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QIAstat-Dx® BCID GPF 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	691812	Version 1

CE 0197

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Sample to Insight

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1. Intended Use

The QIAstat-Dx® BCID GPF Plus AMR Panel is a qualitative multiplexed nucleic acid real-time PCR-based in vitro diagnostic test intended for use with QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GPF Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-positive bacterial and fungal pathogens and selected genetic determinants associated with antimicrobial resistance.

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

- *Bacillus cereus* group
- *Corynebacterium*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Listeria monocytogenes*
- *Micrococcus* spp.
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus lugdunensis*
- *S. capitis / S. hominis*
- *Streptococcus agalactiae*
- *Streptococcus anginosus* group
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

The following fungi are identified and differentiated using the QIAstat-Dx BCID GPF Plus AMR Panel:

- *Cryptococcus neoformans/gattii*
- *Fusarium*
- *Candida auris*

The QIAstat-Dx BCID GPF Plus AMR Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections.

These include a broad Pan Gram-Negative assay, as well as two Pan *Candida* assays (Group 1 and Group 2) comprising:

***Candida* Group 1**:

- *Candida albicans*
- *Candida tropicalis*
- *Candida dubliniensis*
- *Candida famata*
- *Candida guilliermondii*
- *Candida kefyr*

and ***Candida* Group 2**:

- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida lusitaniae*

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

- *aac(6') aph(2'')*
- *cfr*
- *ermA*
- *ermC*
- *mecA*
- *mecC*
- *tetK*
- *tetM*
- *vanA*
- *vanB*

The QIAstat-Dx BCID GPF Plus AMR Panel is intended for use in patients with gram-positive bacterial or fungal 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- positive bacteria/fungi as determined by Gram stain.

The QIAstat-Dx BCID GPF Plus AMR Panel is intended as an aid in diagnosis of specific pathogens and the antimicrobial-resistant profile of bloodstream infection. 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 GPF 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 GPF Plus AMR Panel results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GPF Plus AMR Panel.

Pure colonies

The test is performed on pure colonies of *Bacilli, Actinobacteria,* or fungi (except *Fusarium).* The QIAstat-Dx BCID GPF Plus AMR Panel is intended as an aid to diagnosis of specific pathogens isolated in culture plates and as an aid to 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 GPF 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 GPF 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 GPF Plus AMR Panel offers rapid multiplex detection of Gram-positive bacteria, fungal pathogens, and key AMR genetic markers associated with Gram-positive 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 lower healthcare costs for patients with BSIs and sepsis.

3.2. Pathogen information

Bacillus cereus* group *(B. cereus, B. thuringiensis)

Members of the *B. cereus* group are catalase-positive, aerobic or facultatively anaerobic, spore-forming Gram-positive environmental bacilli (4). Most human *Bacillus cereus* group infections are caused by *B. cereus*, although infections with other species within the *B. cereus* group such as *Bacillus thuringiensis* have also been described (5). While it was once regarded simply as a contaminant when isolated in a clinical specimen, *B. cereus* has been implicated in a multitude of clinical conditions such as food poisoning, eye infections, sepsis, and central nervous system infections affecting primarily immunosuppressed individuals, intravenous drug abusers, and neonates (6). Given its presence in the environment and its ability to form spores and biofilms, *B. cereus* plays a relevant role in nosocomial infections, particularly associated with intravascular devices such as catheters. *B. cereus* and *B.*

thuringiensis produce a potent β-lactamase conferring marked resistance to β-lactam antibiotics (6).

Corynebacterium (C. jeikeium, C. diptheriae, C. pseudotuberculosis, C. striatum, C. urealyticum, C. afermentans, C. amycolatum, C. coylea, C. imitans, C. ulcerans)

Corynebacterium spp. are Gram-positive rods with a characteristic club-shape that are commonly found in the environment as well as colonizing skin and mucous membranes in humans. Because of this, *Corynebacterium* is typically considered a clinically nonsignificant contaminant in cultures (7,8). However, reports have shown that *Corynebacterium* can also be associated with cases of true bacteremia, particularly in patients with solid tumors and hematological disorders, and many times catheter-related infections. *C. striatum* and *C. jeikeium* seem to be associated with higher rates of bacteremia, higher mortality rates (23-34%), and higher rates of antimicrobial resistance (7,8).

Enterococcus faecalis* and *Enterococcus faecium

Enterococci are Gram-positive facultative anaerobic cocci that typically occur in short and medium chains and are commonly found in environmental sources as well as part of the human microbiota (9). Clinically, *enterococci* pose a significant healthcare burden and, in some regions, represent the second most common organisms in hospital-acquired bloodstream infections (HA-BSI), in addition to causing urinary tract infections and skin and soft tissue infections (10). While there are dozens of species of *Enterococcus, E. faecalis* and *E. faecium* are the most clinically relevant, with both intrinsic and acquired resistance mechanisms contributing to their difficulty in treatment (11). Mortality rates associated with HA-BSI caused by *enterococci* reportedly range between 14.3% and 32.3%, with vancomycin-resistant enterococci (VRE) linked to even higher mortality rates (10).

Listeria monocytogenes

L. monocytogenes is a facultatively anaerobic, rod-shaped, Gram-positive bacterium, ubiquitously in the environment. *L. monocytogenes* is typically a foodborne infection, with a clinical presentation that can range from subclinical to severe invasive disease, also called listeriosis. Listeriosis is an important pregnancy-related infection that can manifest as miscarriage or neonatal sepsis, accounting for 14% of all invasive listeriosis forms. The most common invasive presentation is bacteremia, accounting for more than half of all cases (12). Although the number of infections per year is moderately low, approximately 23,150 cases were estimated globally in 2010. The mortality among infected individuals is high, with 5463 deaths estimated globally in 2010, representing 26.6% of all cases (13).

Micrococcus* spp. *(Micrococcus luteus)

Micrococcus is a genus of Gram-positive non-spore forming cocci, commonly found in environmental sources, as well as in human skin microbiota, and in the microbiome of dairy products (14). While *Micrococcus* is generally considered a contaminant in blood cultures (15), *M. luteus* has been proven to cause infections as an opportunistic pathogen, often related with immunosuppression, invasive surgeries, and the use of indwelling devices (16).

Staphylococcus aureus

Staphylococcus aureus is a cocci-shaped Gram-positive bacteria that tends to arrange in clusters, characteristically described as "grape-like". This bacterium is commonly found in the environment as well as in skin and mucous membranes of about 50% of healthy individuals as part of their normal flora. *S. aureus* can also cause an array of infections in different sites, including bacteremia, infective endocarditis, skin and soft tissue infections, osteomyelitis, prosthetic device infections, meningitis, and toxic shock syndrome (17). Methicillin-resistant *S. aureus* (MRSA) strains possess a mobile genetic element that encodes the genes *mecA* or *mecC*, responsible for its resistance to most β-lactam antibiotics. Prevalence of MRSA strains is widely variable around the world, with around 50% of *S. aureus* isolates in the United States resistant to methicillin, and variable rates between >5% and 50% in European countries (18).

Staphylococcus epidermidis

Staphylococcus epidermidis is a coagulase-negative, Gram-positive cocci that is part of the normal human skin and mucosal flora (19). Although typically non-pathogenic, it has emerged as a significant opportunistic pathogen, particularly in healthcare settings. *S. epidermidis* is a leading cause of bloodstream infections (BSIs), especially in patients with indwelling medical devices such as catheters and prosthetic implants (20). Its ability to form biofilms on synthetic surfaces contributes to its persistence and resistance to antimicrobial treatments, making infections difficult to eradicate. Moreover, *S. epidermidis* is known for its resistance to multiple antibiotics, including methicillin, which further complicates clinical management (21). Due to its prevalence in nosocomial infections and its adaptive resistance mechanisms, *S. epidermidis* represents a major challenge in infection control and treatment in hospitalized patients.

Staphylococcus lugdunensis

Staphylococcus lugdunensis is a Gram-positive coagulase-negative *staphylococcus* (CoNS) that exhibits pathogenicity more akin to *Staphylococcus aureus* than to other CoNS. While it is

part of the normal human skin microbiota, especially in the inguinal and perineal regions, it can also cause severe invasive disease (22). In bloodstream infections (BSI), *S. lugdunensis* is clinically relevant and should not be routinely dismissed as a contaminant. It is notably associated with aggressive native-valve endocarditis, metastatic infection, and high morbidity if not promptly treated (23). *S. lugdunensis* presents variable susceptibility to β-lactams, but oxacillin resistance is uncommon, making accurate identification crucial for appropriate therapy. Misidentification as less virulent CoNS can delay targeted treatment and worsen outcomes. Given its potential severity in BSI, clinicians should approach *S. lugdunensis* isolation with the same vigilance as *S. aureus*.

Staphylococcus capitis/hominis

Staphylococcus capitis is a coagulase-negative *staphylococcus* (CoNS) commonly part of human skin flora that has emerged as an opportunistic pathogen. Notably, the multidrug-resistant NRCS-A clone causes central-line-associated bloodstream infections in neonatal intensive care units (NICUs), aided by its biofilm-forming ability and persistence on indwelling devices (24,25).

Staphylococcus hominis likewise resides on skin, especially in areas rich in apocrine glands, and is one of the 3 most frequently recovered CoNS from bloodstream infections in hospitalized or immunocompromised patients (26). Methicillin-resistant strains commonly harbor *mecA* within diverse SCCmec cassettes, often displaying multidrug resistance. Pathogenicity appears multifactorial, involving adhesion to and invasion of host cells, cytotoxic extracellular products, and biofilm-mediated persistence (27).

Streptococcus agalactiae

Streptococcus agalactiae, or Group B *Streptococcus* (GBS), is a β-hemolytic, Gram-positive coccus that typically forms chains. It possesses a polysaccharide capsule that plays a central role in immune evasion and virulence. Variations in this capsule largely determine which strains are most associated with invasive disease, making the capsule both a key virulence factor and an important target for vaccine development (28). GBS is a common colonizer in the genital and gastrointestinal tracts and can cause serious neonatal bloodstream infections via vertical transmission during childbirth, often leading to sepsis, pneumonia, and sometimes meningitis (29). In adults, particularly the elderly and immunocompromised, GBS may cause bacteremia and endocarditis, as well as noninvasive disease.

