 43735	*Staphylococcus epidermidis*	ATCC 35984
Corynebacterium jeikeium	ATCC BAA-949	*Staphylococcus lugdunensis*	CCUG 74993
Corynebacterium ulcerans	ATCC 51799	*Stenotrophomonas acidaminiphila*§	CCUG 46887T

Table 12. List of off-panel targets tested for cross-reactivity in-vitro analysis (continued)

Pathogen	Source ID	Pathogen	Source ID
Corynebacterium urealyticum	ATCC 43044	*Streptococcus agalactiae*	CCUG 4208
Cryptococcus neoformans	CCUG 23479	*Streptococcus pneumoniae*	CCUG 70149
Cryptococcus gattii	ATCC MYA-4071	*Streptococcus pyogenes*	NCTC 12696
Eikenella corrodens	CCUG 2138	*Streptococcus anginosus*	CCUG 27298
Enterococcus faecalis	CCUG 19916	*Streptococcus galloyticus*	NCTC 13784
Enterococcus faecium	CCUG 68933	*Trichosporon asahii*	CCUG 57655
Fusarium solani	NCPF 7483	*Trichosporon asteroides*	NCPF 3856
Fusobacterium gonidiaformans	CCUG 16790	*Trichosporon dermatis*	CBS 2043
Fusobacterium necrophorum	ATCC 27852	*Trichosporon mucoides*	CBS 8667
Fusobacterium nucleatum	ATCC 25586	*Vibrio alginolyticus*	NCTC 10675
Fusobacterium varium	NCTC 10560	*Vibrio furnissii*	CCUG 37458
Haemophilus parahaemolyticus	CCUG 3716		

* Cross-reaction observed with the *Acinetobacter calcoaceticus-baumannii* complex assay at ≥1.50E+06 CFU/mL and predicted in silico with several sequence mismatches.

† Cross-reaction observed with the *Pseudomonas aeruginosa* assay at ≥2.88E+06 CFU/mL and predicted in silico with several sequence mismatches.

‡ Cross-reaction predicted in silico with the *Escherichia coli* assay but not confirmed in vitro.

§ Cross-reaction observed with the *Stenotrophomonas maltophilia* assay at ≥1.5E+06 CFU/mL and predicted in silico.

Cross-reactivity with the on-panel targets was observed for microorganisms shown in Table 13. The on-panel organisms tested are shown in Table 13 and Table 14, tested as part of the Growth and Detection and Analytical Reactivity, respectively.

Table 13. Summary of cross-reactivities observed for on-panel targets

On-panel pathogen	Source ID	Target in the QIAstat-Dx BCID GN Plus AMR Panel
Enterobacter ludwigii	CCUG 26899	*Klebsiella* spp.
Enterobacter ludwigii	CCUG 26899	*Proteus* spp.
*Citrobacter braaki**	ATCC 51113	*Serratia* spp.

Table 13. Summary of cross-reactivities observed for on-panel targets (continued)

On-panel pathogen	Source ID	Target in the QIAstat-Dx BCID GN Plus AMR Panel
*Hafnia paralvei**	CCUG 59411	*Proteus* spp.
Lelliottia amnigena	ATCC 33072	*Klebsiella* spp.
Leclercia adecarboxylata	NCTC 13032	*Enterobacter* spp.
Shigella sonnei	CCUG 68726	*Escherichia coli*
Shigella boydii	CCUG 49022	*Escherichia coli*
Providentia stuartii	CCUG 74678	*Proteus* spp.
Yersinia enterocolitica	NCTC 12982	*Serratia* spp.
Haemophilus influenzae†	Clinical study	Pan *Enterobacterales*
Pasteurella multocida†	Clinical study	Pan *Enterobacterales*

* Cross-reaction not predicted by in-silico analysis.

† Cross-reaction observed during clinical study.

In addition, apart from the cross-reactions detected in vitro, in silico predictions showed that the following cross-reactions may occur (organisms or AMRs not tested in vitro) (see Table 14).

Table 14. Potential cross-reactions based on in silico analysis

Potential cross-reactive organisms/AMRs	Target in the QIAstat-Dx BCID GN Plus AMR Panel
*Bacteroides hominis**	*Bacteroidis fragilis*
Citrobacter spp. (on-panel)	*Enterobacter* spp.
Enterobacter spp. (on-panel)	*Klebsiella* spp.
Escherichia ruysiae (on-panel)	*Escherichia coli*
Kosakonia cowanii and *Kosakonia radicincitans* (on-panel)†	*Enterobacter* spp.
Pantoea agglomerans (on-panel)	*Proteus* spp.
Pseudomonas denitrificans	Pseudomonas aeruginosa
Shigella flexneri and *Shigella dysenteriae* (on-panel)	*Escherichia coli*
Stenotrophomonas muris‡, *Stenotrophomonas riyadhensis* and *Stenotrophomonas tuberculopleuritidis*	*Stenotrophomonas maltophilia*

Table 14. Potential cross-reactions based on in silico analysis (continued)

Potential cross-reactive organisms/AMRs	Target in the QIAstat-Dx BCID GN Plus AMR Panel
AFM b-lactamases family	NDM
ANT(3'')-II-AAC(6')-IId	*aac(6')-Ib (aacA4)*
bla_{AAK-1}	SHV
$bla_{OKP-c-1}$	SHV
LEN b-lactamases family	SHV
MOX-9	*ampC* (FOX)

* *Bacteroides fragilis* Division II now represents a distinct species, which is recognized as *Bacteroides hominis* (57).

† Organisms currently classified as *Kosakonia cowanii* and *Kosakonia radicincitans* were previously described as *Enterobacter radicincitans,* and have been associated with human disease (58, 59, 60). Cross-reaction with *Kosakonia cowanii* and *Enterobacter* spp. not confirmed in vitro.

‡ This species is classified into the *S. maltophilia* complex (61); therefore, a potential cross-reaction is expected.

13.1.7. Inclusivity (Analytical Reactivity)

This study was performed to evaluate the detection of all clinically relevant organism subtypes, strains, genotypes, serotypes, species, and AMR gene variants representing the genetic, temporal, and geographic diversity for each analyte of the QIAstat-Dx BCID GN Plus AMR Panel on a QIAstat-Dx Analyzer. To further demonstrate the inclusivity of the assays, a deeper in silico analysis was performed for every single PCR assay included in the QIAstat-Dx BCID GN Plus AMR Panel.

For the laboratory testing, a minimum of 5 strains were tested for every On-Panel target analyte. For those targets including more than one species (*Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Salmonella* spp., *Serratia* spp., and Pan *Enterobacterales* assay), at least 5 strains were tested in total. As an exception, AMR genes OXA-58 and SPM were tested in less than 5 strains because of samples availability. First, all assays included in the QIAstat-Dx BCID GN Plus AMR Panel intended to detect presence of organisms were evaluated. All strains described in Table 15 were tested in triplicates at the initial concentration near LoD for the majority of the targets. In cases where results were not positive for all the tested replicates, higher concentrations were tested (e.g., 30x LoD, 300x LoD) to assess the inclusivity of the assay.

Table 15. Summary of pathogen inclusivity results

Target	Species	Source ID	Strain name/ Designation	Result
Acinetobacter calcoaceticus-baumannii complex	*Acinetobacter baumannii*	PA212222	N/A	Detected
	Acinetobacter calcoaceticus	CCUG 57816	(Beijerinck 1911) Baumann et al. 1968 (Approved Lists 1980), RUH2202	
	Acinetobacter nosocomialis	CCUG 74064	Nemec et al. 2011 in [Validation List No. 140 (2011)], NIPH 2119; CCM 7791; LMG 10619; RUH 2376	
	Acinetobacter baumannii	ATCC BAA-2801*	1103521	
	Acinetobacter baumannii	ATCC BAA-2803*	1125209	
	Acinetobacter baumannii	ATCC BAA-2881	Bouvet and Grimont, 1173844	
	Acinetobacter baumannii	ATCC BAA-2901	Bouvet and Grimont, 157075	
	Acinetobacter baumannii	ATCC BAA-2890*	Bouvet and Grimont, 177579	
	Acinetobacter baumannii	ATCC BAA-2895	N/A	
	Acinetobacter baumannii	ATCC BAA-2873	1081925	
	Acinetobacter baumannii	CCUG 57249*	Bouvet and Grimont 1986	
	Acinetobacter baumannii	CCUG 68164	Bouvet and Grimont 1986	
	Acinetobacter baumannii	NCTC 13302	OXA-25, 327009	
	Acinetobacter baumannii	NCTC 13305*	A-15	
	Acinetobacter baumannii	NCTC 13424	UK 20	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Acinetobacter pittii	CCUG 72793	EQUA 2018:03/B	
Bacteroides fragilis	*Bacteroides fragilis*	CCUG 4856T	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (Approved Lists 1980), EN-2, Onslow/VPI 2553 [EN-2; NCTC 9343]	Detected
	Bacteroides fragilis	CCUG 25931	Bergan and Hovig 1968, LRA 048 07 85/ [ICPB 3498, NCTC I0581]	
	Bacteroides fragilis	NCTC 11295	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL), 83008	
	Bacteroides fragilis	NCTC 11625*	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL)	
	Bacteroides fragilis	NCTC 8560*	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL), WPMH 1	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Enterobacter spp.	*Enterobacter amnigenus*	ATCC 33072	(Izard et al. 1981) Brady et al. 2013, CUETM 77-118	Detected
	Lelliottia nimipressuralis	CCUG 69901	(Carter 1945) Brady et al. 2013	
	Enterobacter ludwigii	CCUG 26899	(Jordan 1890) Hormaeche and Edwards 1960 (Approved Lists 1980)	
	Enterobacter ludwigii	CCUG 51323T	Hoffmann et al. 2005, EN-119	
	Enterobacter asburiae	ATCC 35955*	Brenner et al., CDC 14-81	
	Enterobacter cancerogenus	CCUG 48556	(Urosevic 1966) Dickey and Zumoff 1988, strain RSTN 68352/03	
	Enterobacter cloacae	NCTC 14326*	(Jordan 1890) Hormaeche and Edwards 1960, 29	
	Enterobacter hormaechei subsp. *Xiangfangensis*	CCUG 63474	N/A	
	Enterobacter kobei	CCUG 59627	(Jordan 1890) Hormaeche and Edwards 1960 (Approved Lists 1980)	
	Enterobacter bugandensis	CCUG 75194T	N/A, EB-247, 247BMC, DSM 29888, NCCB 100573	
	Enterobacter hormaechei subsp. *Oharae*	CCUG 53905T	Hoffmann et al. 2016, EN-314	
	Enterobacter hormaechei subsp. *Steigerwaltii*	CCUG 60271	O'Hara et al. 1990	
	E. roggenkampii	CCUG 75192T	N/A, EN-117;DSM 16690;LMG 30172	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	E. hormaechei subsp. *Hoffmannii*	NCTC 13870	O'Hara et al. 1990, sp. nov., LBM 93.03.067, CCM 7804, CCUG 60038, 2.5, R26	
	Enterobacter cloacae	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	
	Enterobacter cloacae	NCTC 14322	(Jordan 1890) Hormaeche and Edwards 1960, 42E	
	Enterobacter cloacae subsp. *dissolvens*	CCUG 25230T	(Rosen 1922) Hoffmann et al. 2005, W-4, 8122-8	
	Enterobacter gergoviae	CCUG 33719†‡	(Brenner et al. 1980) Brady et al. 2013	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Escherichia coli	*Escherichia coli*	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	Detected
	Escherichia coli	ATCC BAA-2775	1099675	
	Escherichia coli	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	
	Escherichia coli	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	Escherichia coli	CCUG 67180*	(Migula 1895) Castellani and Chalmers 1919 (Approved Lists 1980)	
	Escherichia coli	NCTC 14321*	(Migula 1895) Castellani and Chalmers 1919, 7	
	Escherichia coli	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919	
	Escherichia coli	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	Escherichia coli	NCTC 14339	(Migula 1895) Castellani and Chalmers 1919, MLST: 361	
	Escherichia coli	NCTC 13351	N/A	
	Escherichia coli	NCTC 13462	N/A	
	Escherichia coli	NCTC 13352	N/A	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Haemophilus influenzae	*Haemophilus influenzae*	NCTC 4560	Haemophilus influenzae corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), NCTC 4560 [18]	Detected
	Haemophilus influenzae	CCUG 23946*	(Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), Kilian HK 394, Pittman 576, 576, HK 394	
	Haemophilus influenzae	CCUG 29539	Haemophilus influenzae corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), L-378	
	Haemophilus influenzae	CCUG 33775*	Haemophilus influenzae corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), 572, LRA 026 05 90/AMC 36-A-1 [572]	
	Haemophilus influenzae	CCUG 7317	Haemophilus influenzae corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), 641/AMC 36-A-4 [641, NCTC 8467]	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Klebsiella spp.	*Klebsiella aerogenes*	ATCC 13048	(Hormaeche and Edwards 1960) Tindall et al. 2017, NCDC 819-56	Detected
	Klebsiella pneumoniae	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
	Klebsiella pneumoniae	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	Klebsiella pneumoniae	ATCC BAA-2783	972863	
	Klebsiella pneumoniae	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	Klebsiella pneumoniae	ATCC BAA-3063§	1121740	
	Klebsiella pneumoniae	ATCC BAA-3068	1104762	
	Klebsiella pneumoniae	ATCC BAA-3077*	875638	
	Klebsiella pneumoniae	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	Klebsiella pneumoniae	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	Klebsiella pneumoniae	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	Klebsiella pneumoniae	NCTC 14337	(Schroeter 1886) Trevisan 1887, 54	
	Klebsiella pneumoniae	JMI Strain 1238756	N/A	
	Klebsiella variicola	ATCC BAA-830	Rosenblueth et al., F2R9 [CFNE 2004, DSM 15968]	
	Klebsiella oxytoca	ATCC BAA-3059	(Flugge) Lautrop, 957532	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Klebsiella pneumoniae	NCTC 13438	Isolate 1, Hospital A	
	Klebsiella pneumoniae	ATCC 700603	N/A, K6 [CCUG 45421, LMG 20218, MCV37]	
Neisseria meningitidis (Encapsulated)	*Neisseria meningitidis*	ATCC 13077*	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980), M1027	Detected
	Neisseria meningitidis	ATCC 13090*	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980), M2092	
	Neisseria meningitidis	CCUG 27650	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980), LNP 638	
	Neisseria meningitidis	CCUG 55208	EQUALIS 07-040/2	
	Neisseria meningitidis	NCTC 8556	(Albrecht and Ghon 1901) Murray 1929 (AL), 60	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Pan *Enterobacterales*	*Cedecea davisae*	NCTC 13724	Grimont et al. 1981, 005, 3278-77	Detected
	Citrobacter braakii	ATCC 51113	Brenner et al. 1993, CDC 80-58	
	Citrobacter freundii	CCUG 418T*	(Braak 1928) Werkman and Gillen 1932 (Approved Lists 1980), [ATCC 13316, NCTC 9750]	
	Citrobacter koseri	ATCC 27156	Frederiksen 1970 (Approved Lists 1980), CDC 3613-63	
	Cronobacter sakazakii	ATCC 29004	(Farmer et al.) Iversen et al., CDC 3225-73	
	Edwardsiella tarda	NCTC 10396	Ewing and McWhorter 1965 (Approved Lists 1980), K 349, K349, 4-78, 1483-59	
	Kluyvera cryocrescens	NCTC 10483	Farmer et al. 1981, 2367, No.4	
	Kosakonia quasisacchari	NCTC 14272	Wang et al. 2019, GDMCC1.1570, WCHEs120001	
	Leclercia adecarboxylata	NCTC 13032	(Leclerc 1962) Tamura et al. 1987, 1783	
	Morganella morganii	ATCC 25829	(Winslow et al. 1919) Jensen et al. 1992, M4	
	Providencia stuartii	CCUG 74678	N/A	
	Rahnella aquatilis	CCUG 52909	Izard et al. 1981	
	Raoultella terrigena	NCTC 13038	Izard et al. 1981, 84, L84/CUETM 77-176 [CIP 80-07, DSM 2687]	
	Shigella sonnei	CCUG 68726	(Levine 1920) Weldin 1927 (Approved Lists 1980), I virulent	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Serratia rubidaea	CCUG 35289	(Stapp 1940) Ewing et al. 1973 (Approved Lists 1980)	
	Tatumella ptyseos	NCTC 11468	Hollis et al. 1982, H36	
	Yersinia enterocolitica subsp *enterocolitica*	NCTC 12982	(Schleifstein and Coleman 1939) Neubauer et al. 2000, 33114	
	Yokenella regensburgei	NCTC 12131	Kosako et al. 1985, 3349-72	
	Citrobacter freundii	ATCC 6879	Werkman and Gillen 1932 (Approved Lists 1980), NCTC 4143 [104, IFO 13539]	
	Hafnia alvei	CCUG 59411	Møller 1954 (Approved Lists 1980), SMI Oth047	
	Citrobacter amalonaticus	CCUG 4860	(Young et al. 1971) Brenner and Farmer 1982, 9823 [NCTC 10805]	
	Escherichia fergusonii	CCUG 18766T	Farmer et al. 1985, CDC 0568-73 [DSM 13698]	
	Morganella Morganii SS siboni	ATCC 51206	Jensen et al., CDC 3522-75	
	Providencia rettgeri	CCUG 14804	(Hadley et al. 1918) Brenner et al. 1978 (Approved Lists 1980), 1163 [CCUG 14804, CIP 103182, DSM 4542, JCM 1675, LMG 3259, NCTC 11801]	
	Raoultella ornithinolytica	NCTC 13096	N/A	
	Shigella boydii	CCUG 49022	Ewing 1949 (Approved Lists 1980), P288/NCTC 12985	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Escherichia hermannii	CCUG 15714T	Brenner et al. 1983, CDC 980-72	Pan *Enterobacterales* not detected
	Kosakonia cowanii	CCUG 45998	(Inoue et al. 2001) Brady et al. 2013, 888-76, KSK 246, UM-79, KSK246, U11-79	
Proteus spp.	*Proteus mirabilis*	ATCC 43071	Hauser, CDC S-17	Detected
	Proteus mirabilis	ATCC BAA-2792*	Hauser, 1104843	
	Proteus mirabilis	NCTC 12737	Hickman et al. 1983, 1808-73	
	Proteus vulgaris	ATCC 6380*	Hauser emend. Judicial Commission	
	Proteus vulgaris	NCTC 13145	Hauser emend. Judicial Commission, CDC PR1	
	Proteus terrae/cibarius	CCUG 35385	Hauser 1885 (Approved Lists 1980), HSCT 3586 T1, CDC 1404-81	
	Proteus hauseri	CCUG 63603	N/A	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	ATCC BAA-2794*	(Schroeter) Migula, 1079232	Detected
	Pseudomonas aeruginosa	NCTC 13437*	N/A	
	Pseudomonas aeruginosa	MRSN 12914*	Snesrud,E. and Mcgann,P., NR-51575	
	Pseudomonas aeruginosa	NCTC 13921*	(Schroeter 1872) Migula 1900 (AL), NCTC 13921	
	Pseudomonas aeruginosa	ATCC BAA-3099	1079205	
	Pseudomonas aeruginosa	ATCC BAA-3108	Strain: 835930, 853930	
	Pseudomonas aeruginosa	ATCC BAA-2796	1106434	
	Pseudomonas aeruginosa	JMI Strain 378769*	N/A	
	Pseudomonas aeruginosa	JMI Strain 338718	N/A	
	Pseudomonas aeruginosa	JMI Strain JMI-147	N/A	
	Pseudomonas aeruginosa	JMI Strain 1227781	N/A	
	Pseudomonas aeruginosa	MRSN 6241	Strain MRSN 6241, NR-51550	
	Pseudomonas aeruginosa	MRSN 8141	Strain MRSN 8141, NR-51558	
	Pseudomonas aeruginosa	NCTC 14383	(Schroeter 1872) Migula 1900 (Approved Lists 1980)	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Salmonella spp.	*Salmonella bongori*	CCUG 63587	(Le Minor et al. 1985) Reeves et al. 1989	Detected
	Salmonella enterica	ATCC 6962*	(ex Kauffmann and Edwards) Le Minor and Popoff serovar Newport, NCTC 129	
	Salmonella enterica subsp. *gallinarum*	ATCC 700623	(Kauffmann and Edwards) Le Minor and Popoff, X-142	
	Salmonella enterica subsp. *seftenberg*	NCTC 13953	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	Salmonella typhimurium	NCTC 13954*	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	Salmonella enterica subsp. *enterica* serotype Westhampton	NCTC 8549	(LE MINOR et al. 1982) LE MINOR and POPOFF 1987, 1314-52	
Serratia spp.	*Serratia ficaria*	CCUG 20935	Grimont et al. 1981, F.Grimont G 5779	Detected
	Serratia fonticola	CCUG 14186	N/A, CUETM 77-165;CIP 78.64;ATCC 29844;LMG 7882;CCM 3407;IAM 1242;	
	Serratia liquefaciens	ATCC 27592*	(Grimes and Hennerty 1931) Bascomb et al. 1971 (Approved Lists 1980), CDC 1284-57	
	Serratia marcescens	ATCC 14041*	Bizio 1823 (Approved Lists 1980), NRRL B-1481	
	Serratia plymuthica	ATCC 7462	(Lehmann and Neumann 1896) Breed et al. 1948 (Approved Lists 1980)/(Dyar) Bergey et al., [Grimont 502]	
	Serratia marcescens	NCTC 13382	Bizio, NRS 116-175 [CIP 104221]	
	Serratia odorifera	CCUG 14508	N/A	