Streptococcus anginosus* group *(S. anginosus, S. constellatus and S. intermedius)

Streptococcus anginosus group (SAG) comprises *S. anginosus, S. constellatus,* and *S. intermedius*—Gram-positive, catalase-negative cocci that are facultative anaerobes known for their propensity to form abscesses and other purulent infections. Though they are common mucosal commensals, SAG species are increasingly recognized as opportunistic pathogens whenever they invade sterile body sites (30).

A population-based surveillance study in Canada covering April 2010 to March 2017 reported an annual incidence of 3.7 SAG bloodstream infection episodes per 100,000 population (31). Earlier population data (1989–2000) recorded a lower incidence of 0.93 per 100,000 per year, indicating a substantial rise in detection or reporting of SAG bacteremia over time.

In bloodstream infections, common origins include the gastrointestinal tract, hepatobiliary system, skin/soft tissue, and cardiovascular sources. Morbidity and mortality can be significant, underscoring the clinical relevance of SAG as serious pathogens (32).

Streptococcus pneumoniae

Streptococcus pneumoniae is a Gram-positive, α-hemolytic diplococcus with more than 90 serotypes, defined by its polysaccharide capsule, which is the major virulence determinant. It colonizes the human nasopharynx asymptomatically, especially in children, but can invade sterile sites causing invasive pneumococcal disease (IPD) including meningitis, pneumonia, bacteremia, and sepsis (33). Bloodstream infections (BSI) due to *S. pneumoniae* carry high morbidity and mortality, particularly among the very young, elderly, immunocompromised individuals, and those with chronic comorbidities (33). The widespread use of pneumococcal conjugate vaccines has significantly reduced incidence of childhood IPD and reduced pneumococcal BSIs also via herd immunity, but serotype replacement and antibiotic resistance are challenges to continued control (34).

Streptococcus pyogenes

Streptococcus pyogenes (Group A *Streptococcus,* GAS) is a β-hemolytic, Gram-positive coccus responsible for a wide spectrum of diseases, from mild pharyngitis to severe invasive infections such as necrotizing fasciitis, streptococcal toxic shock syndrome, and bacteremia (35). GAS bacteremia remains clinically significant, with reported mortality rates around 15–20%, especially when treatment or infectious disease consultation is delayed (36,37). Recent data indicate a concerning rise in GAS bacteremia incidence globally. In the United States,

invasive GAS infections increased substantially between 2018 and 2025 (38), a trend mirrored in Europe, including pediatric populations in Spain (39). Possible drivers include post-pandemic immune shifts, evolving strain virulence, and changes in healthcare-associated exposures. Ongoing surveillance and rapid clinical response are essential to mitigate morbidity and mortality associated with *S. pyogenes* bacteremia.

Cryptococcus neoformans/gattii

Cryptococcus neoformans and *Cryptococcus gattii* are encapsulated basidiomycetous yeasts whose major virulence factors include a polysaccharide capsule, melanin production, and thermotolerance, all of which enable survival in host tissues and evasion of immune defenses (40). Infection typically begins after inhalation of spores or desiccated yeast cells, which can disseminate hematogenously to the central nervous system or other organs. Although bloodstream infection *(cryptococcemia)* is less frequent than meningoencephalitis or pulmonary disease, it signifies severe disseminated infection and carries a high mortality rate. A recent systematic review found that *C. gattii* bloodstream infection was associated with approximately 43% mortality (41). *Cryptococcemia* often reflects profound immunosuppression and demands aggressive antifungal therapy combined with management of complications such as intracranial hypertension. Early recognition and prompt intervention are therefore crucial to improving patient outcomes.

Fusarium (F. solani, F. oxysporum, and F. verticillioides)

Fusarium species are ubiquitous filamentous fungi found in soil, water, and plants, and act as opportunistic pathogens in humans (42). In severely immunocompromised patients—particularly those with neutropenia, hematologic malignancies, or undergoing stem cell transplantation—*Fusarium* can cause invasive fusariosis that frequently disseminates and results in fungemia (43). A distinguishing feature compared to many other molds is that *Fusarium* often yields positive blood cultures in disseminated disease; approximately 82% of reported cases show positive cultures (42). Mortality remains high, exceeding 50% in many series, especially when neutrophil recovery is delayed (43). Optimal management requires prompt initiation of antifungal therapy, such as amphotericin B or voriconazole, combined with efforts to reverse immunosuppression and remove infected catheters when fungemia is catheter-associated (42).

***Candida* spp. Group 1**

The *Candida* spp. group 1 molecular target detects common yeasts implicated in bloodstream and invasive infections, including *Candida albicans, Candida tropicalis, Candida*

dubliniensis, Debaryomyces hansenii (C. famata), Meyerozyma guilliermondii (C. guilliermondii), and *Kluyveromyces marxianus (C. kefyr)*. These species are frequent causes of candidemia, especially in immunocompromised or critically ill patients (44,45). *C. albicans* remains the leading cause of *Candida* bloodstream infections, though non-albicans *Candida* (NAC) species such as *C. tropicalis* and *M. guilliermondii* have gained clinical relevance. Antifungal susceptibility varies: *C. albicans* and *C. dubliniensis* are generally fluconazole-susceptible, while *C. tropicalis* and *M. guilliermondii* may show reduced azole susceptibility and occasional echinocandin tolerance (46). Detecting *Candida* spp. Group 1 aids in early diagnosis and appropriate antifungal selection, crucial to reducing the high morbidity and mortality associated with *candidemia*.

Candida spp. Group 2

The *Candida* spp. Group 2 targets important non-albicans *Candida* species associated with bloodstream infections: *Nakaseomyces glabrata (C. glabrata), Pichia kudriavzevii (C. krusei), Candida parapsilosis,* and *Clavispora lusitaniae (C. lusitaniae)*. These organisms have emerged as major pathogens in hospital settings, often displaying reduced susceptibility to standard antifungals (44,45). *C. glabrata* commonly exhibits dose-dependent resistance to azoles and emerging echinocandin resistance, while *C. krusei* is intrinsically fluconazole-resistant. *C. parapsilosis* is notable for biofilm formation and reduced echinocandin susceptibility due to FKS gene polymorphisms, and *C. lusitaniae* may develop amphotericin B resistance during treatment (46). Rapid molecular detection of *Candida* spp. Group 2 supports timely identification, enabling optimized antifungal therapy, and improved outcomes in patients with candidemia or other invasive candidiasis.

Candida auris

Candida auris is an emerging, multidrug-resistant yeast first identified in 2009 and now recognized as a major cause of healthcare-associated bloodstream infections (47). It has demonstrated an exceptional ability to persist on environmental surfaces and spread nosocomially, leading to outbreaks in hospitals and intensive care units (48). *C. auris* can cause severe invasive infections, including candidemia, particularly among critically ill or immunocompromised patients. Mortality remains high—approximately 38% at 30 days in multicenter studies of *Candida* bloodstream infections (49). Therapeutic management is challenging due to frequent resistance to azoles and variable susceptibility to amphotericin B, making echinocandins the recommended first-line therapy pending antifungal susceptibility testing (50). Early detection and strict infection control measures are essential to limit spread and improve outcomes in *C. auris* bloodstream infections.

Pan Gram-Negative

The Pan Gram-Negative target is designed to detect a broad range of Gram-negative bacterial pathogens that may be present in bloodstream infection (BSI) samples. This assay enables rapid detection even when initial Gram stain results are inconclusive or atypical, or when a Gram-negative organism is missed in the Gram stain. When a Pan Gram-Negative target is detected, additional testing is recommended to determine the specific causative organism and optimize patient management.

aac(6')-aph(2")

The *aac(6')-Ie/aph(2")-Ia* gene encodes a bifunctional aminoglycoside-modifying enzyme that confers high-level resistance to gentamicin, tobramycin, and kanamycin in gram-positive bacteria, particularly *Enterococcus faecalis* and *Enterococcus faecium* (51,52). This enzyme combines acetyltransferase [AAC(6′)] and phosphotransferase [APH(2″)] activities, enabling sequential modification of aminoglycosides, thereby inactivating them. The gene is frequently carried on transposon Tn5281, facilitating horizontal transfer among enterococci and occasionally to *staphylococci* (51,53). Detection of *aac(6')-Ie/aph(2")-Ia* in bloodstream isolates is clinically significant, as it predicts therapeutic failure with aminoglycosides and necessitates alternative agents or combination regimens.

cfr

The *cfr* gene encodes a 23S rRNA methyltransferase that modifies adenine at position A2503 of the 23S rRNA, conferring resistance to multiple antibiotic classes, including phenicols, lincosamides, oxazolidinones (e.g., linezolid), pleuromutilins, and streptogramin A—collectively known as the PhLOPSA resistance phenotype (54,55). Originally identified in *Staphylococcus sciuri, cfr* has since disseminated among *Staphylococcus aureus, Enterococcus,* and various gram-negative species via plasmids and transposons (55,56). The presence of *cfr* in bloodstream isolates poses significant therapeutic challenges, reducing the effectiveness of last-resort agents like linezolid and requiring careful antimicrobial stewardship.

ermA / ermC

The *ermA* and *ermC* genes encode rRNA methyltransferases that confer resistance to macrolide–lincosamide–streptogramin B (MLSB) antibiotics in Gram-positive bacteria, most notably in *staphylococci* (57,58). These enzymes methylate a specific adenine residue (A2058) in the 23S rRNA of the 50S ribosomal subunit, preventing antibiotic binding and

thereby inhibiting their ability to block protein synthesis. The *ermA* gene is commonly found on transposon Tn*554* integrated into the bacterial chromosome, whereas *ermC* is typically located on small, mobilizable plasmids (59,60). Expression of these genes may be constitutive or inducible, with inducible resistance often revealed by the "D-test" phenotype in clinical isolates. The presence of *ermA* or *ermC* is clinically important as it predicts resistance to macrolides and possible therapeutic failure with clindamycin if inducible resistance is undetected.