Table 15. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	ATCC 13637	(Hugh 1981 ex Hugh and Ryschenkow 1961) Palleroni and Bradbury 1993, 810-2	Detected
	Stenotrophomonas maltophilia	CCUG 72210	N/A	
	Stenotrophomonas maltophilia	NCTC 10258*	(Hugh 1981 ex Hugh and Ryschenkow 1961) Palleroni and Bradbury 1993, 560 [CDC3903, group I, MDB strain BS 1639, NCTC 10258]	
	Stenotrophomonas maltophilia	NCTC 10259	(Hugh) Palleroni and Bradbury, 611 [NCTC 10259]	
	Stenotrophomonas maltophilia	NCTC 10498	(Hugh 1981) Palleroni and Bradbury 1993, RH 661-1	
	Stenotrophomonas maltophilia	NCTC 10499*	(Hugh 1981) Palleroni and Bradbury 1993, RH 873-3 (NRC 730, NCIB 9204)	

N/A: Information not available.

* These strains were evaluated during the LoD study (Section 13.1.5 "Limit of Detection" on page 82).

† Detected with reduced sensitivity below the mean bottle positive concentration.

‡ Lower concentrations of these strains were not tested in the original dataset, and it is not known whether this strain would be detected closer to the LoD determined for *Enterobacter* spp.

§ ATCC BAA-3063 detected at bottle positive concentration as observed in the contrived samples during the clinical study. Lower pathogen concentrations could not be evaluated in this study because *E. amnigenus* was also included in the mix, which has been shown to cross-react with the *Klebsiella* spp. assay.

In addition, all the assays included in the QIAstat-Dx BCID GN Plus AMR Panel intended to detect AMRs were also evaluated. Table 16 summarizes all results obtained.

Table 16. Summary of AMR markers inclusivity results

Target	AMR variant	Species	Catalog number	Strain designation	Result
aac(6')-Ib	*aac(6')-Ib*	*Pseudomonas aeruginosa*	JMI Strain 378769	N/A	Detected
	aac(6')-Ib	*Pseudomonas aeruginosa*	JMI Strain 338718	N/A	
	aac(6')-Ib	*Pseudomonas aeruginosa*	JMI Strain JMI-147	N/A	
	aac(6')-Ib3	*Klebsiella pneumoniae*	ATCC BAA-3068	1104762	
	aac(6')-Ib-cr	*Escherichia coli*	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	
	aac(6')-Ib	*Escherichia coli*	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	aac(6')-Ib4	*Klebsiella pneumoniae*	ATCC BAA-3077*	875638	
	aac(6')-Ib7	*Proteus mirabilis*	ATCC BAA-2792*	Hauser, 1104843	
	aac(6')-Ib	*Pseudomonas aeruginosa*	ATCC BAA-2799*	1145009	
	aac(6')-Ib	*Escherichia coli*	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	
	aac(6')-Ib3	*Acinetobacter baumannii*	ATCC BAA-2901	Bouvet and Grimont, 157075	
	aac(6')-Ib	*Pseudomonas aeruginosa*	ATCC BAA-2794*	(Schroeter) Migula, 1079232	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	aac(6')-Ib	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	aac(6')-Ib	*Pseudomonas aeruginosa*	NCTC 13921*	(Schroeter 1872) Migula 1900 (AL), NCTC 13921	
	aac(6')-Ib	*Klebsiella pneumoniae*	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	aac(6')-Ib	*Klebsiella pneumoniae*	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	aac(6')-Ib	*Escherichia coli*	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919, N/A	
	aac(6')-Ib3, aac(6')-Ib-cr5	*Klebsiella pneumoniae*	ATCC BAA-2783	972863	
	aac(6')-Ib	*Pseudomonas aeruginosa*	ATCC BAA-3108	853930, Strain: 835930	
	aac6-Ib-cr	*Klebsiella pneumoniae*	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
	aac(6')-Ib3, aac(6')-Ib-cr, aac(6')-IIc	*Klebsiella pneumoniae*	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	aac(6')-Ib-cr	*Klebsiella pneumoniae*	ATCC BAA-3063§	1121740	
	aac(6')-Ib	*Klebsiella oxytoca*	ATCC BAA-3059	(Flugge) Lautrop, 957532	
	aac(6')-Ib-cr5	*Enterobacter bugandensis*	CCUG 75194T	N/A, EB-247, 247BMC, DSM 29888, NCCB 100573	
	aac(6')-Ib	*Pseudomonas aeruginosa*	NCTC 14383	(Schroeter 1872) Migula 1900 (Approved Lists 1980)	
	aac(6')-Ib	*Acinetobacter baumannii*	NCTC 13424	UK 20	
	aac(6')-Ib	*Pseudomonas aeruginosa*	MRSN 6241	N/A	
	aac(6')-Ib	*Pseudomonas aeruginosa*	MRSN 8141	N/A	
	aac(6')-Ib	*Klebsiella pneumoniae*	NCTC 14337	54, (Schroeter 1886) Trevisan 1887	
	aac(6')-Ib	*Escherichia coli*	NCTC 13351	N/A	
	aac(6')-Ib	*Klebsiella pneumoniae*	NCTC 13438	Isolate 1, Hospital A,	
	aac(6')-Ib	*Acinetobacter baumannii*	CCUG 68164	Bouvet and Grimont 1986	*aac(6')-Ib* Detected with reduced sensitivity (2.31E+06 CFU/mL)†

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
ampC (CMY/DHA/FOX/LAT)	*ampC* (DHA-D7)	*Klebsiella pneumoniae*	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	Detected
	ampC (FOX)	gBlock *ampC* FOX-X77455.1**	gBlock ampC FOX-X77455.1**	N/A	
	ampC (CMY-16)	*Proteus mirabilis*	ATCC BAA-2792*	Hauser, 1104843	
	ampC (CMY-LAT)	*Citrobacter freundii*	ATCC 6879	Werkman and Gillen 1932 (Approved Lists 1980), NCTC 4143 [104, IFO 13539]	
	ampC (CMY-2)	*Citrobacter brakkii*	ATCC 51113	Brenner et al. 1993, CDC 80-58	
	ampC (CMY-LAT)	*Salmonella enterica*	NCTC 13953	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	ampC (CMY-LAT) *ampC* (DHA)	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	ampC (CMY-72)	*Citrobacter freundii*	CCUG 418*	(Braak 1928) Werkman and Gillen 1932 (Approved Lists 1980), [ATCC 13316, NCTC 9750]	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	ampC (DHA-4)	*Morganella morgannii SS siboni*	ATCC 51206	*Morganella morganii* subsp. *sibonii* Jensen et al., CDC 3522-75 [RB 2405]	
	ampC (DHA)	*Morganella morganii*	ATCC 25829	(Winslow et al. 1919) Jensen et al. 1992, M4	
	ampC (FOX-5)	*Klebsiella pneumoniae*	JMI Strain 1238756	N/A	
	ampC (CMY-LAT)	*Escherichia coli*	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	ampC (CMY-LAT)	*Escherichia coli*	NCTC 14339	(Migula 1895) Castellani and Chalmers 1919, MLST: 361	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
armA	*armA*	*Acinetobacter baumannii*	ATCC BAA-2803*	1125209	Detected
	armA	*Acinetobacter baumannii*	NCTC 13424	UK 20	
	armA	*Klebsiella pneumoniae*	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
	armA	*Acinetobacter baumannii*	ATCC BAA-2873	1081925	
	armA	*Klebsiella pneumoniae*	ATCC BAA-2783	972863	
	armA	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	armA	*Klebsiella oxytoca*	ATCC BAA-3059	(Flugge) Lautrop, 957532	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
CTX-M	CTX-M-15 (Group 1)	*Escherichia coli*	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	Detected
	CTX-M-14 (Group 9)	*Escherichia coli*	ATCC BAA-2775	1099675	
	CTX-M-2, CTX-M-15 (Group 1 and Group 2	*Klebsiella pneumoniae*	ATCC BAA-2783	972863	
	CTX-M-15 (Group 1)	*Klebsiella pneumoniae*	ATCC BAA-3077*	875638	
	CTX-M-26 (Group 25)	gBlock_CTX-M (group 25)_ AY157676.1 *Klebsiella pneumoniae* CTX-M-26 beta-lactamase (blaCTX-M-26) gene, complete cds**	gBlock_CTX-M (group 25)_ AY157676.1**	N/A	
	CTX-M-15 (Group 1)	*Klebsiella pneumoniae*	ATCC BAA-3063§	1121740	
	CTX-M-15 (Group 1)	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	CTX-M	*Escherichia coli*	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919	
	CTX-M-15 (Group 1)	*Escherichia coli*	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	
	CTX-M-3 (Group 1)	*Klebsiella oxytoca*	ATCC BAA-3059	(Flugge) Lautrop, 957532	
	CTX-M-2 (Group 2)	*Escherichia coli*	NCTC 13462	N/A	
	CTX-M-15 (Group 1)	*Enterobacter bugandensis*	CCUG 75194T	EB-247, 247BMC, DSM 29888, NCCB 100573	
	CTX-M-14 (Group 9)	*Enterobacter cloacae*	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
GES	GES-5	*Escherichia coli*	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	Detected
	GES-6	*Klebsiella pneumoniae*	ATCC BAA-3068	1104762	
	GES-1	*Klebsiella pneumoniae*	ATCC BAA-3077*	875638	
	GES-19, GES-26	*Pseudomonas aeruginosa*	ATCC BAA-3108	Strain: 835930, 853930	
	GES-11	*Acinetobacter baumannii*	CCUG 68164	Bouvet and Grimont 1986	
	GES-5	*Pseudomonas aeruginosa*	ATCC BAA-2794*	(Schroeter) Migula, 1079232	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
IMP	IMP-1	*Escherichia coli*	CCUG 67180*	(Migula 1895) Castellani and Chalmers 1919 (Approved Lists 1980)	Detected
	IMP-21	gBlock_IMP 21_ AB204557.1 *Pseudomonas aeruginosa* $blaI_{MP-21}$ gene for metallo-beta-lactamase IMP-21, complete cds**	gBlock_IMP 21_ AB204557.1**	N/A	
	IMP-14	gBlock_IMP 14_ AY553332.1:114-854 *Pseudomonas aeruginosa* class 1 integron IMP-14 ($blaI_{MP-14}$) and aminoglycoside 6'-N-acetyltransferase *(aac(6'))* genes, complete cds**	gBlock_IMP 14_ AY553332.1:114-854**	N/A	
	IMP	*Escherichia coli*	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	IMP-4	*Klebsiella pneumoniae*	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	IMP-1	*Klebsiella pneumoniae*	NCTC 14337	54, (Schroeter 1886) Trevisan 1887	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
KPC	KPC-2	*Escherichia coli*	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	Detected
	KPC	*Escherichia coli*	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	KPC	*Escherichia coli*	NCTC 14321*	(Migula 1895) Castellani and Chalmers 1919, 7	
	KPC-2	*Klebsiella pneumoniae*	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	KPC-2	*Klebsiella pneumoniae*	ATCC BAA-3068	1104762	
	KPC-3	*Klebsiella pneumoniae*	NCTC 13438	Isolate 1, Hospital A	
	KPC-4	*Enterobacter cloacae*	NCTC 14322	(Jordan 1890) Hormaeche and Edwards 1960, 42E	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
NDM	NDM-16	*Klebsiella pneumoniae*	ATCC BAA-3063§	1121740	Detected
	NDM-1	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	NDM-1	*Pseudomonas aeruginosa*	ATCC BAA-2796	1106434	
	NDM-1	*Salmonella enterica seftenberg*	NCTC 13953	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	NDM-1	*Pseudomonas aeruginosa*	JMI Strain 1227781	N/A	
	NDM-7	*Escherichia coli*	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919	
	NDM-4	*Escherichia coli*	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	NDM-5	*Escherichia coli*	NCTC 14339	(Migula 1895) Castellani and Chalmers 1919, MLST: 361	
	NDM-1	*Klebsiella pneumoniae*	ATCC BAA-3072	(Schroeter) Trevisan, 979620	NDM detected with reduced sensitivity (4.37E+06CFU/mL) †

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
OXA-23	OXA-23	*Acinetobacter baumannii*	ATCC BAA-2801*	1103521	Detected
	OXA-23	*Acinetobacter baumannii*	ATCC BAA-2873	1081925	
	OXA-23	*Acinetobacter baumannii*	ATCC BAA-2803*	1125209	
	OXA-23	*Acinetobacter baumannii*	CCUG 68164	Bouvet and Grimont 1986	
	OXA-23	*Acinetobacter baumannii*	NCTC 13424	UK 20	
OXA-24/40	OXA-24	*Acinetobacter baumannii*	ATCC BAA-2881*	Bouvet and Grimont, 1173844	Detected
	OXA-24	*Acinetobacter baumannii*	CCUG 57249*	Bouvet and Grimont 1986	
	OXA-25	*Acinetobacter baumannii*	NCTC 13302	OXA-25, 327009	
	OXA-24	*Acinetobacter baumannii*	PA212222	N/A	
	OXA-40	gBlock OXA 24/40_ AF509241.1 *Acinetobacter baumannii* carbapenem-hydrolyzing beta-lactamase OXA-40 (bla_{OXA-40}) gene, complete cds**	**gBlock OXA 24/40_ AF509241.1	N/A	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
OXA-48-like	OXA-48-like	*Escherichia coli*	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	Detected
	OXA-48-like	*Escherichia coli*	NCTC 14321*	(Migula 1895) Castellani and Chalmers 1919, 7	
	OXA-48	*Klebsiella pneumoniae*	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	OXA-48	*Salmonella typhimurium*	NCTC 13954*	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	OXA-48	*Klebsiella pneumoniae*	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
OXA-58	OXA-58	*Acinetobacter baumannii*	ATCC BAA-2890*	Bouvet and Grimont, 177579	Detected
	OXA 58	*Acinetobacter baumannii*	ATCC BAA-2901	Bouvet and Grimont, 157075	
	OXA-58	*Acinetobacter baumannii*	ATCC BAA-2895	N/A	
	OXA-58	*Acinetobacter baumannii*	NCTC 13305*	A-15	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
PER	PER-1	*Acinetobacter baumannii*	ATCC BAA-2801*	1103521	Detected
	PER-1	*Pseudomonas aeruginosa*	MRSN 6241	Strain MRSN 6241, NR-51550	
	PER-1	*Pseudomonas aeruginosa*	MRSN 8141	Strain MRSN 8141, NR-51558	
	PER-14	gBlock PER 14_ MN715315.1 *Raoultella ornithinolytica* strain 1256861 class A extended-spectrum beta-lactamase PER-2 and PER-14 (bla_{PER}) gene, bla_{PER-14} allele, complete cds**	gBlock PER-2_PER-14_ MN715315.1**	N/A	
	PER-1	*Pseudomonas aeruginosa*	ATCC BAA-2799*	1145009	
	PER	*Pseudomonas aeruginosa*	NCTC 14383	(Schroeter 1872) Migula 1900 (Approved Lists 1980)	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
SHV	SHV	*Klebsiella pneumoniae*	NCTC 14337	54, (Schroeter 1886) Trevisan 1887	Detected
	SHV-11	*Klebsiella pneumoniae*	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	SHV-11	*Klebsiella pneumoniae*	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	SHV-27	*Klebsiella pneumoniae*	ATCC BAA-3068	N/A, 1104762	
	SHV-1	*Klebsiella pneumoniae*	ATCC BAA-3077*	N/A, 875638	
	SHV-11	*Klebsiella pneumoniae*	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	SHV	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	SHV-12	*Salmonella enterica seftenberg*	NCTC 13953	ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987, N/A	
	SHV	*Klebsiella pneumoniae*	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	SHV-187	*Klebsiella pneumoniae*	JMI 1238756	N/A, NA	
	SHV-11	*Klebsiella pneumoniae*	NCTC 13438	Isolate 1, Hospital A, N/A	
	SHV	*Enterobacter cloacae*	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960, N/A	
	SHV-18	*Klebsiella pneumoniae*	ATCC 700603	N/A, K6 [CCUG 45421, LMG 20218, MCV37]	
	SHV-28	*Klebsiella pneumoniae*	ATCC BAA-3063¶	N/A, 1121740	
	SHV-28	*Klebsiella pneumoniae*	ATCC BAA-3072	(Schroeter) Trevisan, 979620	SHV Detected with reduced sensitivity (4.37E+06 CFU/mL)†
	SHV-1	*Klebsiella pneumoniae*	ATCC BAA-2783	N/A, 972863	SHV Detected with reduced sensitivity (4.37E+07 CFU/mL)†
	SHV	*Escherichia coli*	NCTC 14325	(Migula 1895) Castellani and Chalmers 1919, N/A	SHV Not detected

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
SPM	SPM-1	*Pseudomonas aeruginosa*	NCTC 13921*	(Schroeter 1872) Migula 1900 (AL), NCTC 13921	Detected
	SPM-1	*Pseudomonas aeruginosa*	JMI Strain 378769*	N/A	
	SPM-1	*Pseudomonas aeruginosa*	JMI Strain 338718	N/A	
	SPM-1	*Pseudomonas aeruginosa*	JMI Strain JMI-147	N/A	
TEM	TEM-1	*Escherichia coli*	ATCC BAA-2775	1099675	Detected
	TEM-1	*Klebsiella pneumoniae*	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	TEM-1	*Klebsiella pneumoniae*	ATCC BAA-3077*	875638	
	TEM-1	*Klebsiella pneumoniae*	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	TEM-1	*Klebsiella pneumoniae*	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	TEM-2	*Proteus mirabilis*	ATCC BAA-2792*	Hauser, 1104843	
	TEM	*Escherichia coli*	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	TEM	*Escherichia coli*	CCUG 67180*	(Migula 1895) Castellani and Chalmers 1919 (Approved Lists 1980)	Detected
	TEM-1	*Klebsiella oxytoca*	ATCC BAA-3059*	(Flugge) Lautrop, 957532	
	TEM-1	*Enterobacter bugandensis*	CCUG 75194T	EB-247, 247BMC, DSM 29888, NCCB 100573	
	TEM	*Escherichia coli*	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	TEM-3	*Escherichia coli*	NCTC 13351	N/A	
	TEM-10	*Escherichia coli*	NCTC 13352	N/A	
	TEM	*Enterobacter cloacae*	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	
	TEM	*Escherichia fergusonnii*	CCUG 18766T	Farmer et al. 1985, CDC 0568-73 [DSM 13698]	
	TEM-1	*Klebsiella pneumoniae*	ATCC BAA-3063¶	1121740	
	TEM-1	*Klebsiella pneumoniae*	ATCC BAA-3068	1104762	TEM Detected with reduced sensitivity (4.37E+06 CFU/ml)†
	TEM-1	*Klebsiella pneumoniae*	ATCC BAA-2783	972863	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
	TEM-1	*Acinetobacter baumannii*	ATCC BAA-2881	Bouvet and Grimont, 1173844	TEM Detected with reduced sensitivity (2.31E+06 CFU/mL)†
	TEM-1	*Acinetobacter baumannii*	ATCC BAA-2873	1081925	
	TEM	*Salmonella enterica seftenberg*	NCTC 13953	ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	TEM Detected with reduced sensitivity (2.25E+05 CFU/mL)†
	TEM-1	*Acinetobacter baumannii*	ATCC BAA-2801	1103521	TEM Detected with reduced sensitivity (2.31E+08 CFU/mL)‡
	TEM-1	*Escherichia coli*	NCTC 13462	N/A	TEM Detected with reduced sensitivity (6.78E+07 CFU/mL)†
	TEM	*Escherichia coli*	NCTC 14321	(Migula 1895) Castellani and Chalmers 1919, 7	TEM Detected with reduced sensitivity (1.71E+09 CFU/mL)‡ **
	TEM	*Klebsiella pneumoniae*	ATCC BAA-1705	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	TEM Detected with reduced sensitivity (6.25E+09 CFU/mL)‡ **

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
VEB	VEB-14	*Pseudomonas aeruginosa*	ATCC BAA-3099	1079205	Detected
	VEB	*Pseudomonas aeruginosa*	MRSN 12914*	Snesrud,E. and Mcgann,P., NR-51575	
	VEB-22	gBlock VEB_ MN201581.1 *Pseudomonas aeruginosa* strain 1879174 class A extended-spectrum beta-lactamase VEB-22 (bla_{VEB}) gene, bla_{VEB-22} allele, complete cds**	**gBlock VEB_ MN201581.1	N/A	
	VEB-14	*Pseudomonas aeruginosa*	JMI Strain 1227781	N/A	
	VEB-9	*Pseudomonas aeruginosa*	ATCC BAA-2796	1106434	
	VEB-1	*Pseudomonas aeruginosa*	NCTC 13437*	N/A	

Table 16. Summary of AMR markers inclusivity results (continued)

Target	AMR variant	Species	Catalog number	Strain designation	Result
VIM	VIM-1	*Enterobacter cloacae*	NCTC 14326*	(Jordan 1890) Hormaeche and Edwards 1960, 29	Detected
	VIM-1	*Proteus mirabilis*	ATCC BAA-2792*	Hauser, 1104843	
	VIM-5	*Pseudomonas aeruginosa*	ATCC BAA-3099	1079205	
	VIM-10	*Pseudomonas aeruginosa*	NCTC 13437*	N/A	
	VIM-5	*Pseudomonas aeruginosa*	ATCC BAA-2799*	1145009	
	VIM-4	*Enterobacter cloacae*	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	

N/A: Information not available.

* These AMRs were evaluated during the LoD study (Section 13.1.5 "Limit of Detection" on page 82).

† Detected with reduced sensitivity below the mean bottle positive concentration determined for the pathogen.

‡ Detected with reduced sensitivity above the mean bottle positive concentration determined for the pathogen.

§ This AMR was detected in ATCC BAA-3063 at bottle positive concentration as observed in the contrived samples during the clinical study. Lower pathogen concentrations could not be evaluated in this study because *E. amnigenus* was also included in the mix which has been shown to cross react with the *Klebsiella* spp. assay. It is not known whether this AMR in this strain would be detected near the combined LoD determined for *Klebsiella* spp.

¶ This AMR was detected in ATCC BAA-3063 at bottle positive concentration as observed in the contrived samples during the clinical study. In this study, it was not detected at concentrations below (4.37E+06 CFU/mL (44.4x the combined LoD determined for *Klebsiella* spp)). Because the root cause was dropout of the AMR target, the AMR is reported as detected with reduced sensitivity for this strain.

** Concentrations between Limit of Detection study test concentrations and stock not tested. It is not known if TEM would be detected at a lower concentration.

In parallel, the bioinformatic prediction of the inclusivity assessment of the QIAstat-Dx BCID GN Plus AMR Panel was performed separately for the PCR assays detecting targeted organisms (organism-PCR assays) or AMR genes (AMR-PCR assays). In case of the organism-PCR assays, the regular bioinformatic analysis was performed analyzing all complete genomes available for every target organism included in the Taxonomy Browser Tool included in NCBI database (**www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi**). After sequence

collection, all PCR assay's oligonucleotides (primers and probes) included in the QIAstat-Dx BCID GN Plus AMR Panel were mapped (allowing 3 or fewer mismatches) to evaluate their correct amplification by the PCR assay. An alternative analysis was performed for those PCR assays with a higher level of complexity (i.e., PAN assays or organisms with a larger set of genomes available). This second analysis was a BLAST- based homology analysis (**blast.ncbi.nlm.nih.gov/Blast.cgi**) of all the individual primers and probes included in the QIAstat-Dx BCID GN Plus AMR Panel, and combining those BLAST hits obtained in a combined list.

On the other hand, the AMR-PCR assays were analyzed using the sequences available in the Comprehensive Antibiotic Resistance Database (CARD) (**card.mcmaster.ca**), focused on the correct characterization of resistance genes, their products, and associated phenotypes, providing curated AMR reference sequences. All available AMR sequences described to be present in plasmids and/or chromosomes were evaluated against the corresponding AMR-PCR assay's oligonucleotides.

All analyses were performed during September 2025. In all cases including both organism-PCR assays and AMR-PCR assays, sequences were considered positive if all the following requirements are fulfilled:

- At least one Forward, one Probe, and one Reverse primer from the same assay included in the QIAstat-Dx BCID GN Plus AMR Panel matched with the analyzed sequence
- A maximum of 500 bp of amplicon size
- Sequence Identity resulted in a maximum of 2 or fewer mismatches within the last 5 bases of the primers 3'-end or at the first 5 bases of the probes 5'-end; 3 or fewer mismatches within the overall primer or probe sequence; and at the most one gap within the last 10 bases of the primers 3'-end or at the first 10 bases of the probes 5'-end. In case of BLAST analysis, sequence identity shall result in at least 70% of Query Cover between the BLAST hit sequence and every single primer/probe sequence.

As a result, all the organism-PCR assays (Table 17) are expected to detect the complete list of sequences analyzed, with only a small portion of sequences predicted undetected and not considered critical, so no additional analyses were performed. These individual sequences predicted not to be detected seem to be isolated sequences most probably caused by an incorrect submission to the NCBI database based on their poor sequence quality. Despite of these isolated events, the overall inclusivity level for each of the PCR assays included in the QIAstat-Dx BCID GN Plus AMR Panel was close to 100% for all the relevant species and generally expected to be detected by the device. On the other hand, the AMR-PCR assays

(Table 17) showed perfect inclusivity levels for all the AMR genes targeted by the panel with few observations.

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
Organism-PCR assays	*Acinetobacter calcoaceticus-baumannii* complex	1403 (100.00%)	Species detected list includes at least *A. baumannii, A. calcoaceticus, A. pitti, A. nosocomialis, A. lactucae, A. seifertii*
	Bacteroides fragilis	79 (100%)	Inclusivity determined for *B. fragilis*
	Enterobacter spp.	959 (100.00%)	*Enterobacter* species detected includes at least *E. adelaidei, E. asburiae, E. bugandensis, E. cancerogenus, E. chengduensis, E. chuandaensis, E. cloacae* (*E. cloacae* spp., *E. cloacae* subsp. *Cloacae, E. cloacae* subsp. *dissolvens), E. dykesii, E. hormaechei* (*E. hormaechei* spp., *E. hormaechei* subsp. *Hoffmannii, E. hormaechei* subsp. *Hormaechei, E. hormaechei* subsp. *Oharae, E. hormaechei* subsp. *Steigerwaltii, E. hormaechei* subsp. *xiangfangensis), E. huaxiensis, E. intestinihominis, E. kobei, E. ludwigii, E. mori, E. oligotrophicus, E. pasteurii, E. pseudoroggenkampii, E. quasiroggenkampii, E. roggenkampii, E. sichuanensis, E. soli, E. vonholyi, E. wuhouensis*. In addition, the following species are also detected: *Lelliottia amnigena (E. amnigenus), Lelliottia nimipressuralis (E. nimipressuralis), Pluralibacter gergoviae (E. gergoviae).*
	Escherichia coli	2845 (100%)	Inclusivity determined for *E. coli*
	Haemophilus influenzae	416 (100.00%)	*H. influenzae* sequences detected include all encapsulated serotypes (a, b, c, d, e, f) and unencapsulated strains (nontypable, NTHi) including var. *H. aegyptius*.
	Klebsiella spp.	4742 (100.00%)	*Klebsiella* detected species list includes at least *K. oxytoca, K. pneumoniae, K. aerogenes, K. variicola, K. quasipneumoniae, K. quasivariicola, K. Africana.*
	Neisseria meningitidis (Encapsulated)	227 (100%)	*N. meningitidis* species detected correspond to encapsulated serotypes (A, B, C, D, E, H, I, K, L, NG, W, W135, X, Y, Z, 29E).

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Pan *Enterobacterales*†	3294 (100.00%)	List of species detected includes at least *Atlantibacter (A. hermannii), Brenneria (B. rubrifaciens), Cedecea (C. lapagei), Chania (C. multitudinisentens); Chimaeribacter (C. arupi); Citrobacter (C. braakii, C. cronae, C. europaeus, C. freundii, C. koseri, C. meridianamericanus, C. portucalensis, C. werkmanii), Cronobacter (C. condiment, C. malonaticus, C. sakazakii), Dickeya (D. oryzae, D. zeae), Dryocola (Dryocola sp.), Edwardsiella (E. ictalurid, E. tarda), Enterobacter (E. bugandensis, E. cancerogenus, E. cloacae, E. hormaechei, E. kobei, E. ludwigii, E. mori, E. pasteurii, E. roggenkampii), Erwinia (E. amylovora, E. aphidicola, E. billingiae, E. persicina, E. rhapontici, E. tracheiphila), Escherichia (E. albertii, E. coli, E. fergusonii, E. marmotae, E. ruysiae), Ewingella (E. americana), Gibbsiella (G. quercinecans), Hafnia (H. alvei, H. paralvei), Klebsiella (K. aerogenes, K. africana, K. electrica, K. grimontii, K. michiganensis, K. oxytoca, K. pasteurii, K. pneumoniae, K. quasipneumoniae, K. quasivariicola, K. variicola),*

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			Kluyvera (K. genomospecies, K. intermedia, K. ascorbata), Kosakonia (K. cowanii, K. pseudosacchari, K. radicincitans), Leclercia (L. adecarboxylata, L. pneumoniae), Lelliottia (Lelliottia sp.), Limnobaculum (L. parvum, L. zhutongyuii), Lonsdalea (L. populi), Morganella (M. morganii), Obesumbacterium (O. proteus), Pectobacterium (P. aroidearum, P. brasiliense, P. peruviense, P. versatile), Photorhabdus (P. asymbiotica, P. luminescens), Phytobacter (P. diazotrophicus, P. ursingii), Pluralibacter (P. gergoviae), Pragia (P. fontium), Proteus (P. columbae, P. hauseri, P. mirabilis, P. terrae, P. vulgaris), Providencia (P. alcalifaciens, P. hangzhouensis, P. heimbachae, P. huaxiensis, P. manganoxydans, P. rettgeri, P. rustigianii, P. stuartii, P. vermicola), Pseudescherichia (P. vulneris), Rahnella (R. bonaserana), Raoultella (R. ornithinolytica, R. planticola, R. terrigena), Salmonella (S. bongori, S. enterica), Scandinavium (S. goeteborgense), Serratia (S. aquatilis, S. bockelmannii, S. entomophila, S. ficaria, S. fonticola, S. grimesii, S. inhibens, S. liquefaciens, S. marcescens, S. myotis, S. nematodiphila, S. nevei, *S. odorifera, S. plymuthica, S. proteamaculans, S. quinivorans, S. rhizosphaerae, S. rubidaea, S. sarumanii, S. ureilytica), Shigella (S. boydii, S. dysenteriae, S. flexneri, S. sonnei), Shimwellia (S. blattae), Sodalis (S. glossinidius, S. ligni, S. praecaptivus), Tatumella (T. citrea, T. ptyseos), Xenorhabdus (X. budapestensis, X. griffiniae, X. stockiae), Yersinia (Y. enterocolitica, Y. frederiksenii, Y. intermedia, Y. massiliensis, Y. mollaretii, Y. pestis, Y. pseudotuberculosis, Y. ruckeri), Yokenella (Y. regensburgei).*
	Proteus spp.	300 (100.00%)	*Proteus* detected species list includes at least *P. alimentorum, P. appendicitidis, P. cibi, P. columbae, P. faecis, P. mirabilis, P. penneri, P. terrae* (including *cibarius*), *P. vulgaris, P. hauseri.*

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Pseudomonas aeruginosa	1595 (99.94%)‡	Inclusivity determined for *P. aeruginosa*. Two *P. aeruginosa* chromosome sequences (CP047066 & CP104695)) not detected
	Salmonella spp.	3114 (100%)	Species detected list includes at least *S. bongori* and *S. enterica* (including serovars 42:r,1, 4, 43:a:1, *Abaetetuba, Abeokuta, Aberdeen, Abony, Abortusequi, Abortusovis, Adelaide, Adjame, Agona, Alachua, Albany, Albert, Anatum, Antsalova, Apapa, Bardo, Bareilly, Bergen, Berta, Birkenhead, Bispebjerg, Blegdam, Blockley, Borreze, Bovismorbificans, Braenderup, Brancaster, Brandenburg, Bredeney, Buzu, California, Cerro, Chester, Choleraesuis, Concord, Corvallis, Crossness, Cubana, Daytona, Derby, Dessau, Djakarta, Dublin, Eastbourne, Enteritidis, Fresno, Gallinarum, Gallinarum/Pullorum, Gaminara, Give, Gloucester, Goldcoast, Gombe, Hadar, Hartford, Havana, Hayindogo, Heidelberg, Hillingdon, Hissar, Hvittingfoss, India, Indiana, Infantis, Inverness, Irumu, Isangi, Itami, Java, Javiana, Johannesburg, Karamoja, Kedougou, Kentucky, Kiambu, Koessen, Kottbus, Krefeld, Kunzendorf, Litchfield, Livingstone, London, Lubbock, Macclesfield, Manchester, Manhattan, Mbandaka, Meleagridis, Miami, Mikawasima, Milwaukee, Minnesota, Moero, Montevideo, Moscow, Muenchen, Muenster,* *Nchanga, Newlands, Newport, Nitra, Ohio, Onderstepoort, Oranienburg, Othmarschen, Ouakam, Panama, Paratyphi, Pomona, Poona, Potsdam, Pullorum, Quebec, Reading, Rissen, Rough, Rubislaw, Saintpaul, Sandiego, Sanjuan, Schwarzengrund, Senftenberg, Shamba, Singapore, Sloterdijk, Soerenga, Stanley, Stanleyville, Strathcona, Tennessee, Thompson, Typhi, Typhimurium, Uganda, Virchow, Wandsworth, Waycross, Weltevreden, Westhampton, Wien, Worthington, Yovokome*).

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Serratia spp.	347 (100%)	*Serratia* species list detected includes at least *S. marcescens, S. ficaria, S. fonticola, S. liquefaciens, S. plymuthica, S. bockelmannii, S. nevei, S. rubidaea, S. sarumanii, S. surfactantfaciens, S. ureilytica, S. inhibens, S. nematodiphila, S. proteamaculans, S. quinivorans*.
	Stenotrophomonas maltophilia	135 (99.26%)	1 sequence (CP133415) of *S. maltophilia* not detected.