mecA / mecC

The *mecA* and *mecC* genes encode alternative penicillin-binding proteins, PBP2a and PBP2c respectively, which confer resistance to nearly all β-lactam antibiotics, including methicillin, oxacillin, and cephalosporins, in *Staphylococcus aureus* and coagulase- negative staphylococci (61,62). These proteins have a markedly reduced affinity for β-lactams, allowing peptidoglycan synthesis to continue even in the presence of inhibitory drug concentrations. The *mecA* gene is carried on the staphylococcal cassette chromosome mec (SCCmec), a mobile genetic element that facilitates horizontal dissemination among staphylococcal species (63). The more recently identified *mecC* gene shares approximately 70% nucleotide identity with *mecA* and is often associated with SCCmec type XI, found in both human and animal isolates, highlighting its zoonotic potential (64). Detection of *mecA* or *mecC* is the molecular hallmark of methicillin-resistant *Staphylococcus aureus* (MRSA) and is essential for accurate diagnosis and infection control measures.

tetK / tetM

The *tetK* and *tetM* genes encode tetracycline resistance determinants that protect bacteria against the inhibitory effects of tetracyclines, particularly in *Staphylococcus aureus, Enterococcus* spp., and other gram-positive organisms (65,66). The *tetK* gene encodes a membrane-associated efflux pump belonging to the major facilitator superfamily (MFS), which actively exports tetracycline from the cell, reducing intracellular drug concentrations. In contrast, *tetM* encodes a ribosomal protection protein that binds to the ribosome and displaces tetracycline, thereby restoring normal protein synthesis (67). The *tetK* gene is typically located on small multicopy plasmids, such as pT181, commonly found in staphylococci, while *tetM* is associated with the conjugative transposon Tn916, facilitating horizontal gene transfer among diverse gram-positive and gram-negative bacteria (65,68). The coexistence of *tetK* and *tetM* within a single isolate can confer high-level and broad-spectrum tetracycline resistance, posing a therapeutic challenge in both clinical and veterinary settings.

vanA / vanB

The *vanA* and *vanB* genes encode enzymes that confer high-level resistance to glycopeptide antibiotics, notably vancomycin and teicoplanin, in *Enterococcus faecalis* and *Enterococcus faecium* (69). These genes are part of operons that mediate the synthesis of altered peptidoglycan precursors ending in D-Ala–D-Lac instead of the usual D-Ala–D-Ala termini, thereby reducing the binding affinity of glycopeptides by approximately 1000-fold. The *vanA* operon, typically carried on transposon Tn1546 located on plasmids, confers resistance to both vancomycin and teicoplanin, whereas *vanB*—usually found on chromosomal transposons such as Tn1549 or Tn5382—confers variable resistance to vancomycin but retains susceptibility to teicoplanin (70,71). Horizontal transfer of these elements among enterococci and to other gram-positive species, including *Staphylococcus aureus,* poses a significant public health threat due to the potential emergence of vancomycin-resistant *S. aureus* (VRSA).

3.3. Principle of the procedure

The QIAstat-Dx BCID GPF Plus AMR Panel Cartridge is a single-use, fully automated molecular testing device designed to detect Gram-positive bacteria, fungal pathogens, and 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 GPF 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 GPF Plus AMR Panel Cartridge is shown in Figure 1.

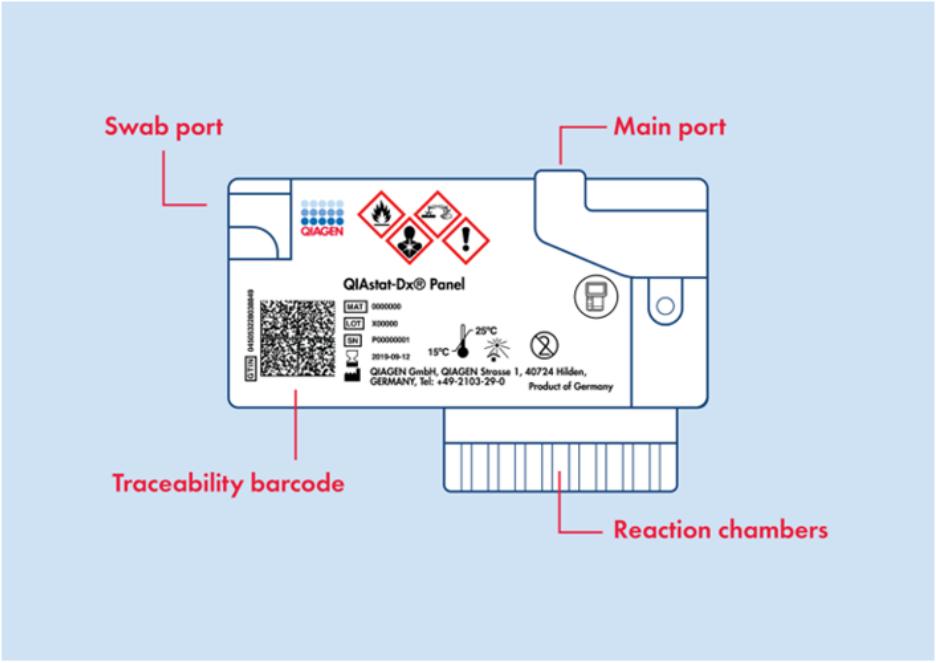


Figure 1. Layout of the QIAstat-Dx BCID GPF Plus AMR Panel Cartridge and its features.

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

4. Materials Provided

4.1. Kit contents

QIAstat-Dx BCID GPF Plus AMR Panel	
Catalog no.	**691812**
Number of preps	**6**
QIAstat-Dx BCID GPF 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 GPF Plus AMR Panel Cartridge.

4.2. Active ingredients

Reagent	Critical/Active ingredient	Concentration/range
QIAstat-Dx BCID GPF Plus AMR Panel	Internal Control	40,000–60,000 CFU/cartridge
	Proteinase K	≥0.1%–<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 GPF 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 GPF Plus AMR Panel installed in the Operational module or Operational Module PRO

Note: QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 may have specific ADFs to ensure proper functionalities on each instrument. Those specific ADF are 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 GPF Plus AMR Panel is for in vitro diagnostic use.
- The QIAstat-Dx BCID GPF 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 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 GPF 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 GPF 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 GPF 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 GPF 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 organizations have published guidelines for the notification of reportable diseases. While the list of reportable conditions varies by state, the Council of State and Territorial Epidemiologists (CSTE) has recommended that state health departments report cases of selected diseases to CDC's National Notifiable Diseases Surveillance System (NNDSS). The list of notifiable infectious diseases includes invasive disease caused by pathogens such as *Streptococcus pneumoniae*, as well as instances of antimicrobial resistance, such as Vancomycin- intermediate and Vancomycin- resistant *Staphylococcus aureus*.

Pathogens are reportable due to their outbreak potential or impact on public health. 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 21.
- Follow recommendations in the Safety Data Sheet (SDS).

8. Storage and Handling

8.1. Reagent storage and handling

Store the QIAstat-Dx BCID GPF Plus AMR Panel Cartridges in a dry, clean storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx BCID GPF 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 GPF 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 GPF 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 21.

8.1.1. In-use stability

After the cartridge package is opened, the sample should be introduced into the QIAstat-Dx BCID GPF 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 GPF 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 GPF 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 GPF Plus AMR Panel.

10. Protocol

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.

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.
- Gently invert the positive blood culture bottle 3 times to ensure mixing of the contents.
- Allow the bottle to sit for 10 seconds to allow any resin which may be present to settle at the bottom.

- Wipe the septum of the blood culture bottle with a 70% IPA wipe (or equivalent) and allow to air dry prior to collecting sample.
- 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.
- 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.
- Close the lid of the tube until ready to proceed with loading the sample into the QIAstat-Dx BCID GPF Plus AMR Panel Cartridge.
- Transfer pipettes for loading the QIAstat-Dx BCID GPF 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 GPF Plus AMR Panel Cartridge, as per the procedure described in Section 10.3.

10.2. Pure colony suspended in saline samples

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

Important: Pure colony suspension in saline shall not be prepared for Fusarium target.

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

- More colonies can be picked or extra saline added, as necessary to adjust the suspension to 1.0 McFarland Standard suspension.
- Ensure a homogenous organism suspension has been prepared.
- Dispose of materials used as per regulations.
- 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 GPF Plus AMR Panel

1. Thoroughly decontaminate the consumables and lab areas used to load a QIAstat-Dx BCID GPF 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 GPF 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 GPF 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).

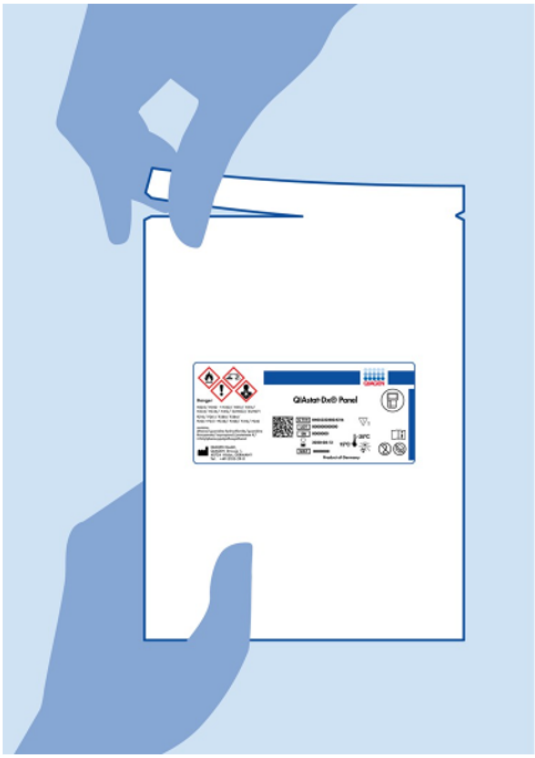


Figure 2. Opening the QIAstat-Dx BCID GPF Plus AMR Panel Cartridge.

3. Remove the QIAstat-Dx BCID GPF 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 GPF Plus AMR Panel Cartridge (Figure 4). Ensure that the label is properly positioned and does not block the lid opening (Figure 3).