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
AMR-PCR assays	*aac(6')-Ib*	957 (99.79%)	All available *aac(6')-Ib* sequences detected (Including *aac(6')-Ib; aac(6')-Ib'; aac(6')-Ib10; aac(6')-Ib11; aac (6')-Ib3; aac(6')-Ib4; aac(6')-Ib7; aac(6')-Ib8; aac(6')-Ib9; aac(6')-Ib-cr1; aac(6')-Ib-cr10; aac(6')-Ib-cr11; aac (6')-Ib-cr3; aac(6')-Ib-cr4; aac(6')-Ib-cr5; aac(6')-Ib-cr6; aac(6')-Ib-cr7; aac(6')-Ib-cr8; aac(6')-Ib-cr9; aac6_IB_ HZ; aac_6_IB_Su; aac6_30_aac6_Ib; aac_3Ib_aac_ 6Ib), with the exception of aaac(6')-Ib-SK,* specific for *Streptomyces kanamyceticus.*§
	ampC (CMY/LAT)¶	702 (98.45%)	All available CMY and LAT sequences detected (including CMY-2; CMY-4 to CMY-7; CMY-12 to CMY-18; CMY-20 to CMY-51; CMY-53 to CMY-87; CMY-89 to CMY-90; CMY-93 to CMY-97; CMY-99 to CMY-119; CMY-121 to CMY-122; CMY-124 to CMY-125; CMY-127 to CMY-186; CMY-188 to CMY-189; CMY-191 to CMY-192; CMY-194 to CMY-199; and LAT-1), with the exception of CMY-1; CMY-8 to CMY-11; CMY-19; CMY-98; CMY-190; CMY-8b)
	ampC (DHA)	272 (100.00%)	All available DHA sequences detected, including DHA-1 to DHA-7; DHA-9 to DHA-10; DHA-12 to DHA-34.
	ampC (FOX)	25 (100.00%)	All available FOX sequences detected, including FOX-1 to FOX-10; FOX-12 to FOX-21.
	armA	436 (100.00%).	All available *armA* sequences detected.
	CTX-M	2659 (99.36%)	All available CTX-M sequences detected (including CTX-M-1 to CTX-M-17; CTX-M-19 to CTX-M-56; CTX-M-58 to CTX-M-69; CTX-M-71 to CTX-M-73; CTX-M-76 to CTX-M-117; CTX-M-121 to CTX-M-122; CTX-M-124 to CTX-M-127; CTX-M-129 to CTX-M-131; CTX-M-133 to CTX-M-134; CTX-M-136 to CTX-M-144; CTX-M-146 to CTX-M-148; CTX-M-150; CTX-M-152; CTX-M-154 to CTX-M-233; CTX-M-235 to CTX-M-249; CTX-M-251 to CTX-M-278), with the exception of CTX-M-74, CTX-M-75, CTX-M-123, CTX-M-132, CTX-M-151, CTX-M-153, CTX-M-234.

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	GES	117 (99.15%)	All available GES sequences detected (including GES-1 to GES-22; GES-24 to GES-62; GES-65 to GES-66), with the exception of GES-23.
	IMP	280 (100.00%)	All available IMP sequences detected, including IMP-1 to IM-35; IMP-37 to IMP-49; IMP-51 to IMP-56; IMP-58 to IMP-71; IMP-73 to IMP-102; IMP-104 to IMP-105.
	KPC	1052 (100.00%)	All available KPC sequences detected, including KPC-1 to KPC-19; KPC-21 to KPC-197; KPC-201 to KPC-209; KPC-211 to KPC-218; KPC-223 to KPC-228; KPC-230 to KPC-234; KPC-236 to KPC-242.
	NDM	655 (100.00%)	All available NDM sequences detected, including NDM-1 to NDM-15; NDM-16a; NDM-16b; NDM-17 to NDM-31; NDM-33 to NDM-58; NDM-60 to NDM-61; NDM-64 to NDM-74.
	OXA-23**	384 (100.00%)	OXA alleles detected: OXA-23; OXA-27; OXA-49; OXA-73; OXA-103; OXA-105; OXA-133; OXA-146; OXA-165 to OXA-171; OXA-225; OXA-239, OXA-366; OXA-398; OXA-422 to OXA-423; OXA-435; OXA-440; OXA-481 to OXA-483; OXA-565; OXA-657; OXA-806 to OXA-818; OXA-893; OXA-911; OXA-966 to OXA-969; OXA-1216; OXA-1221; OXA-1223; OXA-1236; OXA-1241. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-22; OXA-24 to OXA-26; OXA-28 to OXA-37; OXA-40; OXA-42 to OXA-43; OXA-45 to OXA-48; OXA-50 to OXA-51; OXA-53 to OXA-72; OXA-74 to OXA-101; OXA-104; OXA-106 to OXA-113; OXA-114a to OXA-114n; OXA114p to OXA114x; OXA-115 to OXA-132; OXA-134; OXA-136 to OXA-145; OXA-147 to OXA-164; OXA-172 to OXA-185; OXA-192 to OXA-217; OXA-219; OXA-223 to OXA-224; OXA-226; OXA-228 to OXA-237; OXA-240 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-365; OXA-368; OXA-370 to OXA-392; OXA-395 to OXA-397; OXA-400 to OXA-418; OXA-420 to OXA-421;

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			OXA-424 to OXA-427; OXA-429 to OXA-433; OXA-436 to OXA-439; OXA-441 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-480; OXA-484 to OXA-486; OXA-488 to OXA-489; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-564; OXA-566 to OXA656; OXA-658 to OXA791; OXA-793 to OXA-805; OXA-819 to OXA-892; OXA-894 to OXA-910; OXA-912 to OXA-965; OXA-970 to OXA-1053; OXA-1055 to OXA-1094; OXA-1096 to OXA-1178; OXA-1181 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1208; OXA-1211 to OXA-1215; OXA-1217 to OXA-1220; OXA-1222; OXA-1224 to OXA-1235; OXA-1237 to OXA-1240; OXA-1242 to OXA-1309.
	OXA-48-like**	473 (100.00%)	OXA alleles detected: OXA-48; OXA-162 to OXA-163; OXA-181; OXA-199; OXA-204; OXA-232; OXA-244 to OXA-245; OXA-247; OXA-252; OXA-370; OXA-405; OXA-416; OXA-438 to OXA-439; OXA-484; OXA-505; OXA-514 to OXA-515; OXA-517; OXA-519; OXA-538; OXA-546 to OXA-547; OXA-566 to OXA-567; OXA-788; OXA-793; OXA-833; OXA-894; OXA-918; OXA-920; OXA-922 to OXA-924; OXA-929; OXA-933 to OXA-934; OXA-1012; OXA-1038 to OXA-1039; OXA-1055; OXA-1119; OXA-1146; OXA-1167; OXA-1181; OXA-1200 to OXA-1201; OXA-1205; OXA-1207; OXA-1211 to OXA-1213; OXA-1226; OXA-1240; OXA-1242; OXA-1304 to OXA-1309. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-37; OXA-40; OXA-42 to OXA-43; OXA-45 to OXA-47; OXA-49 to OXA-51; OXA-53 to OXA-101; OXA-103 to OXA-113; OXA-114a to OXA-114n; OXA-114p to OXA-114x; OXA-115 to OXA-134; OXA-136 to OXA-161; OXA-164 to OXA-180; oxa-182 to OXA-185; OXA-192 to OXA-198; OXA-200 to OXA-203;

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			OXA-205 to OXA-217; OXA-219; OXA-223 to OXA-226; OXA-228 to OXA-231; OXA-233 to OXA-237; OXA-239 to OXA-243; OXA-246; OXA-248 to OXA-251; OXA-253 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-366; OXA-368; OXA-371 to OXA-392; OXA-395 to OXA-398; OXA-400 to OXA-404; OXA-406 to OXA-415; OXA-417 to OXA-418; OXA-420 to OXA-427; OXA-429 to OXA-433; OXA-435 to OXA-437; OXA-440 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-483; OXA-485 to OXA-486; OXA-488 to OXA-489; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-504; OXA-506 to OXA-513; OXA-516; OXA-518; OXA-520 to OXA-537; OXA-539 to OXA-545; OXA-548 to OXA-565; OXA-568 to OXA-787; OXA-789 to OXA-791; OXA-794 to OXA-832; OXA-834 to OXA-893; OXA-895 to OXA-917; OXA-919; OXA-921; OXA-925 to OXA-932; OXA-935 to OXA-1011; OXA-1013 to OXA-1037; OXA-1040 to OXA-1053; OXA-1056 to OXA-1118; OXA-1120 to OXA-1145; OXA-1147 to OXA-1166; OXA-1168 to OXA-1178; OXA-1182 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1199; OXA-1202 to OXA-1204; OXA-1206; OXA-1208; OXA-1214 to OXA-1225; OXA-1227 to OXA-1239; OXA-1241; OXA-1243 to OXA-1303.

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	OXA-24/40**	59 (100.00%)	OXA alleles detected: OXA-24 to OXA-26; OXA-40; OXA-72; OXA-139; OXA-160; OXA-207; OXA-437; OXA-653; OXA-897; OXA-1040; OXA-1081; OXA-1225; OXA-1303. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-23; OXA-27 to OXA-37; OXA-42 to OXA-43; OXA-45 to OXA-51; OXA-53 to OXA-71; OXA-73 to OXA-101; OXA-103 to OXA-113; OXA-114a to OXA-114n; OXA-114p to OXA-114x; OXA-115 to OXA-134; OXA-136 to OXA-138; OXA-140 to OXA-159; OXA-161 to OXA-185; OXA-192 to OXA-206; OXA-208 to OXA-217; OXA-219; OXA-223 to OXA-226; OXA-228 to OXA-237; OXA-239 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-366; OXA-368; OXA-370 to OXA-392; OXA-395 to OXA-398; OXA-400 to OXA-418; OXA-420 to OXA-427; OXA-429 to OXA-433; OXA-435 to OXA-436; OXA-438 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-486; OXA-488 to OXA-499; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-652; OXA-654 to OXA-791; OXA-793 to OXA-896; OXA-898 to OXA-1039; OXA-1041 to OXA-1053; OXA-1055 to OXA-1080; OXA-1082 to OXA-1178; OXA-1181 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1208; OXA-1211 to OXA-1224; OXA-1226 to OXA-1302; OXA-1304 to OXA-1309

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	OXA-58**	80 (100.00%)	OXA alleles detected: OXA-58; OXA-96 to OXA-97; OXA-164; OXA-397; OXA-420; OXA-512; OXA-1178. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-37; OXA-40; OXA-42 to OXA-43; OXA-45 to OXA-51;OXA-53 to OXA-57; OXA-59 to OXA-95; OXA-98 to OXA-101; OXA-103 to OXA-113; OXA-114a to OXA-114n; OXA-114p to OXA-114x; OXA-115 to OXA-134; OXA-136 to OXA-163; OXA-165 to OXA-185; OXA-192 to OXA-217; OXA-219; OXA-223 to OXA-226; OXA-228 to OXA-237; OXA-239 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-366; OXA-368; OXA-370 to OXA-392; OXA-395 to OXA-396; OXA-398; OXA-400 to OXA-418; OXA-421 to OXA-427; OXA-429 to OXA-433; OXA-435 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-486; OXA-488 to OXA-489; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-511; OXA-513 to OXA-791; OXA-793 to OXA-1053; OXA-1055 to OXA-1177; OXA-1181 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1208; OXA-1211 to OXA-1309.
	PER††	88 (100.00%)	All available PER sequences detected(including PER-1 to PER-5; PER-7 to PER-18), with the exception of PER-6
	SHV	2296 (100.00%)	All available SHV sequences detected, including SHV-1 to SHV-9; SHV-11 to SHV-16; SHV-18 to SHV-38; SHV-40 to SHV-46; SHV-48 to SHV-53; SHV-55 to SHV-57; SHV-59 to SHV-67; SHV-69 to SHV-86; SHV-89; SHV-92 to SHV-111; SHV-115 to SHV-116; SHV-119 to SHV-129; SHV-132 to SHV-135; SHV-137; SHV-140 to SHV-165; SHV-167 to SHV-168; SHV-171 to SHV-173; SHV-178 to SHV-180; SHV-182 to SHV-183; SHV-185 to SHV-191; SHV-193 to SHV-245; SHV-1b-b; SHV-2A; SHV-5a; SHV-1-2a; SHV-5-2a; SHV-136; SHV-122b.
	SPM	9 (100.00%)	All available SPM sequences detected, including SPM-1.

Table 17. Summary and observations found in the in silico prediction of the QIAstat-Dx BCID GN Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	TEM	3371 (100.00%)	All available TEM sequences detected, including TEM-1; TEM-1b; TEM-2 to TEM-12; TEM-14 to TEM-17; TEM-19 to TEM-22 to TEM-24; TEM-26; TEM-26b; TEM-28 to TEM-37; TEM-39 to TEM-40; TEM-42 to TEM-43; TEM-45; TEM-47 to TEM-49; TEM-52 to TEM-55; TEM-57; TEM-59 to TEM-61; TEM-63 to TEM-64; TEM-67 to TEM-68; TEM-70 to TEM-73; TEM-75 to TEM-76; TEM-78 to TEM-99; TEM-101 to TEM-118; TEM-120 to TEM-139; TEM-141 to TEM-160; TEM-162 to TEM-164; TEM-166 to TEM-169; TEM-171; TEM-176 to TEM-178; TEM-181 to TEM-199; TEM-201; TEM-205 to TEM-217; TEM-219 to TEM-220; TEM-224 to TEM-258; RTEM-1; TEM-1B; TEM-E2; TEM-HM.
	VEB	88 (100.00%)	All available VEB sequences detected, including VEB-1 to VEB-39; VEB-1a; VEB-1b.
	VIM	218 (100.00%).	All available VEB sequences detected, including VIM-1 to VIM-20; VIM-23 to VIM-91.

* Number of sequences analyzed from the total of sequences included in the analysis after removing preliminary sequences and artificial sequences.

† In silico analyses could not be performed for Izhakiella as no sequences were available. This is deemed low to no risk given that this genus has not been found to be implicated in human disease (62, 63).

‡ *Pseudomonas aeruginosa* Accession Number CP104695 was not detected during primer mapping. This Accession Number corresponds to *P. aeruginosa* strain 2021CK-01281, which also carries a plasmid (Accession Number CP104696) where the target gene of the QIAstat-Dx BCID GN Plus AMR Panel is placed. The primers and probe mapped with 100% homology with this genetic region of the plasmid, thus confirming full inclusivity for this *P. aeruginosa* strain.

§ The *aac(6')-Ib-SK* is a chromosomal-encoded aminoglycoside acetyltransferase specific for *Streptomyces kanamyceticus* (64). Based on the big amount of sequences described for this allele, percentages were calculated excluding this allele in order to homogenize the data. In addition, 2 out of 305 *aac(6')-Ib9* sequences were predicted not to be detected because of the presence of mismatches.

¶ One out of 6 (1/6) sequences of the CMY-136 allele was predicted not to be detected because of the presence of mismatches.

** In case of OXA family PCR assays (OXA-23, OXA-58, OXA-48, OXA-24/40), analysis was performed using the entire list of OXA genes and alleles. Therefore, all percentages correspond to the sequences detected into the detected OXA alleles.

†† PER-6 has not been included in the analyzed sequences assessment.

13.1.8. Interfering substances (Positive Blood Culture samples)

The effect of potentially interfering substances on the detectability of the QIAstat-Dx BCID GN Plus AMR Panel organisms was evaluated. Thirty-two potentially interfering substances were spiked into the sample mixes at a level predicted to be above the concentration of the substance likely to be found in positive blood culture media specimens. Endogenous substances such as bilirubin, human genomic DNA, and hemoglobin were tested alongside exogenous substances like antibiotics, other sepsis-related medications, and different technique-specific substances.

Testing included samples containing negative blood culture media with and without the addition of each potentially interfering substance. Samples containing organism mixes with one strain for 3 representative organisms also harboring a total of 5 AMR were tested at 3x LoD or lower. The positive mix covered all reaction chambers of the QIAstat-Dx BCID GN Plus AMR Panel. Testing was performed in triplicate. Additionally, negative blood culture media were spiked with only the test substance to evaluate the potential for false positive results due to the test substance itself.

The only interference that was observed for the substances tested was Amoxicillin at 0.075 mg/mL; however, inhibitory effect was not observed when tested at 0.038 mg/mL. Results from the 32 interfering substances that could be present or introduced in a positive blood culture specimen are provided in Table 18.

Table 18. Final highest concentration without observable inhibitory effect

Substance name	Concentration in blood culture matrix (units/mL)	Result
Exogenous Substances		
Acetaminophen	0.156 mg/mL	No Interference
Amoxicillin	0.038 mg/mL	No Interference
Amoxicillin trihydrate: Potassium clavulanate (4:1)	0.075 mg/mL	No Interference
Amphotericin B	0.002 mg/mL	No Interference
Ara-C Triphosphate	2.64 µg/mL	No Interference
Biotin (Vitamin B7)	0.00351 mg/mL	No Interference
Sodium hypochlorite solution (Bleach)	5% (v/v) (6 mg/mL)	No Interference

Table 18. Final highest concentration without observable inhibitory effect (continued)

Substance name	Concentration in blood culture matrix (units/mL)	Result
Caspofungin Diacetate	0.005 mg/mL	No Interference
Ceftriaxone Disodium Hemiheptahydrate	0.966 mg/mL	No Interference
Ciprofloxacin	0.01 mg/mL	No Interference
Ethanol	5% (v/v) (39.4 mg/mL)	No Interference
Fluconazole	0.075 mg/mL	No Interference
5-Fluorocytosine	0.09 mg/mL	No Interference
Gentamicin sulphate	0.03 mg/mL	No Interference
Heparin Sodium	3 IU/mL	No Interference
Ibuprofen	0.219 mg/mL	No Interference
Imipenem Monohydrate	0.5 mg/mL	No Interference
Povidone (iodinated)	5 mg/mL	No Interference
Salicylic Acid	0.0286 mg/mL	No Interference
Sodium Polyanethol Sulfonate (SPS)	0.0025 mg/mL	No Interference
Tetracycline Hydrochloride	0.015 mg/mL	No Interference
Vancomycin (hydrochloride)	0.12 mg/mL	No Interference
Endogenous Substances		
Bilirubin	0.25 mg/mL	No Interference
Cholesterol	0.5 mg/mL	No Interference
D-Glucose	5 mg/mL	No Interference
Fibrinogen	0.5 mg/mL	No Interference
Haemoglobin	5 mg/mL	No Interference
Magnesium Sulphate ($MgSO_4$)	0.1 mg/mL	No Interference
hgDNA	10.55 µg/mL	No Interference
Human Serum Albumin	25 mg/mL	No Interference
Triglycerides mixtures (Lipid standards)	15 mg/mL	No Interference
γ-globulin	60 mg/mL	No Interference

13.1.9. Competitive inhibition

The QIAstat-Dx BCID GN Plus AMR Panel was evaluated for its ability to simultaneously detect multiple analytes within a single sample under conditions of differential pathogen concentrations—1 present at a high level (approximately bottle positivity + 24 hours) and another at a lower level (approximately 3×LoD). The study focused on clinically relevant and prevalent analyte combinations observed in polymicrobial blood cultures. Testing included a mixture of panel targets and mixtures of target analytes with non-target organisms, including common skin contaminants. If fewer than 3 replicates (<3/3) were detected for the pathogen (or associated AMR) when tested at 3xLoD in a sample mix, then repeat testing was performed with the pathogen tested at a higher concentration (i.e., >3xLoD) until 100% hit rate was observed. If the pathogen was still not detected when concentration was increased close to that typical of a "bottle positive" sample, the concentration of the other pathogen in the mix was reduced to determine the concentration at which co-detection was achieved.

Details of the organisms assessed and their respective concentrations are summarized in Table 19.

Note: The reported concentrations refer to values established in direct positive blood cultures for VersaTREK media or in positive blood cultures that underwent 1:1 dilution for other media types (BD BACTEC and BACT/ALERT).