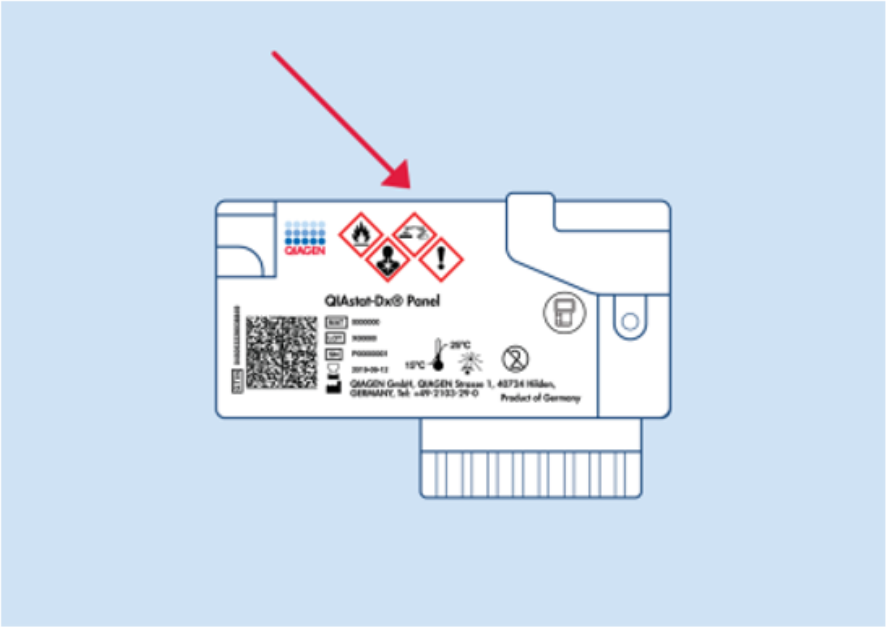


Figure 3. Sample information placement on top of QIAstat-Dx BCID GPF Plus AMR Panel Cartridge.

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

   Important: Do not flip the QIAstat-Dx BCID GPF 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 GPF Plus AMR Panel Cartridge if it is agitated while the lid is open.

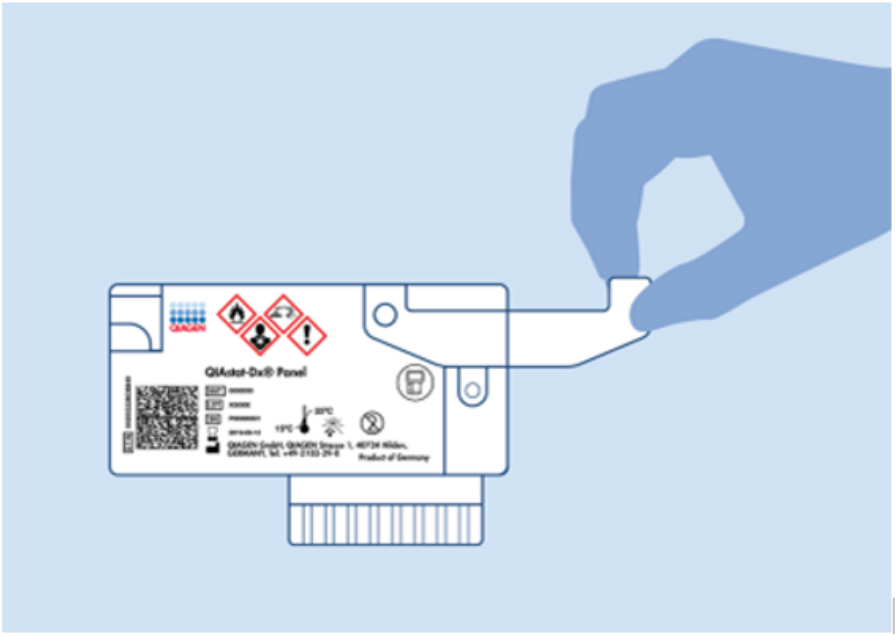


Figure 4. Opening the sample lid of main port.

7. To ensure that the sample to be tested is thoroughly mixed, invert the tube at least 5 times before processing. (See "Blood culture samples" on page 29).
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 GPF 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.

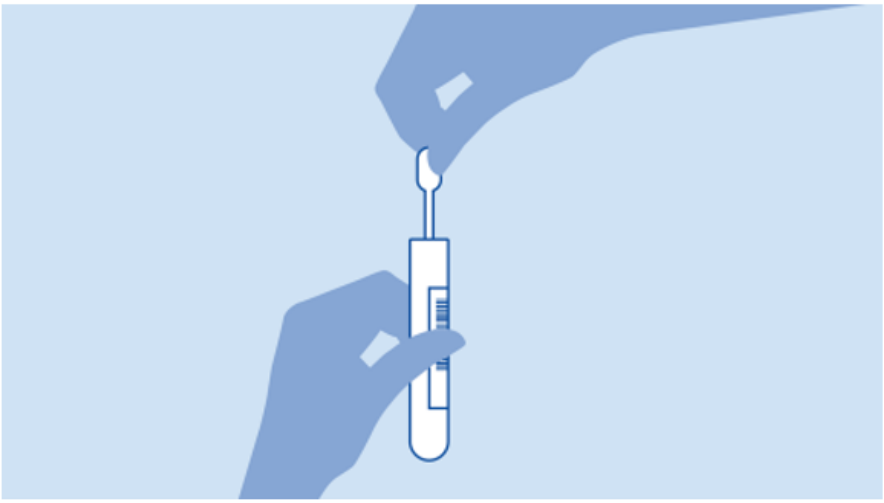


Figure 5. Drawing sample into the supplied transfer pipette.

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

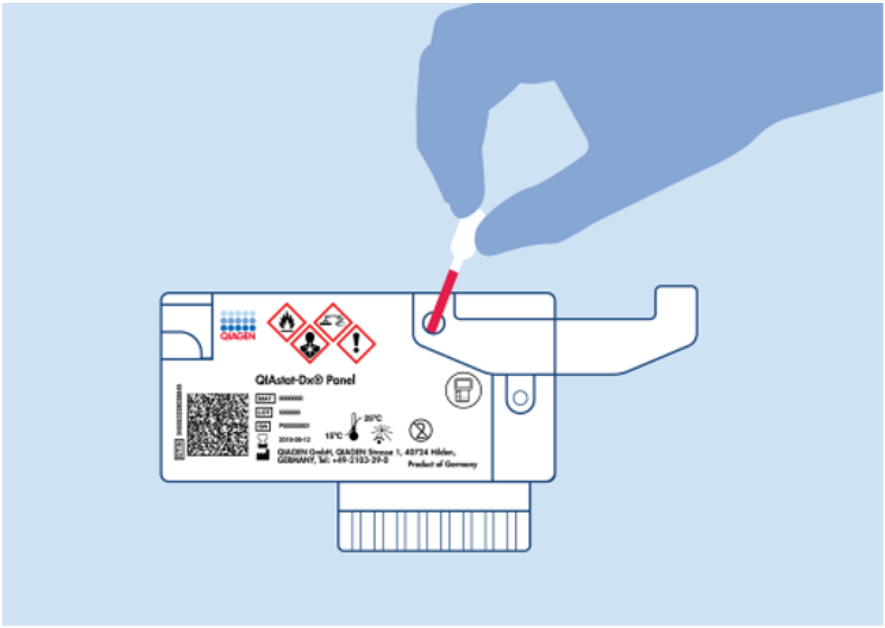


Figure 6. Transferring sample to main port of QIAstat-Dx BCID GPF Plus AMR Panel Cartridge.

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

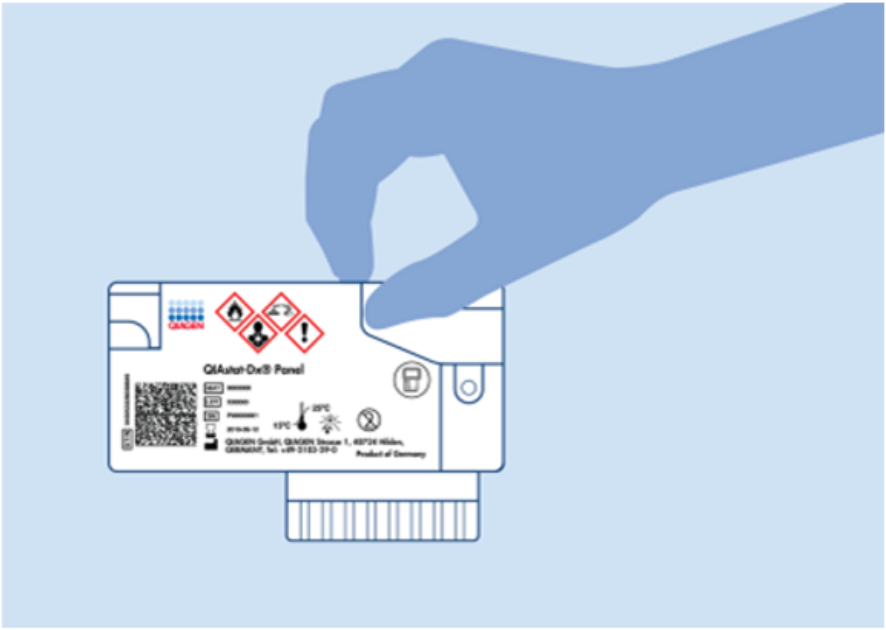


Figure 7. Closing the lid of the main port.

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

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

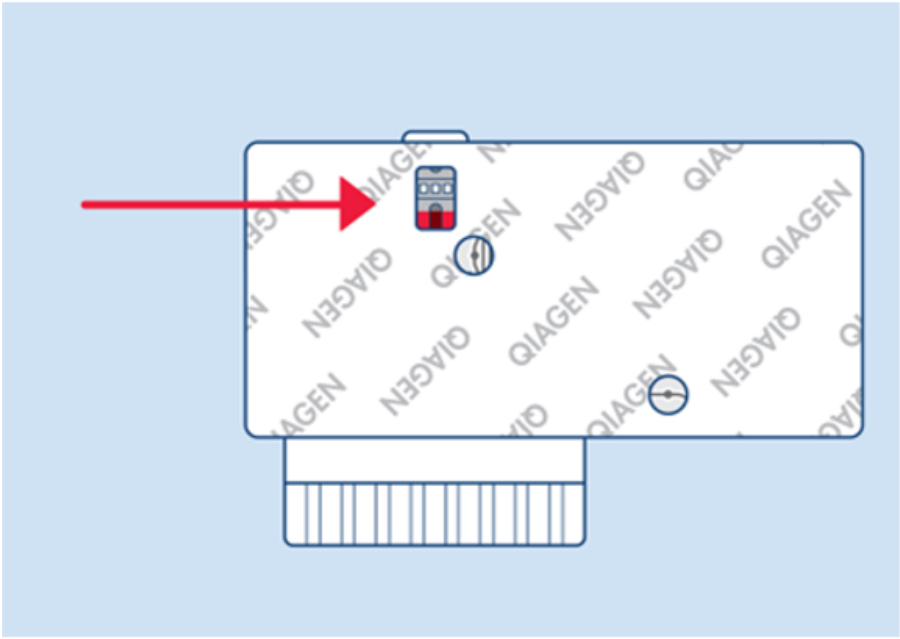


Figure 8. Sample inspection window (red arrow).

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 the **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 ("Appendix A: Installing the Assay Definition File" on page 186 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 bar code on the tube containing the sample, or scan the specimen information bar code located on top of the QIAstat-Dx BCID GPF Plus AMR Panel Cartridge (see step 3) using the integrated front bar code 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.

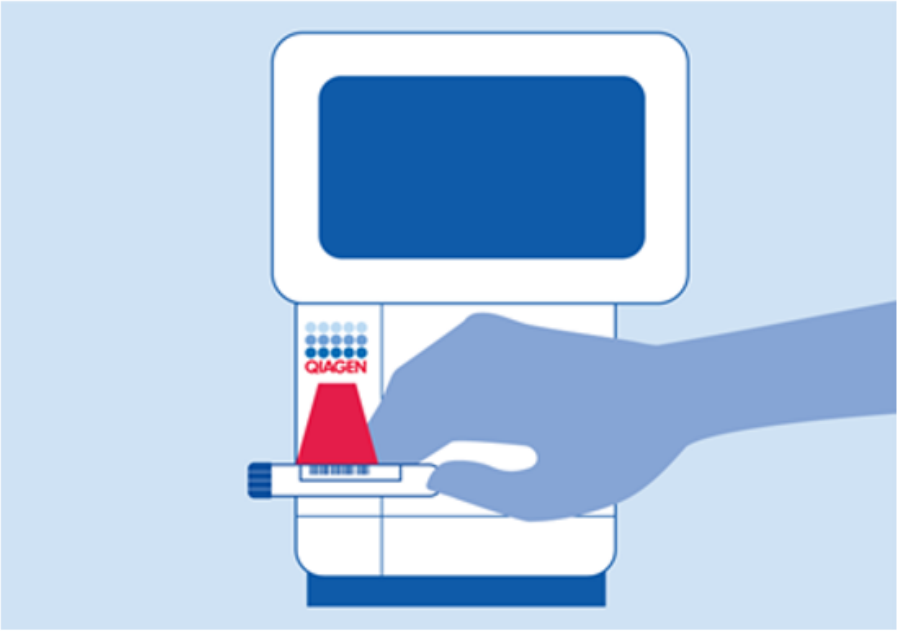


Figure 9. Scanning sample ID barcode.

3. When prompted, scan the bar code of the QIAstat-Dx BCID GPF 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 bar code.

   Note: QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 are designed to reject QIAstat-Dx BCID GPF 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 GPF 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.

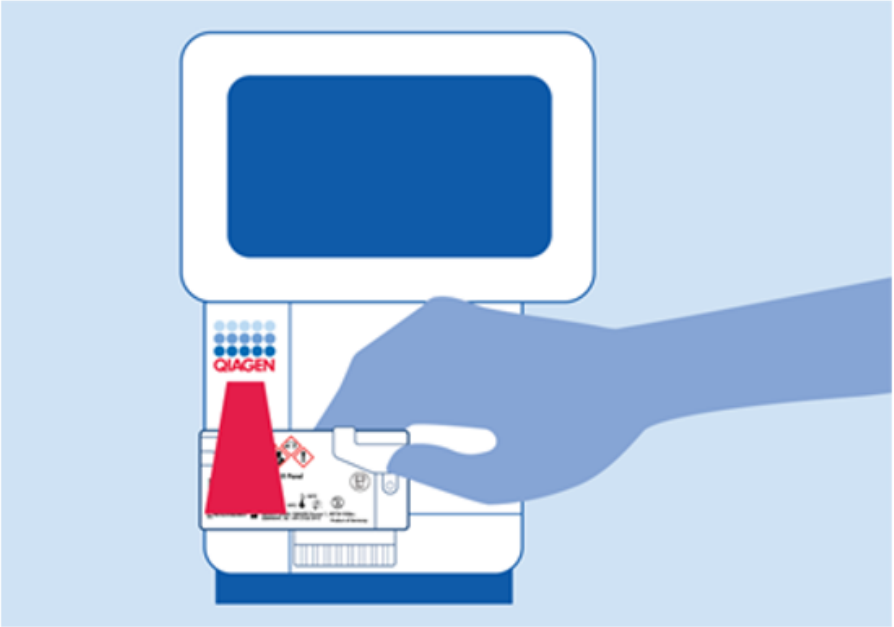


Figure 10. Scanning QIAstat-Dx BCID GPF Plus AMR Panel Cartridge bar code.

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

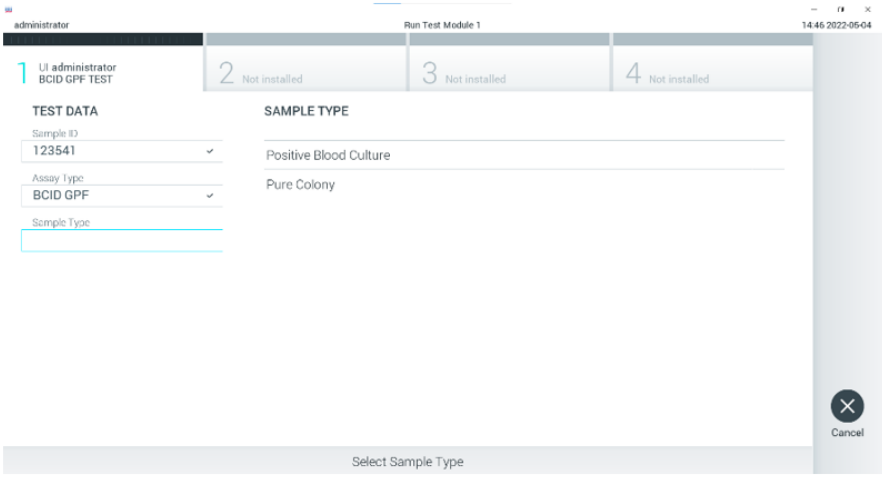


Figure 11. Selecting sample type.

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).

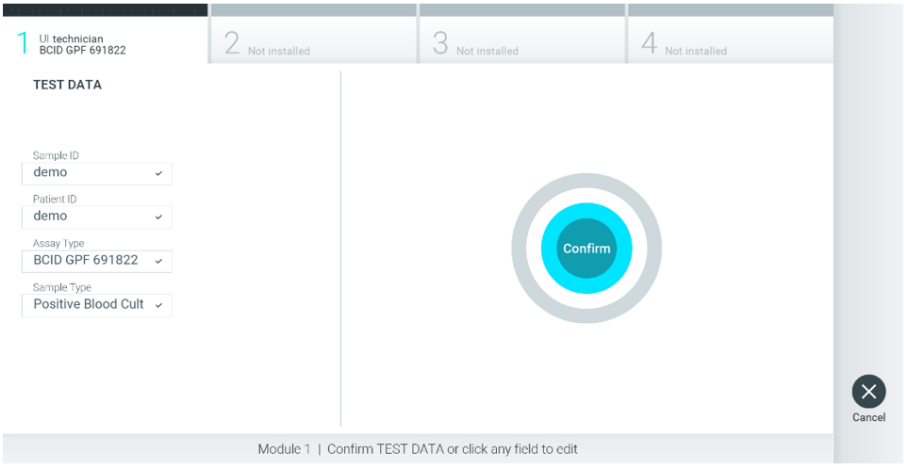


Figure 12. Confirming data entry.

7. Ensure that both sample lids of the swab port and main port of the QIAstat-Dx BCID GPF 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 GPF 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 GPF 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 GPF Plus AMR Panel assay.

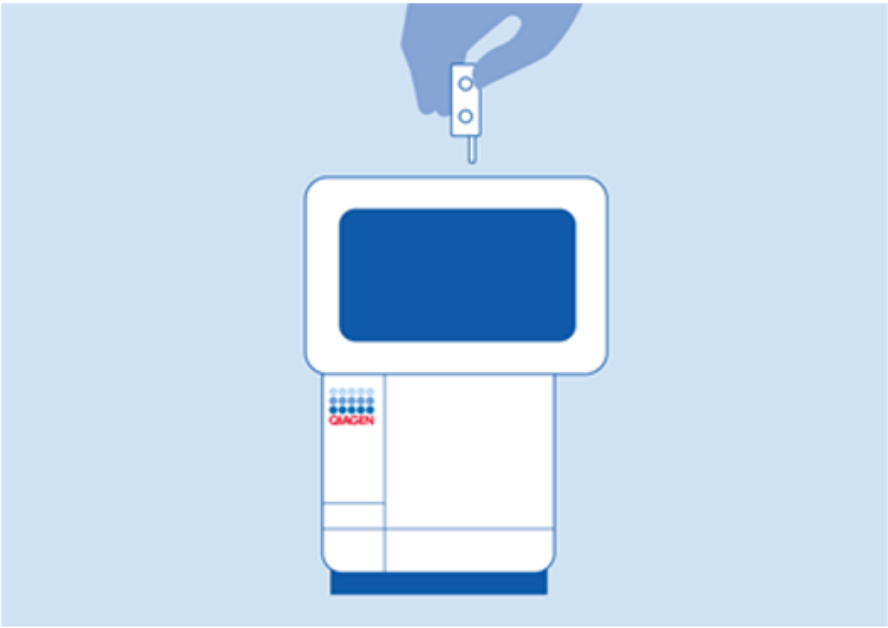


Figure 13. Inserting QIAstat-Dx BCID GPF Plus AMR Panel Cartridge into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

8. Upon detecting the QIAstat-Dx BCID GPF 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 GPF 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 GPF 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 Support.

Figure 14. Eject screen display.

11. Press **Eject** on the touchscreen to remove the QIAstat-Dx BCID GPF 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 GPF 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 GPF 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 GPF 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 GPF 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 GPF 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 GPF Plus AMR Panel Cartridge.