Table 19. Summary of competitive inhibition results

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
Escherichia coli (CCUG 70662)	*Escherichia coli*, Pan *Enterobacterales*	6.08E+08	1.24E+06 (5.5xLoD)
Klebsiella pneumoniae (CCUG 68728)	*Klebsiella* spp., Pan *Enterobacterales* [*aac(6')-Ib, armA, ampC* (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]	1.40E+09	9.00E+06 (266.3xLoD)

Table 19. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
Escherichia coli (NCTC 14320) *Proteus mirabilis* (ATCC BAA 2792)	*Escherichia coli*, Pan *Enterobacterales* [*aac(6')-Ib*, IMP, KPC, OXA-48-like, TEM]	2.01E+09	1.24E+07 (54.7xLoD)
	Proteus spp., Pan *Enterobacterales* [*aac(6')-Ib, ampC* (CMY/LAT/DHA/FOX), VIM, TEM]	3.17E+09	9.75E+06 (BP stock)
Klebsiella pneumoniae (CCUG 68728) *Enterobacter cloacae* (NCTC 14326)	*Klebsiella* spp., Pan *Enterobacterales* [*aac(6')-Ib, armA, ampC* (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]	1.40E+09	3.53E+06 (BP stock)
	Enterobacter spp., Pan *Enterobacterales* [*aac(6')-Ib*, VIM]	8.10E+06	8.10E+06 (3xLoD)
Escherichia coli (NCTC 14320) *Enterobacter cloacae* (NCTC 14326)	*Escherichia coli*, Pan *Enterobacterales* [*aac(6')-Ib*, IMP, KPC, OXA-48-like, TEM]	2.01E+09	1.24E+07 (54.7xLoD)
	Enterobacter spp. [*aac(6')-Ib*, VIM]	9.56E+08	8.10E+06 (3xLoD)
Pseudomonas aeruginosa (NCTC 13921) *Proteus mirabilis* (ATCC BAA 2792)	*Pseudomonas aeruginosa* [*aac(6')-Ib*, SPM]	1.41E+09	2.52E+07 (30xLoD)
	Proteus spp., Pan *Enterobacterales* [*aac(6')-Ib, ampC* (CMY/LAT/DHA/FOX), VIM, TEM]	3.17E+09	9.00E+06 (300xLoD)
Acinetobacter baumannii (ATCC BAA 2801) *Klebsiella pneumoniae* (CCUG 68728)	*Acinetobacter calcoaceticus-baumannii* complex [OXA-23, PER, TEM]	4.81E+06	5.34E+05 (12.9xLoD)
	Klebsiella spp., Pan *Enterobacterales* [*aac(6')-Ib, armA, ampC* (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]	1.40E+09	3.53E+06 (BP stock)
Klebsiella pneumoniae (CCUG 68728) *Proteus mirabilis* (ATCC BAA 2792)	*Klebsiella* spp., Pan *Enterobacterales* [*aac(6')-Ib, armA, ampC* (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]	1.40E+09	3.53E+06 (BP stock)
	Proteus spp., Pan *Enterobacterales* [*ampC* (CMY/LAT/DHA/FOX), VIM, TEM]	8.10E+07	9.75E+06 (BP stock)

Table 19. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
Pseudomonas aeruginosa (NCTC 13921)	*Pseudomonas aeruginosa* [*aac(6')-Ib*, SPM]	1.41E+09	1.29E+06 (BP stock)
Acinetobacter baumannii (NCTC 13302)	*Acinetobacter calcoaceticus-baumannii* complex [OXA-24/40]	4.97E+05	5520 (0.24xLoD)
Escherichia coli (NCTC 14320)	*Escherichia coli*, Pan *Enterobacterales* [*aac(6')-Ib*, IMP, KPC, OXA-48-like, TEM]	1.11E+08	1.24E+08 (546.9xLoD)
Bacteroides fragilis (CCUG 4856T)	*Bacteroides fragilis*	8.19E+09	3.38E+07 (BP stock)
Pseudomonas aeruginosa (NCTC 2799)	*Pseudomonas aeruginosa* [*aac(6')-Ib*, PER, VIM]	8.28E+06	8.28E+06 (3xLoD)
Stenotrophomonas maltophilia (NCTC 10259)	*Stenotrophomonas maltophilia*	2.05E+09	2.54E+08 (3xLoD)
Pseudomonas aeruginosa (NCTC 13921)	*Pseudomonas aeruginosa* [*aac(6')-Ib*, SPM]	1.25E+09	N/A
Stenotrophomonas maltophilia (NCTC 10259)	*Stenotrophomonas maltophilia*	N/A	2.54E+08 (3xLoD)
Klebsiella pneumoniae (CCUG 68728)	*Klebsiella* spp., Pan *Enterobacterales* [*aac(6')-Ib*, *armA*, *ampC* (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]	8.10E+06	9.00E+06 (266.3xLoD)
Serratia marcescens (ATCC 14041)	*Serratia* spp., Pan *Enterobacterales*	4.82E+08	2.10E+07 (BP stock)
Enterobacter cloacae (NCTC 14326)	*Enterobacter* spp. [*aac(6')-Ib*, VIM]	9.56E+08	8.10E+06 (3xLoD)
Acinetobacter baumannii (ATCC BAA 2801)	*Acinetobacter calcoaceticus-baumannii* complex [OXA-23, PER, TEM]	1.38E+08	5.34E+06 (129xLoD)

Table 19. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
Cutibacterium acnes (NCTC 737)	N/A - Off Panel target	1.71E+08	N/A
Escherichia coli (NCTC 14320)	*Escherichia coli*, Pan *Enterobacterales* [*aac(6')-Ib*, IMP, KPC, OXA-48-like, TEM]	N/A	1.24E+07 (54.7xLoD)
Enterococcus faecium (ATCC-BAA 2316)	N/A - Off Panel target	8.96E+08	N/A
Klebsiella pneumoniae (CCUG 68728)	*Klebsiella* spp., Pan *Enterobacterales* [*aac(6')-Ib*, *armA*, *ampC* (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]	N/A	9.00E+05 (26.6xLoD)
Bacillus cereus (ATCC 21769)	N/A - Off Panel target	1.87E+06	N/A
Pseudomonas aeruginosa (ATCC 2799)	*Pseudomonas aeruginosa* [*aac(6')-Ib*, PER, VIM]	N/A	8.28E+06 (3xLoD)
Corynebacterium striatum (ATCC 43735)	N/A - Off Panel target	9.54E+08	N/A
Acinetobacter baumannii (NCTC 13302)	*Acinetobacter calcoaceticus-baumannii* complex [OXA-24/40]	N/A	5.52E+04 (2.4xLoD)
Candida albicans (ATCC 10231)	N/A - Off Panel target	1.83E+07	N/A
Enterobacter cloacae (NCTC 14326)	*Enterobacter* spp., Pan *Enterobacterales* [*aac(6')-Ib*, VIM]	9.56E+08	8.10E+06 (3xLoD)
Micrococcus luteus (NCTC 7011)	N/A - Off Panel target	2.13E+08	N/A
Serratia marcescens (ATCC 14041)	*Serratia* spp., Pan *Enterobacterales*	N/A	1.89E+08 (3xLoD)

Table 19. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
Staphylococcus aureus (ATCC BAA 2313)	N/A - Off Panel target	2.09E+08	N/A
Proteus mirabilis (ATCC BAA 2792)	*Proteus* spp. [*ampC* (CMY/LAT/DHA/FOX), VIM, TEM]	N/A	9.75E+06 (300xLoD)
Staphylococcus epidermidis (ATCC 35984)	N/A - Off Panel target	7.29E+08	N/A
Bacteroides fragilis (CCUG 4856T)	*Bacteroides fragilis*	N/A	3.90E+04 (3xLoD)
Enterococcus faecalis (ATCC 51299)	N/A - Off Panel target	7.25E+08	N/A
Stenotrophomonas maltophilia (NCTC 10259)	*Stenotrophomonas maltophilia*	N/A	2.54E+08 (3xLoD)

* The high positive concentration tested corresponds to the highest concentration at which no dropout was observed for any target associated with the co-infecting organism. The low positive concentration detected corresponds to the lowest concentration tested at which a 100% hit rate was achieved for all the targets within the low concentration microorganism.

13.1.10. Carry-over

A carry-over study was performed to evaluate the potential occurrence of cross-contamination between consecutive runs when using the QIAstat-Dx BCID GN Plus AMR Panel on a QIAstat-Dx Analyzer. Pathogen samples of positive blood culture media and pure colony samples, alternating high-positive (at least 1.00 E+09 CFU/mL, and 4.50E+08 CFU/mL, respectively) and negative blood culture media and saline samples, respectively, were tested on 2 QIAstat-Dx Analyzer instruments. No carryover between samples was observed in the QIAstat-Dx BCID GN Plus AMR Panel, demonstrating that the system design and recommended sample handling and testing practices are effective at preventing false positive results from carryover or cross-contamination.

13.1.11. Reproducibility

Reproducibility testing of contrived samples was performed at 3 test sites including 1 internal site (Site A) and 2 external sites (Site B and Site C). The study incorporated a range of potential variation introduced by sites, days, replicates, operators, and QIAstat-Dx Analyzers.

For each site, testing was performed across 6 non-consecutive days with 3 replicates per day by each of the 2 operators (leading to a total of 36 replicates per target, concentration, and site), 6–7 QIAstat-Dx Analyzers (at least 2 QIAstat-Dx Analyzers per operator and per site), and at least 2 operators on each testing day.

For the Positive Blood Culture Matrix (PBCM) sample type, 3 sample mixes were prepared. Two combined samples were prepared from pathogens grown independently and collected at different incubation stages: one at the time of bottle positivity and one following an additional 24 hours of incubation after bottle positivity. The third sample was a negative control containing an off-panel organism (*Cutibacterium acnes,* NCTC 737) incubated to bottle positivity.

For the Pure Colony (PC) sample type, 2 sample mixes were prepared: 1 combined sample containing a PC suspension of 5 pathogens at 1.0 McFarland unit, and 1 negative control sample containing an off-panel organism (*Cutibacterium acnes,* NCTC 737) at 1.0 McFarland unit.

Table 20 and Table 21 shows the detection rate per target and concentration for each site of the Reproducibility study. In addition, data obtained at all 3 sites have been compiled to calculate the exact 2-sided 95% CI by target and concentration.

Table 20. Reproducibility hit rate results and confidence intervals established for all targets for PBCM samples

				Agreement with expected results			
Pathogen	**Target**	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All Sites (95% Confidence Interval)**
Acinetobacter baumannii (NCTC 13302)	*Acinetobacter calcoaceticus-baumannii* complex	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)
	OXA-24/40	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)

Table 20. Reproducibility hit rate results and confidence intervals established for all targets for PBCM samples (continued)

				Agreement with expected results			
Pathogen	**Target**	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All Sites (95% Confidence Interval)**
Salmonella enterica (NCTC 13954)	*Salmonella* spp.	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)
	OXA-48-like	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)

Table 20. Reproducibility hit rate results and confidence intervals established for all targets for PBCM samples (continued)

				Agreement with expected results			
Pathogen	**Target**	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All Sites (95% Confidence Interval)**
Pseudomonas aeruginosa (MRSN 12914)	*Pseudomonas aeruginosa*	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)
	VEB	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)
Proteus vulgaris (ATCC 6380)	*Proteus* spp.	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)

Table 20. Reproducibility hit rate results and confidence intervals established for all targets for PBCM samples (continued)

				Agreement with expected results			
Pathogen	**Target**	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All Sites (95% Confidence Interval)**
Stenotrophomonas maltophilia (NCTC 10499)	*Stenotrophomonas maltophilia*	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)
Proteus vulgaris (CCUG 6380)/*Salmonella enterica* (NCTC 13954)	Pan *Enterobacterales*	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7–100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0–3.4%)

Table 21. Reproducibility hit rate results and confidence intervals established for all targets for PC samples

				Agreement with expected results			
Pathogen	**Target**	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All Sites (95% Confidence Interval)**
Acinetobacter baumannii (NCTC 13302)	*Acinetobacter calcoaceticus-baumannii* complex	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
	OXA-24/40	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
Salmonella enterica (NCTC 13954)	*Salmonella* spp.	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
	OXA-48-like	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)

Table 21. Reproducibility hit rate results and confidence intervals established for all targets for PC samples (continued)

				Agreement with expected results			
Pathogen	**Target**	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All Sites (95% Confidence Interval)**
Pseudomonas aeruginosa (MRSN 12914)	*Pseudomonas aeruginosa*	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
	VEB	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
Proteus vulgaris (ATCC 6380)	*Proteus* spp.	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
Stenotrophomonas maltophilia (NCTC 10499)	*Stenotrophomonas maltophilia*	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)
Proteus vulgaris (CCUG 6380)/*Salmonella enterica* (NCTC 13954)	Pan *Enterobacterales*	Positive	Positive	36/36	36/36	36/36	108/108 (96.6–100.0%)
		Negative	Negative	0/36	0/36	0/37	0/109 (0.0–3.3%)

13.1.12. Repeatability

A repeatability study was conducted for both sample types on a QIAstat-Dx Analyzer. For the blood culture sample type, positive test samples were combined from individually grown pathogens, which were contrived by inoculating blood culture bottles with whole blood and the pathogenic material. Pathogens were incubated in a blood culture instrument until positive ring to obtain positive samples and negative sample containing an off-panel organism (*Cutibacterium acnes,* NCTC 737) incubated at bottle positivity. In addition, cultures were allowed to incubate for an additional 24 hours after positive ring to obtain the high positive sample. For the pure colony sample type, a combined positive sample was prepared, containing a suspension of 5 pathogens at 1.0 McFarland and 1 negative sample was prepared containing an off-panel target (*Cutibacterium acnes,* NCTC 737) at 1.0 McFarland. For both sample types, the QIAstat-Dx BCID GN Plus AMR Panel detected pathogens included in the positive samples were *Acinetobacter baumannii,* OXA-24/40 (NCTC 13302), *Salmonella enterica,* OXA-48-like (NCTC 13954), *Pseudomonas aeruginosa,* VEB (MRSN 12914), *Proteus vulgaris* (ATCC 6380) and *Stenotrophomonas maltophilia* (NCTC 10499). Negative samples included *Cutibacterium acnes*. All samples were tested on 3 instruments per day over 16 days on 3 cartridge lots. In total, for each sample type, 90 replicates of positive and 90 replicates of high positive per each of the tested targets and 90 replicates of negative samples were run per cartridge lot. For all positive samples, 100% detection was obtained for all expected targets (90/90 detected positive hits) for both sample types. Negative samples showed 100% of negative calls for all panel analytes for both sample types.

13.2. Clinical performance

The clinical performance described in this section was demonstrated using QIAstat-Dx Analyzer 1.0. QIAstat-Dx Analyzer 2.0 uses the same Analytical Modules as QIAstat-Dx Analyzer 1.0; therefore, performance is not impacted by QIAstat-Dx Analyzer 2.0.

The performance characteristics of the QIAstat-Dx BCID GN Plus AMR Panel was assessed by a multi-center, observational, prospective, and retrospective, clinical performance study, on Positive Blood Culture Media (PBCM) and Pure Colony isolates (PC) from subjects with signs and symptoms of bloodstream infection. The study was conducted at 10 geographically diverse study sites: 8 US sites and 2 European sites.

13.2.1. Testing of prospective specimens

Between November 2023 and May 2025, a total of 1711 prospective specimens were enrolled for the clinical performance study of the QIAstat-Dx BCID GN Plus AMR Panel. A total of 1688 prospective specimens were eligible overall. The most common reason for specimen withdrawal was that the sample did not meet eligibility criteria. Out of these specimens, 694 prospective residual gram-negative by staining PBCM and a total of 691 prospective PC samples were eligible for the clinical performance evaluation Study of the QIAstat-Dx BCID GN Plus AMR Panel. The final dataset consisted of 661 and 688 prospective specimens for PBCM and PC, respectively. The most common reason for specimen withdrawal was that the sample did not meet eligibility criteria. Additionally, some prospective samples could not be included in the agreement analysis due to a change in the device workflow for PBCM samples after study initiation.

The demographic information for the 661 PBCM specimens evaluated in the prospective study is summarized in Table 22.

Table 22. Demographic summary for prospective PBCM samples for QIAstat-Dx BCID GN Plus AMR Panel clinical evaluation

Sample Type	Variable	Subgroup	N	%
Prospective Fresh	Age group	<1 year	5	0.8
		1–17 years	18	2.9
		18–44 years	75	11.9
		45–64 years	167	26.5
		65–89 years	340	54.0
		90+ years	25	4.0
	Sex	Female	315	50.0
		Male	315	50.0

Table 22. Demographic summary for prospective PBCM samples for QIAstat-Dx BCID GN Plus AMR Panel clinical evaluation (continued)

Sample Type	Variable	Subgroup	N	%
Prospective Frozen	Age group	<1 year	1	3.2
		18–44 years	4	12.9
		45–64 years	5	16.1
		65–89 years	21	67.7
	Sex	Female	13	41.9
		Male	18	58.1
Prospective Total	Age group	<1 year	6	0.9
		1–17 years	18	2.7
		18–44 years	79	12.0
		45–64 years	172	26.0
		65–89 years	361	54.6
		90+ years	25	3.8
	Sex	Female	328	49.6
		Male	333	50.4

Residual PBCM and PC specimens were tested with the QIAstat-Dx BCID GN Plus AMR Panel and Standard Laboratory Techniques (SLT) following the study sites' respective local procedures as comparator method for pathogens. Additional reflex testing was performed if SLT results did not provide sufficient species-level identification.

Discordant testing for pathogens was carried out using an additional FDA-cleared, CE-marked test which was not used as part of SLT.

For all AMR targets on the QIAstat-Dx BCID GN Plus AMR Panel, the reference method was a lab developed qPCR, followed by confirmatory single PCR assays and Bidirectional sequencing (BDS) for selected targets.

Phenotypic AST results were also collected, if performed as part of the SLT procedures. Correlation of the QIAstat-Dx BCID GN Plus AMR Panel genotypic AMR target results to available phenotypic AST results was performed as a secondary endpoint.

The Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA) were calculated for the prospective samples.

Clinical sensitivity or Positive Percent Agreement (PPA) was calculated as 100% x (TP / (TP + FN)). True positive (TP) indicates that both QIAstat-Dx BCID GN Plus AMR Panel and comparator method have a positive result for the specific pathogen. False negative (FN) indicates that the QIAstat-Dx result is negative while the comparator result is positive for the specific pathogen. Specificity or Negative Percent Agreement (NPA) was calculated as 100% x (TN / (TN + FP)). True negative (TN) indicates that both the QIAstat-Dx BCID GN Plus AMR Panel and the comparator method have negative results for the specific pathogen. False positive (FP) indicates that the QIAstat-Dx BCID GN Plus AMR Panel result is positive for the specific pathogen, but the comparator result is negative. The two-sided 95% Confidence Intervals were calculated.

13.2.2. QIAstat-Dx BCID GN Plus AMR Panel, Positive Blood Culture Media

The QIAstat-Dx BCID GN Plus AMR Panel prospective data for Positive Percent Agreement and Negative Percent Agreement against the comparator methods are presented by analyte Table 23 and Table 24 for pathogens and AMRs respectively in PBCM samples.

Pathogens

Table 23. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Enterobacter spp.*	Prospective Fresh	40 / 42	95.2	84.2–98.7	584 / 586	99.7	98.8–99.9
	Prospective Frozen	3 / 3	100.0	43.9–100.0	28 / 28	100.0	87.9–100.0
	Total	43 / 45	95.6	85.2–98.8	612 / 614	99.7	98.8–99.9
Escherichia coli†	Prospective Fresh	272 / 277	98.2	95.8–99.2	348 / 352	98.9	97.1–99.6
	Prospective Frozen	14 / 14	100.0	78.5–100.0	17 / 17	100.0	81.6–100.0
	Total	286 / 291	98.3	96.0–99.3	365 / 369	98.9	97.2–99.6
Klebsiella spp.‡	Prospective Fresh	129 / 132	97.7	93.5–99.2	489 / 496	98.6	97.1–99.3
	Prospective Frozen	9 / 9	100.0	70.1–100.0	22 / 22	100.0	85.1–100.0
	Total	138 / 141	97.9	93.9–99.3	511 / 518	98.6	97.2–99.3

Table 23. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Proteus spp.[§]	Prospective Fresh	32 / 32	100.0	89.3–100.0	589 / 596	98.8	97.6–99.4
	Prospective Frozen	0 / 1	0.0	0.0–79.3	30 / 30	100.0	88.6–100.0
	Total	32 / 33	97.0	84.7–99.5	619 / 626	98.9	97.7–99.5
Salmonella spp.	Prospective Fresh	12 / 12	100.0	75.8–100.0	616 / 616	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	12 / 12	100.0	75.8–100.0	647 / 647	100.0	99.4–100.0
Serratia spp.	Prospective Fresh	20 / 20	100.0	83.9–100.0	608 / 608	100.0	99.4–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	30 / 30	100.0	88.6–100.0
	Total	21 / 21	100.0	84.5–100.0	638 / 638	100.0	99.4–100.0
Pseudomonas aeruginosa[¶]	Prospective Fresh	36 / 37	97.3	86.2–99.5	591 / 591	100.0	99.4–100.0
	Prospective Frozen	3 / 3	100.0	43.9–100.0	28 / 28	100.0	87.9–100.0
	Total	39 / 40	97.5	87.1–99.6	619 / 619	100.0	99.4–100.0

Table 23. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Neisseria meningitidis (encapsulated)	Prospective Fresh	1 / 1	100.0	20.7–100.0	627 / 627	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	1 / 1	100.0	20.7–100.0	658 / 658	100.0	99.4–100.0
*Haemophilus influenzae***	Prospective Fresh	2 / 2	100.0	34.2–100.0	625 / 626	99.8	99.1–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	2 / 2	100.0	34.2–100.0	656 / 657	99.8	99.1–100.0
Acinetobacter calcoaceticus-baumannii complex	Prospective Fresh	5 / 5	100.0	56.6–100.0	623 / 623	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	5 / 5	100.0	56.6–100.0	654 / 654	100.0	99.4–100.0
Bacteroides fragilis††	Prospective Fresh	10 / 12	83.3	55.2–95.3	614 / 616	99.7	98.8–99.9
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	10 / 12	83.3%	55.2–95.3	614 / 616	99.7	98.8–99.9

Table 23. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Stenotrophomonas maltophilia	Prospective Fresh	3 / 3	100.0	43.9–100.0	625 / 625	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	3 / 3	100.0	43.9–100.0	656 / 656	100.0	99.4–100.0
Pan *Enterobacterales*‡‡	Prospective Fresh	529 / 531	99.6	98.6–99.9	95 / 99	96.0	90.1–98.4
	Prospective Frozen	26 / 27	96.3	81.7–99.3	4 / 4	100.0	51.0–100.0
	Total	555 / 558	99.5	98.4–99.8	99 / 103	96.1	90.4–98.5

Table 23. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**

* *Enterobacter* spp. was detected in 1/2 FP prospective specimens using an additional molecular method. For the other FP prospective specimen, cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for *Enterobacter* spp. with *Leclercia adecarboxylata* was identified. *Enterobacter* spp. was not detected in 1/2 FN prospective specimens using an additional molecular method.

† *Escherichia coli* was detected in 3/4 FP prospective specimens and not detected in the remaining specimen using an additional molecular method. *Escherichia coli* was detected in all FN specimens using an additional molecular method.

‡ Of the 7 *Klebsiella* spp. FP prospective samples, *Klebsiella* spp. was detected in 1/7 FP specimens, and was not detected in the remaining FP specimens using an additional molecular method. Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for *Klebsiella* spp. and *Proteus* spp. was observed with 4 *Enterobacter* spp. specimens. Additional speciation was completed by 23S sequencing and/or MALDI-TOF and all 4 specimens were identified as *E. ludwigii*. In addition, in silico cross-reactivity was predicted between the QIAstat-Dx BCID GN Plus AMR Panel for *Klebsiella* spp. and *Enterobacter* species. Of the 3 FN samples, *Klebsiella* spp. was detected in one specimen and not detected in 2 specimens using an additional molecular method.

§ *Proteus* spp. was detected in 3 FP specimens and not detected in the remaining 4 FP specimens using an additional molecular method. Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for *Klebsiella* spp. and *Proteus* spp. was observed with 4 *Enterobacter* spp. specimens. Additional speciation was completed by 23S sequencing and MALDI-TOF and all 4 specimens were identified as *E. ludwigii*. No additional testing was performed for the single FN *Proteus* spp. prospective specimen.

¶ *Pseudomonas aeruginosa* was detected in the single FN prospective specimen using an alternative molecular method.

** *Haemophilus influenzae* was detected in the single FP prospective specimen using an additional molecular method.

†† *Bacteroides fragilis* was detected in the 2 FP and not detected in the 2 FN prospective specimens using an alternative molecular method.

‡‡ Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for Pan *Enterobacterales* was predicted by in silico analysis with *Pantoea septica* and observed in 2 FP prospective specimens. Of the remaining 2 Pan *Enterobacterales* FP prospective specimens, an additional molecular method was performed in one specimen where Pan *Enterobacteales* was detected. Of the 3 FN Pan *Enterobacterales* prospective specimens, Pan *Enterobacterales* was not detected in one FN sample using additional molecular method, no additional testing was performed for the remaining 2 FN specimens.

AMR

Table 24. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
ampC (CMY/LAT/DHA/FOX)	Prospective Fresh	15 / 20	75.0	53.1–88.8	545 / 546	99.8	99.0–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	15 / 20	75.0	53.1–88.8	574 / 575	99.8	99.0–100.0
CTX-M	Prospective Fresh	73 / 75	97.3	90.8–99.3	489 / 491	99.6	98.5–99.9
	Prospective Frozen	2 / 2	100.0	34.2–100.0	27 / 27	100.0	87.5–100.0
	Total	75 / 77	97.4	91.0–99.3	516 / 518	99.6	98.6–99.9
IMP	Prospective Fresh	0 / 0	N/A	N/A	543 / 543	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	572 / 572	100.0	99.3–100.0

Table 24. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
KPC	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
NDM	Prospective Fresh	3 / 3	100.0	43.9–100.0	564 / 564	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	3 / 3	100.0	43.9–100.0	593 / 593	100.0	99.4–100.0
OXA-23	Prospective Fresh	1 / 1	100.0	20.7–100.0	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	595 / 595	100.0	99.4–100.0

Table 24. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
OXA-48-like	Prospective Fresh	1 / 1	100.0	20.7–100.0	562 / 562	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	591 / 591	100.0	99.4–100.0
OXA-24/40	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
OXA-58	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0

Table 24. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
SHV	Prospective Fresh	89 / 90	98.9	94.0–99.8	473 / 477	99.2	97.9–99.7
	Prospective Frozen	4 / 4	100.0	51.0–100.0	25 / 25	100.0	86.7–100.0
	Total	93 / 94	98.9	94.2–99.8	498 / 502	99.2	98.0–99.7
TEM	Prospective Fresh	134 / 141	95.0	90.1–97.6	435 / 438	99.3	98.0–99.8
	Prospective Frozen	9 / 9	100.0	70.1–100.0	19 / 20	95.0	76.4–99.1
	Total	143 / 150	95.3	90.7–97.7	454 / 458	99.1	97.8–99.7
VIM	Prospective Fresh	1 / 2	50.0	9.5–90.5	565 / 565	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 2	50.0	9.5–90.5	594 / 594	100.0	99.4–100.0

Table 24. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
PER	Prospective Fresh	1 / 1	100.0	20.7–100.0	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	595 / 595	100.0	99.4–100.0
armA	Prospective Fresh	1 / 1	100.0	20.7–100.0	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	595 / 595	100.0	99.4–100.0
aac(6')-Ib	Prospective Fresh	37 / 40	92.5	80.1–97.4	525 / 527	99.6	98.6–99.9
	Prospective Frozen	1 / 1	100.0	20.7–100.0	28 / 28	100.0	87.9–100.0
	Total	38 / 41	92.7	80.6–97.5	553 / 555	99.6	98.7–99.9

Table 24. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PBCM samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
VEB	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
GES	Prospective Fresh	0 / 0	N/A	N/A	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	595 / 595	100.0	99.4–100.0
SPM	Prospective Fresh	0 / 0	N/A	N/A	40 / 40	100.0	91.2–100.0
	Prospective Frozen	0 / 0	N/A	N/A	3 / 3	100.0	43.9–100.0
	Total	0 / 0	N/A	N/A	43 / 43	100.0	91.8–100.0

13.2.2.1. Co-infections

The QIAstat-Dx BCID GN Plus AMR Panel reported multiple organism detections (i.e., co-infections) for a total of 22/661 (3.3%) prospective specimens. Most multiple detections in prospective specimens (18/22; 81.8%) contained 2 organisms, while (4/22;18.2%) contained 3 organisms.

Table 25. Detection summary combinations determined by the QIAstat-Dx BCID GN Plus AMR Panel in the prospective clinical study

Detection summary	
Detected pathogens on QIAstat-Dx BCID GN Plus AMR Panel	**Number of specimens with multi-detections**
Total co-infection detections	22
Double detections	18
Triple detections	4

The most common multiple infections (>3 instances) are shown in Table 26.

Table 26. Most prevalent multiple detection combinations (>3 instances) as determined by the QIAstat-Dx BCID GN Plus AMR Panel in the prospective clinical study

Detected pathogens on QIAstat-Dx BCID GN Plus AMR Panel	Number of specimens with multi-detections
Detection summary	
Escherichia coli + *Klebsiella* spp.	6
Escherichia coli + *Enterobacter* spp.	3
Haemophilus influenzae + *Pseudomonas aeruginosa*	3
Enterobacter spp. + *Klebsiella* spp. + *Proteus* spp.	4

13.2.2.2. Testing of preselected archived (Retrospective) specimens

Several analytes in the QIAstat-Dx BCID GN Plus AMR Panel were of low prevalence and were not encountered in sufficiently large numbers during the prospective study to adequately demonstrate clinical performance. To supplement the results of the prospective clinical study, an evaluation of frozen archived positive retrospective specimens was performed. The

specimens selected for testing had previously tested positive for one of the QIAstat-Dx BCID GN Plus AMR Panel targets using the clinical laboratory standard of care method. The archived specimen testing was mixed with the prospective specimen testing at the clinical sites to ensure blinding. A total of 145 evaluable archived specimen were collected and 145 were used in the analysis to support the QIAstat-Dx BCID GN Plus AMR Panel performance evaluation. Table 27 provides a summary of demographic information for the archived specimens.

Table 27. Demographic summary of evaluable archived specimens for QIAstat-Dx BCID GN Plus AMR Panel clinical evaluation

Sample type	Variable	Subgroup	N	%
Retrospective Archived	Age group	<1 year	5	3.4
		1–17 years	8	5.5
		18–44 years	29	20.0
		45–64 years	28	19.3
		65–89 years	71	49.0
		90+ years	4	2.8
	Sex	Female	61	42.1
		Male	83	57.2
		Not reported	1	0.7

The QIAstat-Dx BCID GN Plus AMR Panel retrospective archived specimen data in positive percent agreement and negative percent agreement against the comparator methods are presented by analyte in Table 28 and Table 29 for pathogens and AMRs, respectively.

Table 28. QIAstat -Dx BCID GN Plus AMR Panel archived clinical performance summary for pathogens

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Enterobacter spp.	0 / 0	N/A	N/A	145 / 145	100.0	97.4–100.0
Escherichia coli	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
Klebsiella spp.	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
Proteus spp.	29 / 29	100.0	88.3–100.0	116 / 116	100.0	96.8–100.0
Salmonella spp.	22 / 22	100.0	85.1–100.0	123 / 123	100.0	97.0–100.0
Serratia spp.	24 / 24	100.0	86.2–100.0	121 / 121	100.0	96.9–100.0
*Pseudomonas aeruginosa**	1 / 1	100.0	20.7–100.0	139 / 144	96.5	92.1–98.5
Neisseria meningitidis (encapsulated)†	6 / 7	85.7	48.7–97.4	138 / 138	100.0	97.3–100.0
Haemophilus influenzae‡	20 / 20	100.0	83.9–100.0	124 / 125	99.2	95.6–99.9
Acinetobacter calcoaceticus-baumannii complex	8 / 8	100.0	67.6–100.0	137 / 137	100.0	97.3–100.0
Bacteroides fragilis§	28 / 28	100.0	87.9–100.0	116 / 117	99.1	95.3–99.8
Stenotrophomonas maltophilia	6 / 6	100.0	61.0–100.0	139 / 139	100.0	97.3–100.0

Table 28. QIAstat -Dx BCID GN Plus AMR Panel archived clinical performance summary for pathogens (continued)

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Pan *Enterobacterales*¶	76 / 76	100.0	95.2–100.0	68 / 69	98.6	92.2–99.7

* *Pseudomonas aeruginosa* was detected in all 5 FP retrospective specimens using an additional molecular method.

† The single *Neisseria meningitidis* FN retrospective specimen was further investigated by an additional test specific to encapsulated *Neisseria meningitidis* and not detected. Note that the QIAstat-Dx BCID GN Plus AMR Panel only detects encapsulated *Neisseria meningitidis*.

‡ *Haemophilus influenzae* was not detected in the single FP retrospective specimen using an additional molecular method.

§ The single *Bacteroides fragilis* FP retrospective specimen, was detected using an additional molecular method.

¶ Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for Pan *Enterobacterales* was predicted by in silico analysis with *Haemophilus influenzae* and observed in the retrospective FP specimen.

Table 29. QIAstat-Dx BCID GN Plus AMR Panel archived clinical performance summary for AMRs

	PPA			NPA		
AMR	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
ampC (CMY/LAT/DHA/FOX)	0 / 0	N/A	N/A	88 / 89	98.9	93.9–99.8
CTX-M	1 / 1	100.0	20.7–100.0	87 / 87	100.0	95.8–100.0
IMP	0 / 0	N/A	N/A	74 / 74	100.0	95.1–100.0
KPC	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
NDM	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
OXA-23	1 / 1	100.0	20.7–100.0	88 / 88	100.0	95.8–100.0
OXA-48-like	0 / 0	N/A	N/A	81 / 81	100.0	95.5–100.0
OXA-24/40	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
OXA-58	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
SHV	1 / 1	100.0	20.7–100.0	88 / 88	100.0	95.8–100.0
TEM	8 / 8	100.0	67.6–100.0	129 / 129	100.0	97.1–100.0
VIM	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
PER	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
armA	1 / 1	100.0	20.7–100.0	88 / 88	100.0	95.8–100.0
aac(6')-Ib	2 / 2	100.0	34.2–100.0	87 / 87	100.0	95.8–100.0
VEB	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
GES	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
SPM	0 / 0	N/A	N/A	14 / 14	100.0	78.5–100.0

13.2.2.3. Validity of results

The proportion of failed runs in clinical specimens (prospective and retrospective samples) on initial attempt was 1.6% (13/808) and following repeats, it was reduced to 0.5% (4/808), resulting in an overall success rate of 98.4% (795/808) before retesting, and 99.5% (804/808) after retesting.

13.2.2.4. Testing of contrived specimens

Contrived specimen testing was required for targets on the panel as there were insufficient positive specimens obtained from both prospective and archived collection efforts. Contrived specimens were prepared by spiking different strains representative of the genetic diversity of each pathogen and AMRs. The results are summarized in Table 30 and Table 31 for pathogens and AMRs, respectively.

Pathogens

Table 30. Test results summary for contrived specimens

	PPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**
Enterobacter spp.*	10 / 10	100.0	72.2–100.0
*Escherichia coli**	60 / 60	100.0	94.0–100.0
Klebsiella spp.*	100 / 100	100.0	96.3–100.0
Salmonella spp.	50 / 50	100.0	92.9–100.0
Serratia spp.*	30 / 30	100.0	88.6–100.0
*Pseudomonas aeruginosa**	212 / 212	100.0	98.2–100.0
Neisseria meningitidis (encapsulated)	50 / 50	100.0	92.9–100.0
Haemophilus influenzae	50 / 50	100.0	92.9–100.0
Acinetobacter calcoaceticus-baumannii complex	150 / 150	100.0	97.5–100.0
Stenotrophomonas maltophilia	50 / 50	100.0	92.9–100.0
Pan *Enterobacterales**	260 / 260	100.0	98.5–100.0

* Targets co-detected with the target of interest but not intended to be contrived based on prevalence.

The proportion of positive results was ≥95% for all prepared contrived samples for pathogen in all tested analytes.

AMRs

Table 31. Test results summary for contrived specimens

	PPA		
AMR	**TP/(TP+FN)**	**%**	**95% CI (%)**
ampC (CMY/LAT/DHA/FOX)	50 / 50	100.0	92.9–100.0
CTX-M*	50 / 50	100.0	92.9–100.0
IMP	50 / 50	100.0	92.9–100.0
KPC	50 / 50	100.0	92.9–100.0
NDM	82 / 84	97.6	91.7–99.3
OXA-23	60 / 60	100.0	94.0–100.0
OXA-48-like	50 / 50	100.0	92.9–100.0
OXA-24/40	60 / 60	100.0	94.0–100.0
OXA-58	50 / 50	100.0	92.9–100.0
SHV*	110 / 110	100.0	96.6–100.0
TEM*	228 / 230	99.1	96.9–99.8
VIM	68 / 68	100.0	94.7–100.0
PER	48 / 50	96.0	86.5–98.9
armA	60 / 60	100.0	94.0–100.0
aac(6')-Ib	418 / 420	99.5	98.3–99.9
VEB	62 / 62	100.0	94.2–100.0
GES	50 / 50	100.0	92.9–100.0
SPM	76 / 80	95.0	87.8–98.0

* Targets co-detected with the target of interest but not intended to be contrived based on prevalence.