11.2. Sample result interpretation

11.2.1. Pathogen assay result interpretation

A result for a QIAstat-Dx BCID GPF 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 on the facing page.

An overall test result is provided (Table 4) 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. Of the Invalid result persists, contact QIAGEN Technical Services 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. Of the Invalid result persists, contact QIAGEN Technical Support for further instructions.

11.2.2. Antimicrobial Resistance (AMR) assay result interpretation

The QIAstat-Dx BCID GPF 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 pathogen 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 disallowed; 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 GPF Plus AMR Panel

	AMR									
Pathogen	***mecA***	***mecC***	***vanA***	***vanB***	***cfr***	***aac (6')/aph (2")***	***ermC***	***ermA***	***tetK***	***tetM***
Bacillus cereus group	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Corynebacterium	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Enterococcus faecalis	NO	NO	YES	YES	NO	YES	YES	YES	YES	YES
Enterococcus faecium	NO	NO	YES	YES	YES	YES	YES	YES	YES	YES
Listeria monocytogenes	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Micrococcus spp.	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Staphylococcus aureus	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Staphylococcus epidermidis	YES	NO	NO	NO	YES	YES	YES	YES	YES	YES
Staphylococcus lugdunensis	YES	NO	NO	NO	NO	YES	YES	YES	YES	NO

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

	AMR									
Pathogen	***mecA***	***mecC***	***vanA***	***vanB***	***cfr***	***aac (6')/aph (2")***	***ermC***	***ermA***	***tetK***	***tetM***
Staphylococcus capitis/hominis	YES	NO	NO	NO	YES	YES	YES	YES	YES	YES
Streptococcus agalactiae	NO	NO	NO	NO	NO	YES	NO	NO	YES	YES
Streptococcus anginosus group	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES
Streptococcus pneumoniae	NO	NO	NO	NO	YES	NO	NO	NO	YES	YES
Streptococcus pyogenes	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES
Cryptococcus neoformans/gattii	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Fusarium	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Candida Group 1	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Candida Group 2	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Candida auris	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Pan Gram Negative	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

Note: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the QIAstat-Dx BCID GPF 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 assay result interpretation

The QIAstat-Dx BCID GPF Plus AMR Panel contains an assay designed to detect a broad range of Gram-negative bacterial pathogens that may be present in bloodstream infection (BSI) samples, including but not limited to *Enterobacterales, Cedeceae, Citrobacter, Cronobacter, Enterobacter, Escherichia, Erwinia, Hafnia, Klebsiella, Kluyvera, Kosakonia,*

Leclercia, Lelliotia, Morganella, Phytobacter, Pluralibacter, Proteus, Providencia, Pseudoescherichia, Rahnella, Raoultella, Salmonella, Serratia, Sodalis, Shigella, Tatumella, Yersinia, Yokenella, Brenneria, Chania, Dickeya, Edwardsiella, Gibbsiella, Izhakiella, Limnobaclum, Lonsdalea, Metakosakonia, Nissabacter, Obesmbacterium proteus strain, *Pectobacterium, Pragia, Scandinavium, Shimwellia, Xenorhabdus, Bacteroides fragilis, Neisseria meningitidis, Stenotrophomonas maltophilia, Haemophilus influenzae, Pseudomonadales, Acinetobacter* and *Pseudomonas*. The result will follow the same interpretation as described in Table 3, showing detected/non-detected depending on the detection of any Gram-negative bacteria. In case of detection, additional testing is recommended to identify the organism.

The QIAstat-Dx BCID GPF Plus AMR Panel also contains 2 *Candida* group assays, which will follow the same interpretation as detailed in Table 3. In this case, see Table 4 for pathogens included depending on the assay detected.

Table 4. QIAstat-Dx BCID GPF Plus AMR Panel *Candida* Group 1 and 2 result

QIAstat-Dx BCID GPF Plus AMR Panel target	Result	Description
Candida Group 1	Detected	One or more of the following *Candida* organisms has been detected: *Candida albicans, Candida tropicalis, Candida dubliniensis, Candida famata, Candida guilliermondii,*or *Candida kefyr* Additional testing for identification is recommended.
Candida Group 2	Detected	One or more of the following *Candida* organisms has been detected: *Candida glabrata, Candida krusei, Candida parapsilosis,* or *Candida lusitaniae* Additional testing for identification is recommended.

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 GPF Plus AMR Panel Cartridge, the Results Summary screen is automatically displayed (Figure 15).

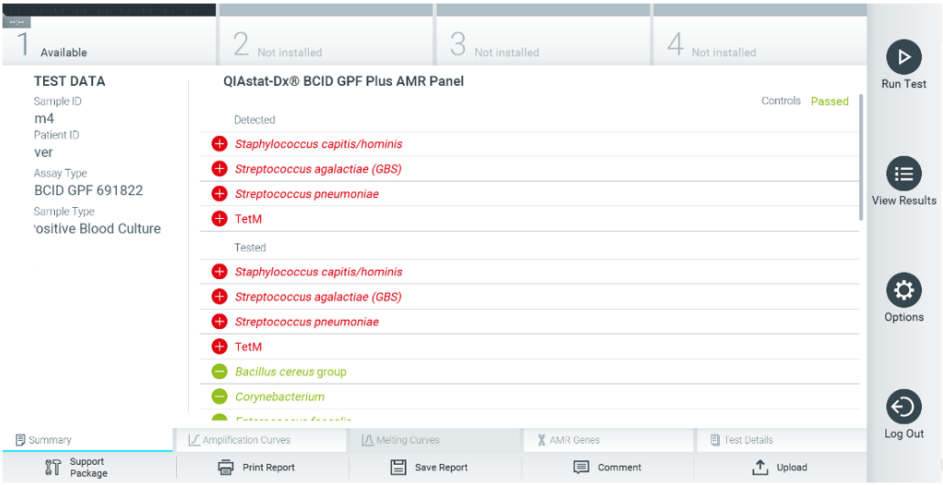


Figure 15. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel.

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 GPF Plus AMR Panel)
- AMR Genes (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 shown 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 shown 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 shown 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 shown 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 GPF 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.

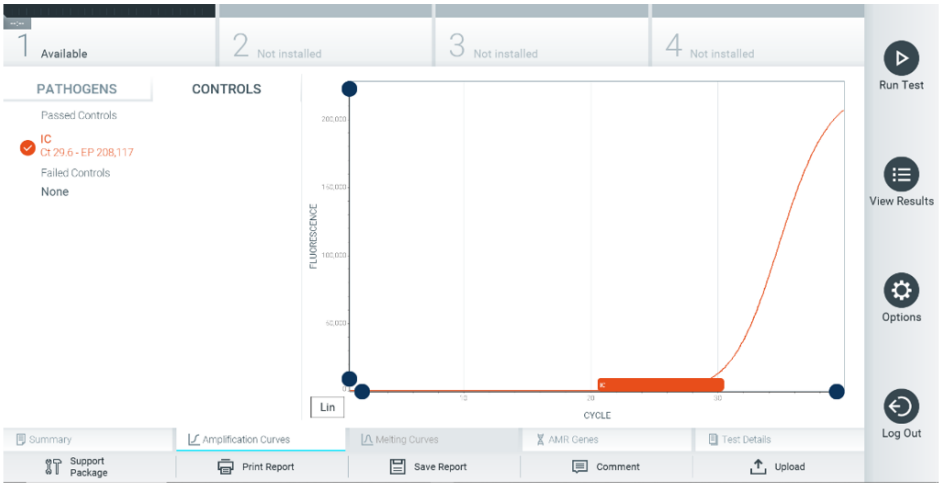


Figure 17. Amplification Curves screen (CONTROLS tab).

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 the **Lin** or **Log** buttons 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 shown 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 GPF pathogen is detected/identified)
  - **Positive with warning** (if at least one BCID GPF pathogen is detected, but the Internal Control Failed)
  - **Negative** (if no BCID GPF 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

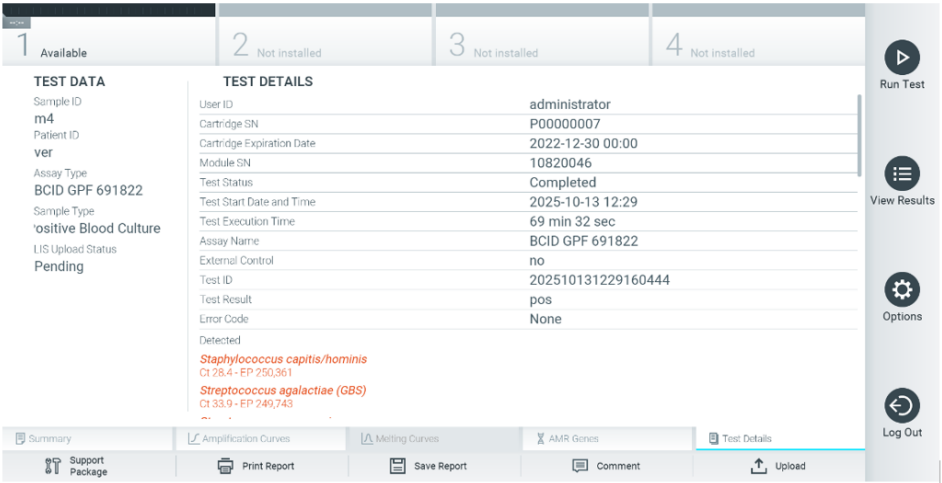


Figure 18. Example screen showing Test Data on the left panel and Test Details in the main panel.

11.3.3. Viewing AMR genes

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 on page 47. A Not Detected result for a resistance gene does not indicate susceptibility to the associated antibiotic classes. Gram-positive bacteria may be resistant to specific antibiotics by mechanisms of resistance not targeted by the QIAstat-Dx BCID GPF 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 GPF Plus AMR Panel does not specifically attribute antibiotic resistance genes to a specific organism.

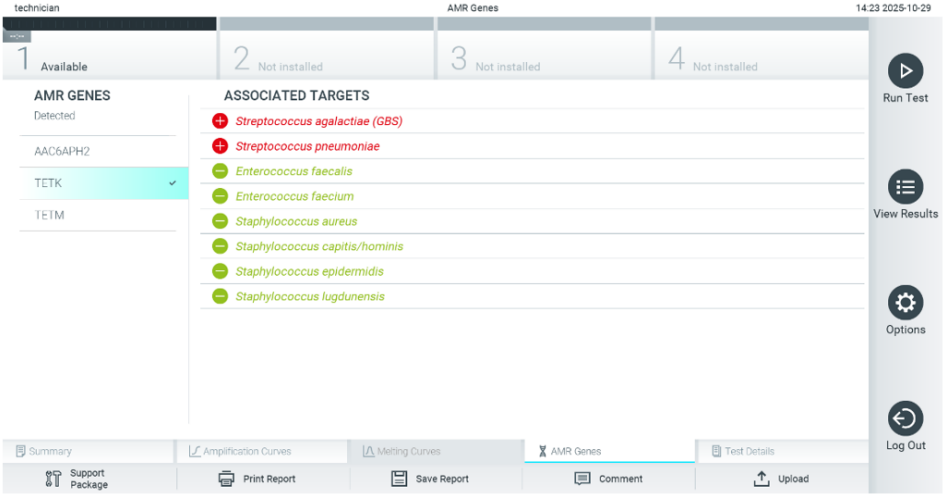


Figure 19. Example screen showing AMR Genes on the left and Associated Targets on the right (when operating with QIAstat-Dx Analyzer 2.0).

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).

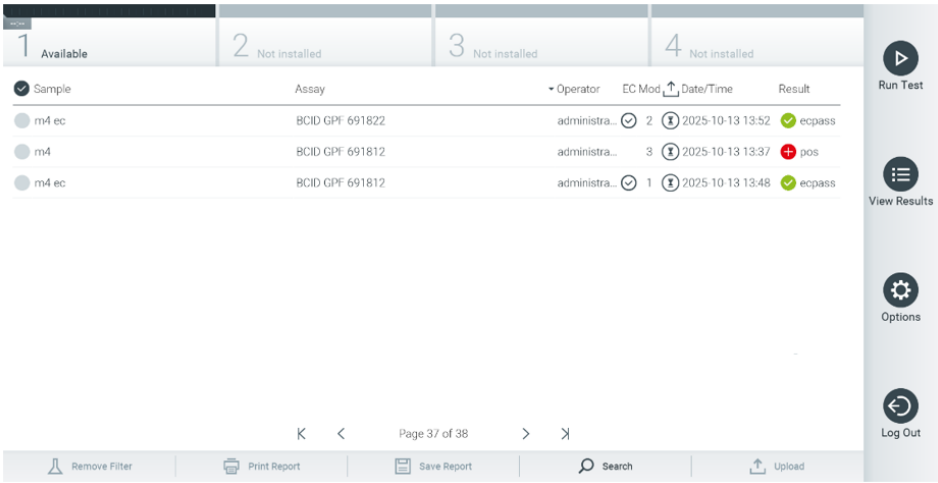


Figure 20. Example View Results screen.

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

- Sample ID
- Assay (name of test assay which is BCID GPF 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).

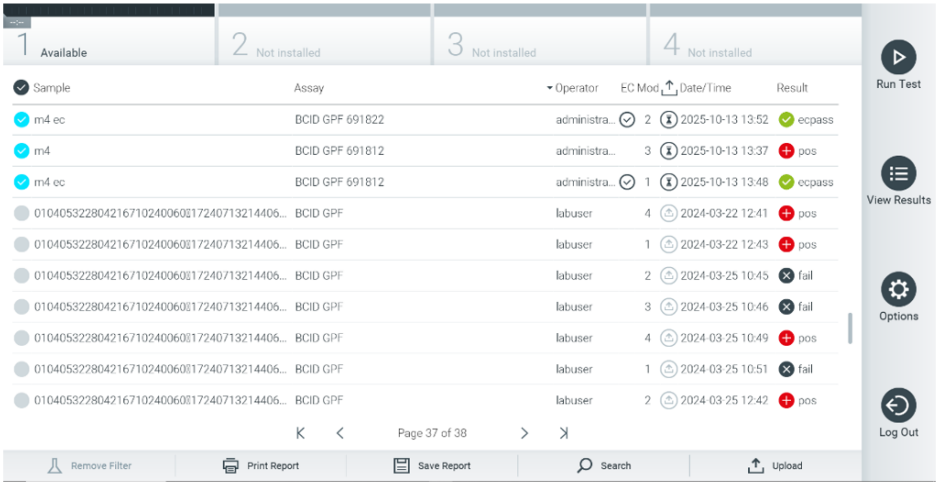


Figure 21. Example of selecting Test Results in the View Results screen.

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 5).

Table 5. 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.

Table 5. Descriptions of the test results in View Results screen (continued)

Outcome	Result	Description	Action
Negative	 neg	No analytes were detected	Refer to the Summary Result Screen or Result Printout for pathogen specific results.
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 Services 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 GPF 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  symbol to the left of a column headline indicates that the column's filter is active.

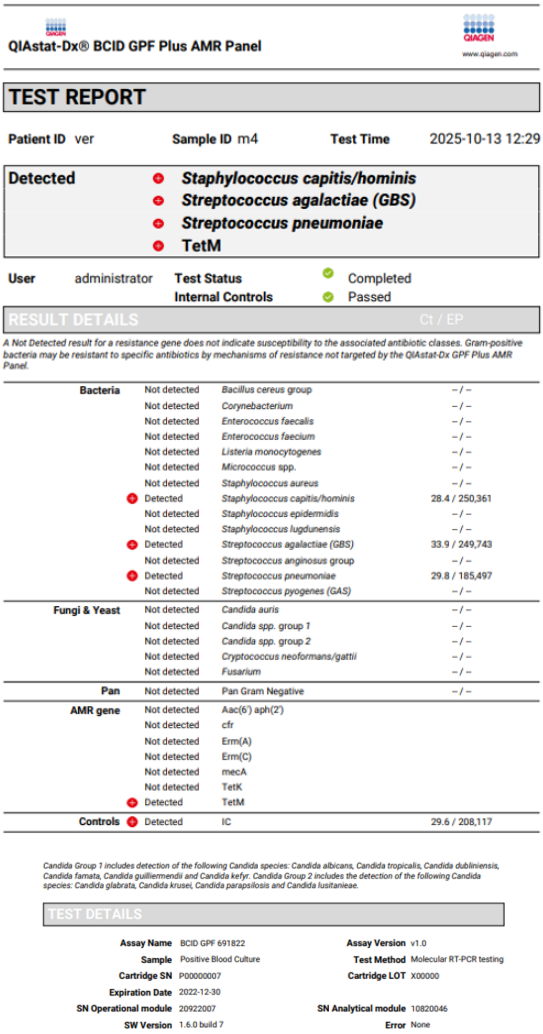
To remove a filter, press **Remove Filter** in the Submenu bar.

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 6 lists the interpretation of results in the PDF file.

Table 6. 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 GPF Plus AMR Panel

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TEST REPORT

Patient ID ver **Sample ID** m4 **Test Time** 2025-10-13 12:29

Detected
- ***Staphylococcus capitis/hominis***
- ***Streptococcus agalactiae (GBS)***
- ***Streptococcus pneumoniae***
- **TetM**

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-positive bacteria may be resistant to specific antibiotics by mechanisms of resistance not targeted by the QIAstat-Dx GPF Plus AMR Panel.

Bacteria	Not detected	*Bacillus cereus group*	– / –
	Not detected	*Corynebacterium*	– / –
	Not detected	*Enterococcus faecalis*	– / –
	Not detected	*Enterococcus faecium*	– / –
	Not detected	*Listeria monocytogenes*	– / –
	Not detected	*Micrococcus spp.*	– / –
	Not detected	*Staphylococcus aureus*	– / –
	Detected	*Staphylococcus capitis/hominis*	28.4 / 250,361
	Not detected	*Staphylococcus epidermidis*	– / –
	Not detected	*Staphylococcus lugdunensis*	– / –
	Detected	*Streptococcus agalactiae (GBS)*	33.9 / 249,743
	Not detected	*Streptococcus anginosus group*	– / –
	Detected	*Streptococcus pneumoniae*	29.8 / 185,497
	Not detected	*Streptococcus pyogenes (GAS)*	– / –
Fungi & Yeast	Not detected	*Candida auris*	– / –
	Not detected	*Candida spp. group 1*	– / –
	Not detected	*Candida spp. group 2*	– / –
	Not detected	*Cryptococcus neoformans/gattii*	– / –
	Not detected	*Fusarium*	– / –
Pan	Not detected	Pan Gram Negative	– / –
AMR gene	Not detected	Aac(6') aph(2')	
	Not detected	cfr	
	Not detected	Erm(A)	
	Not detected	Erm(C)	
	Not detected	mecA	
	Not detected	TetK	
	Detected	TetM	
Controls	Detected	IC	29.6 / 208,117

Candida Group 1 includes detection of the following Candida species: Candida albicans, Candida tropicalis, Candida dubliniensis, Candida famata, Candida guilliermendii and Candida kefyr. Candida Group 2 includes the detection of the following Candida species: Candida glabrata, Candida krusei, Candida parapsilosis and Candida lusitaniae.

TEST DETAILS

Assay Name	BCID GPF 691822	**Assay Version**	v1.0
Sample	Positive Blood Culture	**Test Method**	Molecular RT-PCR testing
Cartridge SN	P00000007	**Cartridge LOT**	X00000
Expiration Date	2022-12-30		
SN Operational module	20922007	**SN Analytical module**	10820046
SW Version	1.6.0 build 7	**Error**	None

Figure 22. Sample test report.