The proportion of positive results was ≥95% for all prepared contrived samples for AMRs in all tested analytes.

13.2.2.5. Expected values for all targets

The number and percentage of positive cases, as determined by the QIAstat-Dx BCID GN Plus AMR Panel, calculated by testing site and by age group are present in Table 32 respectively. Overall, 661 prospective specimens were included in the prevalence assessment and the QIAstat-Dx BCID GN Plus AMR Panel detected at least one organism in a total of 618 prospective specimens (93.5% positivity rate).

Table 32. Expected value (EV) (as determined by the QIAstat-Dx BCID GN Plus AMR Panel) summary overall for prospective samples and by age for all targets

Target	Overall (n = 661)	<1 year (n = 6)	1–17 years (n = 18)	18–44 years (n = 79)	45–64 years (n = 172)	65–89 years (n = 361)	90+ years (n = 25)
Enterobacter spp.	45(6.8%)	2 (33.3%)	1 (5.6%)	5 (6.3%)	14 (8.1%)	23 (6.4%)	0 (0.0%)
Escherichia coli	290 (43.9%)	2 (33.3%)	2 (11.1%)	34 (43.0%)	77 (44.8%)	162 (44.9%)	13 (52.0%)
Klebsiella spp.	145 (21.9%)	0 (0.0%)	1 (5.6%)	18 (22.8%)	43 (25.0%)	79 (21.9%)	4 (16.0%)
Proteus spp.	39 (5.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	10 (5.8%)	25 (6.9%)	3 (12.0%)
Salmonella spp.	12 (1.8%)	0 (0.0%)	6 (33.3%)	4 (5.1%)	2 (1.2%)	0 (0.0%)	0 (0.0%)
Serratia spp.	21 (3.2%)	0 (0.0%)	1 (5.6%)	2 (2.5%)	8 (4.7%)	9 (2.5%)	1 (4.0%)
Pseudomonas aeruginosa	39 (5.9%)	0 (0.0%)	3 (16.7%)	8 (10.1%)	8 (4.7%)	20 (5.5%)	0 (0.0%)
Neisseria meningitidis (encapsulated)	1 (0.2%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Haemophilus influenzae	3 (0.5%)	0 (0.0%)	1 (5.6%)	1 (1.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
Acinetobacter calcoaceticus-baumannii complex	5 (0.8%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.2%)	2 (0.6%)	0 (0.0%)
Bacteroides fragilis	12 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.2%)	8 (2.2%)	1 (4.0%)
Stenotrophomonas maltophilia	3 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.6%)	0 (0.0%)
Pan *Enterobacterales*	559 (84.6%)	4 (66.7%)	12 (66.7%)	63 (79.7%)	154 (89.5%)	303 (83.9%)	23 (92.0%)
ampC (CMY/LAT/DHA/FOX)	16 (2.4%)	0 (0.0%)	1 (5.6%)	1 (1.3%)	4 (2.3%)	10 (2.8%)	0 (0.0%)

Table 32. Expected value (EV) (as determined by the QIAstat-Dx BCID GN Plus AMR Panel) summary overall for prospective samples and by age for all targets (continued)

Target	Overall (n = 661)	<1 year (n = 6)	1–17 years (n = 18)	18–44 years (n = 79)	45–64 years (n = 172)	65–89 years (n = 361)	90+ years (n = 25)
CTX-M	77 (11.6%)	0 (0.0%)	1 (5.6%)	7 (8.9%)	21 (12.2%)	43 (11.9%)	5 (20.0%)
IMP	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
KPC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NDM	3 (0.5%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)
OXA-23	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
OXA-48-like	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
OXA-24/40	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OXA-58	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SHV	97 (14.7%)	0 (0.0%)	0 (0.0%)	12 (15.2%)	28 (16.3%)	54 (15.0%)	3 (12.0%)
TEM	150 (22.7%)	2 (33.3%)	1 (5.6%)	24 (30.4%)	40 (23.3%)	72 (19.9%)	11 (44.0%)
VIM	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
PER	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
armA	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
aac(6')-Ib	40 (6.1%)	0 (0.0%)	0 (0.0%)	3 (3.8%)	12 (7.0%)	22 (6.1%)	3 (12.0%)
VEB	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
GES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SPM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	**618 (93.5%)**	**4 (66.7%)**	**16 (88.9%)**	**74 (93.7%)**	**166 (96.5%)**	**334 (92.5%)**	**24 (96.0%)**

13.2.3. QIAstat-Dx BCID GN Plus AMR Panel, Pure Colony

The QIAstat-Dx BCID GN Plus AMR Panel prospective data for Positive Percent Agreement and Negative Percent Agreement against the comparator methods are presented by analyte in Table 33 and Table 34 for pathogens and AMRs, respectively in PC samples.

Pathogens

Table 33. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Enterobacter spp.*	Prospective Fresh	47 / 47	100.0	92.4–100.0	605 / 606	99.8	99.1–100.0
	Prospective Frozen	2 / 2	100.0	34.2–100.0	33 / 33	100.0	89.6–100.0
	Total	49 / 49	100.0	92.7–100.0	638 / 639	99.8	99.1–100.0
Escherichia coli†	Prospective Fresh	286 / 291	98.3	96.0–99.3	360 / 362	99.4	98.0–99.8
	Prospective Frozen	17 / 18	94.4	74.2–99.0	16 / 17	94.1	73.0–99.0
	Total	303 / 309	98.1	95.8–99.1	376 / 379	99.2	97.7–99.7
Klebsiella spp.‡	Prospective Fresh	135 / 136	99.3	96.0–99.9	512 / 517	99.0	97.8–99.6
	Prospective Frozen	9 / 9	100.0	70.1–100.0	26 / 26	100.0	87.1–100.0
	Total	144 / 145	99.3	96.2–99.9	538 / 543	99.1	97.9–99.6

Table 33. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Proteus spp.[§]	Prospective Fresh	32 / 32	100.0	89.3–100.0	615 / 621	99.0	97.9–99.6
	Prospective Frozen	1 / 1	100.0	20.7–100.0	34 / 34	100.0	89.8–100.0
	Total	33 / 33	100.0	89.6–100.0	649 / 655	99.1	98.0–99.6
Salmonella spp.	Prospective Fresh	11 / 11	100.0	74.1–100.0	642 / 642	100.0	99.4–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	34 / 34	100.0	89.8–100.0
	Total	12 / 12	100.0	75.8–100.0	676 / 676	100.0	99.4–100.0
Serratia spp.	Prospective Fresh	20 / 20	100.0	83.9–100.0	633 / 633	100.0	99.4–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	34 / 34	100.0	89.8–100.0
	Total	21 / 21	100.0	84.5–100.0	667 / 667	100.0	99.4–100.0
Pseudomonas aeruginosa	Prospective Fresh	39 / 39	100.0	91.0–100.0	614 / 614	100.0	99.4–100.0
	Prospective Frozen	2 / 2	100.0	34.2–100.0	33 / 33	100.0	89.6–100.0
	Total	41 / 41	100.0	91.4–100.0	647 / 647	100.0	99.4–100.0

Table 33. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Neisseria meningitidis (encapsulated)	Prospective Fresh	1 / 1	100.0	20.7–100.0	652 / 652	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	35 / 35	100.0	90.1–100.0
	Total	1 / 1	100.0	20.7–100.0	687 / 687	100.0	99.4–100.0
Haemophilus influenzae	Prospective Fresh	2 / 2	100.0	34.2–100.0	651 / 651	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	35 / 35	100.0	90.1–100.0
	Total	2 / 2	100.0	34.2–100.0	686 / 686	100.0	99.4–100.0
Acinetobacter calcoaceticus-baumannii complex	Prospective Fresh	5 / 5	100.0	56.6–100.0	648 / 648	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	35 / 35	100.0	90.1–100.0
	Total	5 / 5	100.0	56.6–100.0	683 / 683	100.0	99.4–100.0
Bacteroides fragilis	Prospective Fresh	9 / 11	81.8	52.3–94.9	642 / 642	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	35 / 35	100.0	90.1–100.0
	Total	9 / 11	81.8	52.3–94.9	677 / 677	100.0	99.4–100.0

Table 33. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Stenotrophomonas maltophilia	Prospective Fresh	3 / 3	100.0	43.9–100.0	650 / 650	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	35 / 35	100.0	90.1–100.0
	Total	3 / 3	100.0	43.9–100.0	685 / 685	100.0	99.4–100.0
Pan Enterobacterales¶	Prospective Fresh	554 / 555	99.8	99.0–100.0	92 / 98	93.9	87.3–97.2
	Prospective Frozen	31 / 31	100.0	89.0–100.0	3 / 4	75.0	30.1–95.4

Table 33. QIAstat -Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
	Total	585 / 586	99.8	99.0–100.0	95 / 102	93.1	86.5–96.6

* For the *Enterobacter* spp. FP specimen, cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel target was identified with *Leclercia adecarboxylata*.

† Of the 3 FP *Escherichia coli* prospective specimens, *Escherichia coli* was detected in one FP specimen using an additional molecular method, additional testing was not performed for the remaining 2 FP specimens. Of the 6 FN *Escherichia coli* prospective samples, *Escherichia coli* was detected in 5 specimens using an additional molecular method, no additional testing result was performed for the remaining one FN specimen.

‡ *Klebsiella* spp. was not detected in the 5 FP *Klebsiella* spp. prospective specimens using an additional molecular method. Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for *Klebsiella* spp. and *Proteus* spp. was observed with 4 *Enterobacter* spp, specimens. Additional speciation was completed by 23S sequencing and/or MALDI-TOF and all 4 specimens were identified as *E. ludwigii*. In addition, in silico cross-reactivity was predicted between the QIAstat-Dx BCID GN Plus AMR Panel *Klebsiella* spp. and *Enterobacter* species. For the one FN *Klebsiella* spp. prospective specimens, *Klebsiella* spp. was detected using an additional molecular method.

§ Of the 6 FP *Proteus* spp. prospective specimens, *Proteus* spp. was detected in one FP specimen and not detected in 4 FP specimens using an additional molecular method. No additional testing was performed for the remaining one FP sample. Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR for *Klebsiella* spp. and *Proteus* spp. was observed with 4 *Enterobacter* spp. specimens. Additional speciation was completed by 23S sequencing and MALDI-TOF and all 4 specimens were identified as *E. ludwigii*.

¶ Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel Pan *Enterobacterales* was predicted based on in silico analysis with *Pantoea septica* and observed in 2 prospective specimens and with *Pasteurella multocida* in one prospective specimen. *Pantoea septica* is an *Enterobacterales* species. No additional testing was performed for the FP and FN specimens.

AMR

Table 34. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
ampC (CMY/LAT/DHA/FOX)	Prospective Fresh	13 / 20	65.00	43.3–81.9	542 / 542	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	13 / 20	65.00	43.3–81.9	575 / 575	100.00	99.3–100.0
CTX-M	Prospective Fresh	69 / 74	93.20	85.1–97.1	485 / 488	99.40	98.2–99.8
	Prospective Frozen	3 / 3	100.00	43.9–100.0	30 / 30	100.00	88.6–100.0
	Total	72 / 77	93.50	85.7–97.2	515 / 518	99.40	98.3–99.8
IMP	Prospective Fresh	0 / 0	N/A	N/A	534 / 534	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	30 / 30	100.00	88.6–100.0
	Total	0 / 0	N/A	N/A	564 / 564	100.00	99.3–100.0
KPC	Prospective Fresh	0 / 0	N/A	N/A	563 / 563	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.00	99.4–100.0
NDM	Prospective Fresh	3 / 3	100.00	43.9–100.0	560 / 560	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	3 / 3	100.00	43.9–100.0	593 / 593	100.00	99.4–100.0

Table 34. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
OXA-23	Prospective Fresh	1 / 1	100.00	20.7–100.0	562 / 562	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	1 / 1	100.00	20.7–100.0	595 / 595	100.00	99.4–100.0
OXA-48-like	Prospective Fresh	1 / 1	100.00	20.7–100.0	558 / 558	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	1 / 1	100.00	20.7–100.0	591 / 591	100.00	99.4–100.0
OXA-24/40	Prospective Fresh	0 / 0	N/A	N/A	563 / 563	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.00	99.4–100.0
OXA-58	Prospective Fresh	0 / 0	N/A	N/A	563 / 563	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.00	99.4–100.0
SHV	Prospective Fresh	87 / 89	97.80	92.2–99.4	470 / 474	99.20	97.9–99.7
	Prospective Frozen	5 / 5	100.00	56.6–100.0	28 / 28	100.00	87.9–100.0
	Total	92 / 94	97.90	92.6–99.4	498 / 502	99.20	98.0–99.7

Table 34. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
TEM	Prospective Fresh	132 / 141	93.60	88.3–96.6	429 / 432	99.30	98.0–99.8
	Prospective Frozen	8 / 9	88.90	56.5–98.0	23 / 24	95.80	79.8–99.3
	Total	140 / 150	93.30	88.2–96.3	452 / 456	99.10	97.8–99.7
VIM	Prospective Fresh	1 / 2	50.00	9.5–90.5	561 / 561	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	1 / 2	50.00	9.5–90.5	594 / 594	100.00	99.4–100.0
PER	Prospective Fresh	1 / 1	100.00	20.7–100.0	562 / 562	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	1 / 1	100.00	20.7–100.0	595 / 595	100.00	99.4–100.0
armA	Prospective Fresh	1 / 1	100.00	20.7–100.0	562 / 562	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	1 / 1	100.00	20.7–100.0	595 / 595	100.00	99.4–100.0
aac(6')-Ib	Prospective Fresh	37 / 40	92.50	80.1–97.4	521 / 523	99.60	98.6–99.9
	Prospective Frozen	1 / 1	100.00	20.7–100.0	32 / 32	100.00	89.3–100.0
	Total	38 / 41	92.70	80.6–97.5	553 / 555	99.60	98.7–99.9

Table 34. QIAstat-Dx BCID GN Plus AMR Panel prospective clinical performance summary for PC samples (continued)

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
VEB	Prospective Fresh	0 / 0	N/A	N/A	563 / 563	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.00	99.4–100.0
GES	Prospective Fresh	0 / 0	N/A	N/A	563 / 563	100.00	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	33 / 33	100.00	89.6–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.00	99.4–100.0
SPM	Prospective Fresh	0 / 0	N/A	N/A	42 / 42	100.00	91.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	2 / 2	100.00	34.2–100.0
	Total	0 / 0	N/A	N/A	44 / 44	100.00	92.0–100.0

13.2.3.1. Co-infections

The QIAstat-Dx BCID GN Plus AMR Panel reported multiple organism detections (i.e., co-infections) for a total of 15/688 (2.18%) prospective PC specimens. Most multiple detections in prospective specimens (10/15; 66.7%) contained 2 organisms, while (5/15; 33.3%) contained 3 organisms.

Table 35. Detection summary combinations determined by the QIAstat-Dx BCID GN Plus AMR Panel in the prospective clinical study

Detection summary	
Detected pathogens on QIAstat-Dx BCID GN Plus AMR Panel	**No. of specimens with multi-detections**
Total co-infection detections	15
Double detections	10
Triple detections	5

The most common multiple infections (>3 instances) are shown in Table 36.

Table 36. Most prevalent multiple detection combinations (>3 instances) as determined by the QIAstat-Dx BCID GN Plus AMR Panel in the prospective clinical study

Detected pathogens on QIAstat-Dx	**No. of specimens with multi-detections**
Detection summary	
Escherichia coli + *Klebsiella* spp.	4
Enterobacter spp. + *Klebsiella* spp. + *Proteus* spp.	4

13.2.3.2. Testing of preselected archived (Retrospective) specimens

Several analytes in the QIAstat-Dx BCID GN Plus AMR Panel were of low prevalence and were not encountered in sufficiently large numbers during the prospective study to adequately demonstrate clinical performance. To supplement the results of the prospective clinical study, an evaluation of frozen archived positive retrospective specimens was performed. The specimens selected for testing had previously tested positive for at least 1 of the QIAstat-Dx BCID GN Plus AMR Panel targets using the clinical laboratory standard of care method. A total of 145 evaluable archived specimen were collected and 145 were used in the analysis

to support the QIAstat-Dx BCID GN Plus AMR Panel performance evaluation. Table 37 provides a summary of demographic information for the archived specimens.

Table 37. Demographic summary of evaluable archived specimens for QIAstat-Dx BCID GN Plus AMR Panel clinical evaluation

Sample Type	Variable	Subgroup	N	%
Retrospective Archived	Age group	<1 year	5	3.4
		1–17 years	8	5.5
		18–44 years	29	20.0
		45–64 years	28	19.3
		65–89 years	71	49.0
		90+ years	4	2.8
	Sex	Female	61	42.1
		Male	83	57.2
		Not reported	1	0.7

The QIAstat-Dx BCID GN Plus AMR Panel retrospective archived specimen data in positive percent agreement and negative percent agreement against the comparator methods are presented by analyte in Table 38 and Table 39 for pathogens and AMRs respectively.

Table 38. QIAstat-Dx BCID GN Plus AMR Panel archived clinical performance summary for pathogens

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Enterobacter spp.	0 / 0	N/A	N/A	145 / 145	100.0	97.4–100.0
Escherichia coli	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
Klebsiella spp.	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
Proteus spp.	29 / 29	100.0	88.3–100.0	116 / 116	100.0	96.8–100.0
Salmonella spp.	22 / 22	100.0	85.1–100.0	123 / 123	100.0	97.0–100.0
Serratia spp.	24 / 24	100.0	86.2–100.0	121 / 121	100.0	96.9–100.0
Pseudomonas aeruginosa	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
Neisseria meningitidis (encapsulated)*	6 / 7	85.7	48.7–97.4	138 / 138	100.0	97.3–100.0
Haemophilus influenzae	20 / 20	100.0	83.9–100.0	125 / 125	100.0	97.0–100.0
Acinetobacter calcoaceticus-baumannii complex	8 / 8	100.0	67.6–100.0	137 / 137	100.0	97.3–100.0
Bacteroides fragilis	28 / 28	100.0	87.9–100.0	117 / 117	100.0	96.8–100.0
Stenotrophomonas maltophilia	6 / 6	100.0	61.0–100.0	139 / 139	100.0	97.3–100.0

Table 38. QIAstat-Dx BCID GN Plus AMR Panel archived clinical performance summary for pathogens (continued)

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Pan *Enterobacterales*†	76 / 76	100.0	95.2–100.0	60 / 69	87.0	77.0–93.0

* The single *Neisseria meningitidis* FN retrospective specimen was further investigated by an additional test specific to encapsulated *Neisseria meningitidis* and not detected. Note that the QIAstat-Dx BCID GN Plus AMR Panel only detects encapsulated *Neisseria meningitidis*.

† Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for Pan *Enterobacterales* was predicted based on in silico analysis with *Haemophilus influenzae* in 9 retrospective specimens. No additional testing was performed for the FP specimens.

Table 39. QIAstat-Dx BCID GN Plus AMR Panel archived clinical performance summary for AMRs

	PPA			NPA		
AMR	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
ampC (CMY/LAT/DHA/FOX)	0 / 0	N/A	N/A	83 / 84	98.8	93.6–99.8
CTX-M	1 / 1	100.0	20.7–100.0	82 / 82	100.0	95.5–100.0
IMP	0 / 0	N/A	N/A	71 / 71	100.0	94.9–100.0
KPC	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
NDM	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
OXA-23	1 / 1	100.0	20.7–100.0	83 / 83	100.0	95.6–100.0
OXA-48-like	0 / 0	N/A	N/A	76 / 76	100.0	95.2–100.0
OXA-24/40	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
OXA-58	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
SHV	1 / 1	100.0	20.7–100.0	83 / 83	100.0	95.6–100.0
TEM	8 / 8	100.0	67.6–100.0	129 / 129	100.0	97.1–100.0
VIM	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
PER	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
armA	1 / 1	100.0	20.7–100.0	83 / 83	100.0	95.6–100.0
aac(6')-Ib	1 / 2	50.0	9.5–90.5	82 / 82	100.0	95.5–100.0
VEB	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
GES	0 / 0	N/A	N/A	84 / 84	100.0	95.6–100.0
SPM	0 / 0	N/A	N/A	9 / 9	100.0	70.1–100.0

13.2.3.3. Validity of results

The proportion of failed runs in clinical specimens (prospective and retrospective samples) on initial attempt was 0.8% (7/868) and following repeats was 0.1% (1/868), yielding an overall success rate of 99.1% (861/868) before retesting, and 99.9% (867/868) after retesting.

13.2.3.4. Testing of contrived specimens

Contrived specimen testing was required for targets on the panel where insufficient positive specimens were obtained from both prospective and archived collection efforts. Contrived specimens were prepared by spiking different strains representative of the genetic diversity of each pathogen and AMRs. The results are summarized in Table 40 and Table 41 for pathogens and AMRs, respectively.

Pathogens

Table 40. Test results summary for pathogens contrived PC specimens

Target	TP/(TP+FN)	%	95% CI (%)
Enterobacter spp.*	10 / 10	100.0	72.2–100.0
Escherichia coli*	60 / 60	100.0	94.0–100.0
Klebsiella spp.*	100 / 100	100.0	96.3–100.0
Salmonella spp.	50 / 50	100.0	92.9–100.0
Serratia spp.*	30 / 30	100.0	88.6–100.0
*Pseudomonas aeruginosa**	212 / 212	100.0	98.2–100.0
Neisseria meningitidis (encapsulated)	50 / 50	100.0	92.9–100.0
Haemophilus influenzae	50 / 50	100.0	92.9–100.0
Acinetobacter calcoaceticus-baumannii complex	150 / 150	100.0	97.5–100.0
Stenotrophomonas maltophilia	50 / 50	100.0	92.9–100.0
Pan *Enterobacterales**	260 / 260	100.0	98.5–100.0

* Targets co-detected with the target of interest but not intended to be contrived based on prevalence.

The proportion of positive results was ≥95% for all prepared contrived samples for pathogen in all tested analytes.

AMRs

Table 41. Test results summary for AMR contrived PC specimens

	PPA		
AMR	**TP/(TP+FN)**	**%**	**95% CI (%)**
ampC (CMY/LAT/DHA/FOX)	50 / 50	100.0	92.9–100.0
CTX-M*	50 / 50	100.0	92.9–100.0
IMP	50 / 50	100.0	92.9–100.0
KPC	50 / 50	100.0	92.9–100.0
NDM	82 / 84	97.6	91.7–99.3
OXA-23	60 / 60	100.0	94.0–100.0
OXA-48-like	50 / 50	100.0	92.9–100.0
OXA-24/40	60 / 60	100.0	94.0–100.0
OXA-58	50 / 50	100.0	92.9–100.0
SHV*	110 / 110	100.0	96.6–100.0
TEM*	228 / 230	99.1	96.9–99.8
VIM	68 / 68	100.0	94.7–100.0
PER	48 / 50	96.0	86.5–98.9
armA	60 / 60	100.0	94.0–100.0
aac(6')-Ib	418 / 420	99.5	98.3–99.9
VEB	62 / 62	100.0	94.2–100.0
GES	50 / 50	100.0	92.9–100.0
SPM	76 / 80	95.0	87.8–98.0

* Targets co-detected with the target of interest but not intended to be contrived based on prevalence.

The proportion of positive results was ≥95% for all prepared contrived samples for AMR in all tested analytes.

13.2.3.5. Expected values for all targets

The number and percentage of positive cases, as determined by the QIAstat-Dx BCID GN Plus AMR Panel, calculated by testing site and by age group are present in Table 42 respectively. Overall, 688 prospective specimens were included in the prevalence assessment and the QIAstat-Dx BCID GN Plus AMR Panel detected at least one organism in a total of 651 prospective specimens (94.6% positivity rate).

Table 42. Expected value (EV) (as determined by the QIAstat-Dx BCID GN Plus AMR Panel) summary overall for prospective samples and by age for all targets

Target	Overall (n = 688)	<1 year (n = 6)	1–17 years (n = 18)	18–44 years (n = 80)	45–64 years (n = 181)	65–89 years (n = 376)	90+ years (n = 27)
Enterobacter spp.	50 (7.3%)	2 (33.3%)	1 (5.6%)	7 (8.8%)	16 (8.8%)	24 (6.4%)	0 (0.0%)
Escherichia coli	306 (44.5%)	2 (33.3%)	2 (11.1%)	34 (42.5%)	84 (46.4%)	170 (45.2%)	14 (51.9%)
Klebsiella spp.	149 (21.7%)	0 (0.0%)	2 (11.1%)	19 (23.8%)	42 (23.2%)	82 (21.8%)	4 (14.8%)
Proteus spp.	39 (5.7%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	9 (5.0%)	25 (6.6%)	4 (14.8%)
Salmonella spp.	12 (1.7%)	0 (0.0%)	6 (33.3%)	4 (5.0%)	2 (1.1%)	0 (0.0%)	0 (0.0%)
Serratia spp.	21 (3.1%)	0 (0.0%)	1 (5.6%)	2 (2.5%)	8 (4.4%)	9 (2.4%)	1 (3.7%)
Pseudomonas aeruginosa	41 (6.0%)	0 (0.0%)	3 (16.7%)	7 (8.8%)	8 (4.4%)	23 (6.1%)	0 (0.0%)
Neisseria meningitidis (encapsulated)	1 (0.1%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Haemophilus influenzae	2 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)
Acinetobacter calcoaceticus-baumannii complex	5 (0.7%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.1%)	2 (0.5%)	0 (0.0%)
Bacteroides fragilis	9 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	6 (1.6%)	1 (3.7%)
Stenotrophomonas maltophilia	3 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.5%)	0 (0.0%)
Pan *Enterobacterales*	592 (86.0%)	4 (66.7%)	13 (72.2%)	66 (82.5%)	164 (90.6%)	320 (85.1%)	25 (92.6%)
ampC (CMY/LAT/DHA/FOX)	15 (2.2%)	0 (0.0%)	1 (5.6%)	1 (1.3%)	6 (3.3%)	7 (1.9%)	0 (0.0%)

Table 42. Expected value (EV) (as determined by the QIAstat-Dx BCID GN Plus AMR Panel) summary overall for prospective samples and by age for all targets (continued)

Target	Overall (n = 688)	<1 year (n = 6)	1–17 years (n = 18)	18–44 years (n = 80)	45–64 years (n = 181)	65–89 years (n = 376)	90+ years (n = 27)
CTX-M	79 (11.5%)	0 (0.0%)	1 (5.6%)	6 (7.5%)	24 (13.3%)	44 (11.7%)	4 (14.8%)
IMP	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
KPC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NDM	3 (0.4%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	2 (0.5%)	0 (0.0%)
OXA-23	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
OXA-48-like	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
OXA-24/40	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OXA-58	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SHV	99 (14.4%)	0 (0.0%)	0 (0.0%)	12 (15.0%)	28 (15.5%)	56 (14.9%)	3 (11.1%)
TEM	154 (22.4%)	2 (33.3%)	1 (5.6%)	24 (30.0%)	41 (22.7%)	75 (19.9%)	11 (40.7%)
VIM	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
PER	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
armA	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
aac(6')-Ib	41 (6.0%)	0 (0.0%)	0 (0.0%)	3 (3.8%)	12 (6.6%)	23 (6.1%)	3 (11.1%)
VEB	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
GES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SPM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	**651 (94.6%)**	**4 (66.7%)**	**16 (88.9%)**	**75 (93.8%)**	**176 (97.2%)**	**354 (94.1%)**	**26 (96.3%)**

13.2.4. Conclusion

The QIAstat-Dx BCID GN Plus AMR Panel demonstrated robust clinical performance characteristics to aid in the diagnosis of specific agents of Blood Stream Infection but also to

identify probable resistance mechanism to antibiotics. Results must be used in conjunction with other clinical, epidemiological, and laboratory data.

13.2.5. Summary of safety and performance

The summary of safety and performance information can be downloaded from the EUDAMED website.

14. References

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Lelliottia nimipressuralis comb. nov. and Lelliottia amnigena comb. nov., respectively, E. gergoviae and E. pyrinus into Pluralibacter gen. nov. as Pluralibacter gergoviae comb. nov. and Pluralibacter pyrinus comb. nov., respectively, E. cowanii, E. radicincitans, E. oryzae and E. arachidis into Kosakonia gen. nov. as .... *Systematic and applied microbiology*, 36(5), 309-319.

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15. Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: **www.qiagen.com/FAQ/FAQList.aspx** (for contact information, visit **www.qiagen.com**).

16. Symbols

The following symbols appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol definition
	Contains reagents sufficient for <N> reactions
	Use by
	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Global Trade Item Number
	Unique Device Identifier
	Contains
	Component
	Number

Symbol	Symbol definition
Rn	R is for revision of the Instructions for Use and n is the revision number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Protect from light
	Do not reuse
	Caution, consult accompanying documents
SN	Serial number
	Do not use if package is damaged
	Flammable, risk of fire
	Corrosive, risk of chemical burn

Symbol	Symbol definition
	Health Hazard, risk of sensitization, carcinogenicity
	Risk of harm
	BCID application

17. Contact Information

For technical assistance and more information, please see our Technical Support Center at **support.qiagen.com**.

18. Appendices

18.1. Appendix A: Installing the Assay Definition File

The Assay Definition File of the QIAstat-Dx BCID GN Plus AMR Panel must be installed on the or QIAstat-Dx Analyzer 2.0 prior to testing with QIAstat-Dx BCID GN Plus AMR Panel Cartridges.

Note: Whenever a new version of the QIAstat-Dx BCID GN Plus AMR Panel assay is released, the new QIAstat-Dx BCID GN Plus AMR Panel Assay Definition File must be installed prior to testing.

Note: Assay Definition Files are available at **www.qiagen.com**. The Assay Definition File (.asy file type) must be saved onto a USB drive prior to installation on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0. This USB drive must be formatted with a FAT32 file system.

To import assays into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, proceed with the following steps:

1. Insert the USB storage device containing the Assay Definition File into one of the USB ports on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.
2. Press **Options** > **Assay Management**.

   The Assay Management screen appears in the Content area of the display (Figure 24).

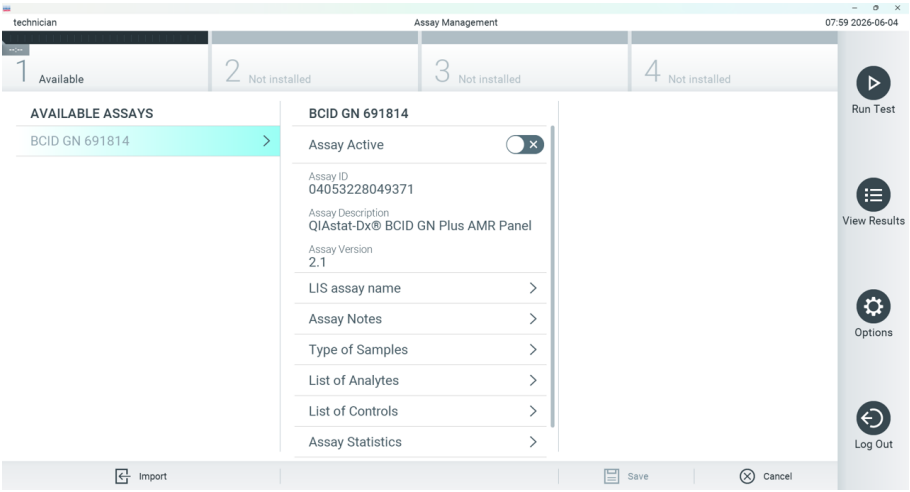

Figure 24. Assay Management screen.

3. Press **Import** located in the bottom left of the screen.
4. Select the applicable assay file to be imported.
   A dialog box will appear to confirm the upload of the file.
5. If a previous version of the QIAstat-Dx BCID GN Plus AMR Panel is installed, a dialog box will appear to override the current version with the new one. Press **Yes** to override.
6. Enable **Assay Active** to activate the assay (Figure 25).

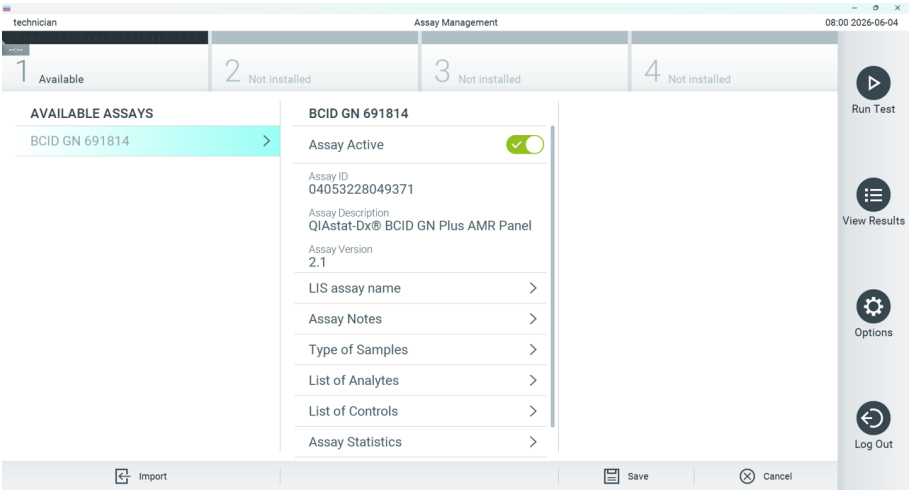

Figure 25. Activating the assay.

7. To assign the active assay to a user, perform the following steps:
   a. Press **Options** > **User Management**.
   b. Select the user who should be allowed to run the assay.
   c. From the **User Options** list, select **Assign Assays** (Figure 26).
   d. Enable the assay and press **Save**.

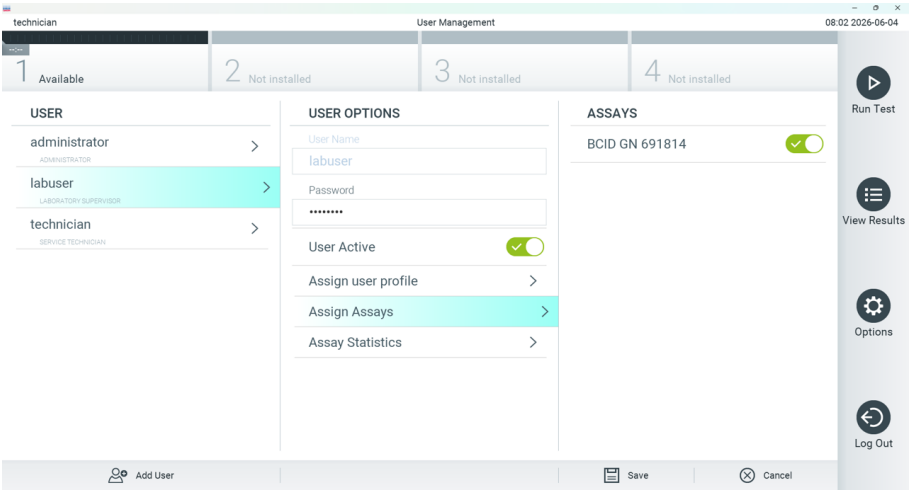

Figure 26. Assigning the active assay.

18.2. Appendix B: Glossary

Amplification curve: Graphical representation of the multiplex real-time RT-PCR amplification data.

Analytical Module (AM): The main QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 hardware module, in charge of executing tests on QIAstat-Dx BCID GN Plus AMR Panel Cartridges. It is controlled by the Operational Module. Several Analytical Modules can be connected to one Operational Module.

QIAstat-Dx Analyzer 1.0: QIAstat-Dx Analyzer 1.0 consists of an Operational Module and an Analytical Module. The Operational Module includes elements that provide connectivity to the Analytical Module and enables user interaction with QIAstat-Dx Analyzer 1.0. The Analytical Module contains the hardware and software for sample testing and analysis.

QIAstat-Dx Analyzer 2.0: The QIAstat-Dx Analyzer 2.0 consists of an Operational Module PRO and an Analytical Module. The Operational Module PRO includes elements that provide connectivity to the Analytical Module and enables user interaction with the QIAstat-Dx Analyzer 2.0. The Analytical Module contains the hardware and software for sample testing and analysis.

QIAstat-Dx BCID GN Plus AMR Panel Cartridge: A self-contained disposable plastic device with all pre-loaded reagents required for the complete execution of fully automated molecular assays for the detection of multiple bacterial pathogens and selected genetic determinants associated with antimicrobial resistance.

IFU: Instructions For Use.

Main port: In the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, inlet for transport medium liquid samples.

Nucleic acids: Biopolymers, or small biomolecules composed of nucleotides, which are monomers made of 3 components: a 5-carbon sugar, a phosphate group, and a nitrogenous base.

Operational Module (OM): The dedicated QIAstat-Dx Analyzer 1.0 hardware that provides the user interface for 1–4 Analytical Modules (AM).

Operational Module PRO (OM PRO): The dedicated QIAstat-Dx Analyzer 2.0 hardware that provides the user interface for 1–4 Analytical Modules (AM).

PCR: Polymerase Chain Reaction.

Swab port: In the QIAstat-Dx BCID GN Plus AMR Panel Cartridge, inlet for dry swabs. The swab port is not used for the QIAstat-Dx BCID GN Plus AMR Panel assay.

User: A person who operates the QIAstat-Dx Analyzer 1.0 / QIAstat-Dx Analyzer 2.0 / QIAstat-Dx BCID GN Plus AMR Panel Cartridge in the intended way.

19. Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx BCID GN Plus AMR Panel	For 6 tests: 6 individually packaged QIAstat-Dx BCID GN Plus AMR Panel Cartridges and 6 individually packaged transfer pipettes	691814
Related Products		
QIAstat-Dx Analyzer 2.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module PRO, and related hardware and software to run molecular diagnostic QIAstat-Dx assay cartridges	9002828

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit Instructions for Use. QIAGEN kit Instructions for Use are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

20. Document Revision History

Revision	Description
Rev. 01, August 2026	Initial release

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