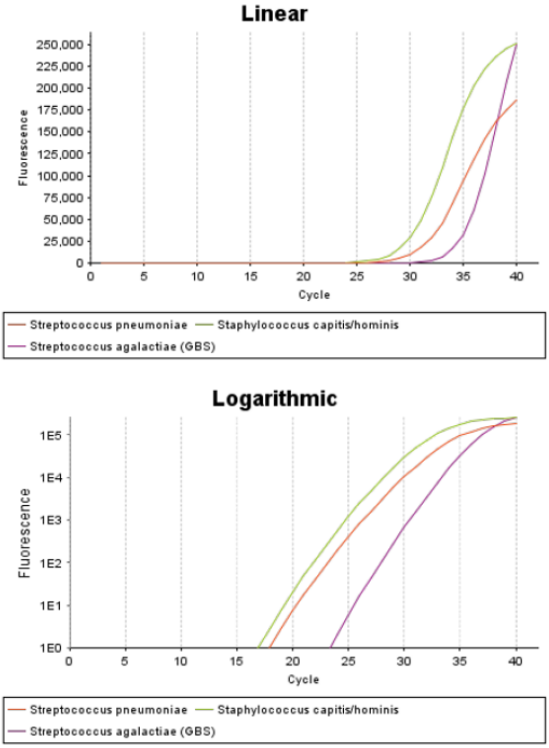

Figure 23. Sample test report showing assay data.

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 GPF 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.
- This assay cannot be run on positive charcoal blood culture bottles.
- Samples in bioMérieux and Becton Dickinson media require dilution prior to loading into the cartridge.
- Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx BCID GPF Plus AMR Panel. The agent detected may not be the definitive cause of the disease.
- The QIAstat-Dx BCID GPF Plus AMR Panel provides qualitative results and does not provide a quantitative value for detected organisms.
- Negative results for targeted microorganisms or antimicrobial resistance genes do not preclude the presence of pathogens or resistance genes that are not detected by this test.
- A negative result with the QIAstat-Dx BCID GPF 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. False negative assay results may originate from several factors and their combinations, including improper specimen collection, 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, organism levels of included organisms that are below the limit of detection for the assay, or use of certain medications, therapies, or agents by the patient.
- The QIAstat-Dx BCID GPF Plus AMR Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping, and/or antimicrobial susceptibility testing where applicable.
- All identification results from the QIAstat-Dx BCID GPF Plus AMR Panel should be interpreted alongside the Gram stain findings from the positive blood culture. The QIAstat-Dx BCID GPF Plus AMR Panel is indicated to be used on positive blood culture samples identified via Gram stain as Gram-positive bacteria/fungi. Gram stain result, including cellular morphology (such as gram-positive cocci in clusters, pairs, or chains) must be considered in correlation with the panel results.
- Results from the QIAstat-Dx BCID GPF 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 GPF Plus AMR Panel can be used with QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0.
- The QIAstat-Dx BCID GPF Plus AMR Panel is a qualitative assay and does not provide a quantitative value for detected organisms.
- Bacterial and fungal nucleic acids may persist in vivo, even if the organism is not viable or infectious, leading to false positive results. Detection of a target marker does not imply that the corresponding organism is the causative agent of the infection or the clinical symptoms.
- Detection of bacterial and fungal nucleic acids depends on proper sample collection, handling, transportation, storage, and loading into the QIAstat-Dx BCID GPF Plus AMR Panel Cartridge. Failure to observe proper procedures in any of these steps could lead to incorrect results.
- Isolation on solid media is needed to differentiate mixed growth with other microorganisms and to identify possible blood cultures yielding a negative device result.
- The performance of this test for bottle culture samples 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 on page 69).
- The QIAstat-Dx BCID GPF Plus AMR Panel contains targets designed to detect but not differentiate certain species. Mixed cultures with species belonging to the same target cannot be identified in a specimen (e.g. *S. hominis* and *S. capitis,* or *C. albicans* and *C. tropicalis*).
- Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the QIAstat-Dx BCID GPF Plus AMR Panel antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates is required to determine antimicrobial susceptibility.
- 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 GPF Plus AMR Panel does not specifically attribute antibiotic resistance genes to a specific organism.
- In mixed cultures, the assay may not identify all detectable organisms in the specimen, depending upon the concentration of each target present, as well as growth characteristics of each bacteria or fungi in the sample.

- Competitive inhibition has been observed for certain pathogens in mixed cultures (see Section 13.1.9 on page 131) for combinations tested in Competitive Inhibition).
- In silico analysis has shown potential cross-reaction of *Listeria innocua* with the *Listeria monocytogenes* assay and *Streptococcus periodonticum* with the *Streptococcus anginosus* assay.
- *Micrococcus luteus,* a panel target organism, was shown to cross-react with the *Corynebacterium* assay, generating a false positive signal for *Corynebacterium*. Additional off-panel microorganisms, including *Ochrobactrum anthropi* and *Bacteroides ureolyticus* (also known as *Campylobacter ureolyticus*) were found to cross-react with the *Corynebacterium* assay, generating a false positive signal for *Corynebacterium*.
- *Staphylococcus caprae* and *Staphylococcus epidermidis* (on-panel organism) have shown cross-reactivity with the *S. capitis/hominis* assay generating a false positive signal for *S. capitis/hominis*. Other staphylococcal microorganisms such as *S. debuckii* and *S. piscifermentans* exhibited potential in silico cross-reactivity with the *S. capitis/hominis* assay, and could potentially generate a false positive signal for *S. capitis/hominis*.
- Several genetically related species to the *Corynebacterium* genus – including *Cutibacterium acnes, Priopionibacterium/Cutibacterium granulosum, Mycobacterium tuberculosis, Rhodococcus equi, Rhodococcus fascians, Rothia dentocariosa, Rothia mucilaginosa* and *Lawsonella clevelandensis* – have demonstrated cross-reactivity with the *Corynebacterium* assay, generating a false positive signal for *Corynebacterium*.
- *Enterococcus lactis* was shown to cross-react with the *Enterococcus faecium* assay, generating a false positive signal for *Enterococcus faecium*.
- Organism and amplicon contamination may produce erroneous results for this test. Particular attention should be given to the Laboratory Precautions noted under the "Laboratory Precautions" section.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids, or the amplified product, or from non-specific signals in the assay.
- There is a risk of false negative results due to the presence of strains with sequence variability in the target regions of the oligonucleotides design. Refer to the “Inclusivity (analytical reactivity)” section of this document for additional information.
- 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 the “Interfering Substances” section of this Instruction for Use can lead to erroneous results.

- Cross-reactivity with bloodstream infection organisms other than those listed in the "Analytical Specificity" section of this Instructions for Use may lead to erroneous results.
- The performance of this test has not been established for monitoring treatment of infection with any of the panel organisms.
- The in silico analyses predicting detection and cross-reactivity of organisms and antimicrobial resistance genes were based on comparisons between CARD Database (McMaster University) and GenBank (NCBI) target sequences and QIAstat-Dx BCID GPF Plus AMR Panel primers. These analyses were conducted in September 2025, and sequences added after this date have not been evaluated. Additional limitations may arise as new sequence data are deposited or novel variants emerge.
- The genus level and group assays included as a part of the QIAstat-Dx BCID GPF Plus AMR Panel (*Bacillus cereus* group, *Candida* group 1 and 2, *Corynebacterium, Fusarium, Micrococcus* spp., Pan Gram negative, and *Streptococcus anginosus* group), 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, please refer to the "Inclusivity (analytical reactivity)" section.
- Inclusivity testing demonstrated that the QIAstat-Dx BCID GPF 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 the "Inclusivity (analytical reactivity)" section for further details.
- Inclusivity testing demonstrated that the QIAstat-Dx BCID GPF Plus AMR Panel may have reduced sensitivity for some AMR variants, and 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 the "Inclusivity (analytical reactivity)" section for further details.
- For certain *Candida* species encompassed within the panel, such as *Candida famata,* successful growth could not be established at the point of bottle positivity during continuous-monitoring blood bottle incubation at 37°C for 5 days.

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 GPF Plus AMR Panel. Each bacterium or fungus present in the QIAstat-Dx BCID GPF Plus AMR Panel was represented by a single 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 GPF 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 7. The concentrations listed below indicate approximate levels that may typically occur in a clinical setting. All estimated concentrations at bottle positivity are higher than the established Limit of Detection (LoD).

Table 7. 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)
Streptococcus agalactiae	ATCC 12401	*Streptococcus agalactiae* (GBS)	3.02E+08	7.47E+08

Table 7. 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)
Streptococcus anginosus	CCUG 27298	*Streptococcus anginosus* group	4.38E+07	7.50E+07
Enterococcus faecalis	ARBANK-0786	*Enterococcus faecalis [aac (6')-aph("'), vanB]*	6.78E+08	2.86E+09
Enterococcus faecium	NCTC 12204	*Enterococcus faecium [tetM, vanA]*	1.06E+09	1.60E+09
Staphylococcus lugdunesis	CCUG 71098	*Staphylococcus lugdunensis*	1.28E+07	5.45E+08
Listeria monocytogenes	CCUG 67296	*Listeria monocytogenes*	9.63E+07	7.28E+08
Candida albicans	ATCC 10231	*Candida* spp. group 1	1.59E+05	3.71E+07
Candida glabrata	ATCC 15126	*Candida* spp. group 2	1.20E+06	1.44E+08
Staphylococcus capitis	CCUG 42761	*Staphylococcus capitis/hominis*	3.60E+06	3.45E+09
Corynebacterium striatum	ATCC 43735	*Corynebacterium*	1.20E+08	1.29E+09
Staphylococcus aureus	ATCC BAA-1556	*Staphylococcus aureus [ermC, mecA, tetK]*	1.78E+06	1.03E+08
Staphylococcus epidermis	ATCC 35984	*Staphylococcus epidermidis [aac(6')-aph (2"), mecA, ermA]*	5.50E+06	1.57E+09
Streptococcus pyogenes	ATCC 12384	*Streptococcus pyogenes* (GAS)	7.37E+08	2.28E+07
Acinetobacter baumannii	NCTC 13302	Pan Gram Neg	2.17E+08	4.16E+08
Staphylococcus epidermis	PA212221	*Staphylococcus epidermidis [aac(6')-aph (2"), mecA, cfr]*	5.17E+07	5.65E+08
Staphylococcus aureus	ATCC BAA-2313	*Staphylococcus aureus [mecC]*	6.45E+06	4.33E+08
Bacillus cereus	ATCC 21769	*Bacillus cereus* group	2.78E+08	4.23E+06
Micrococcus luteus	NCTC 2665	*Micrococcus* spp.	2.17E+08	2.01E+08

Table 7. 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)
Cryptococcus gattii	ATCC MYA-4071	*Cryptococcus neoformans/gattii*	1.78E+06	1.62E+07
Streptococcus pneumoniae	CCUG 70149	*Streptococcus pneumoniae*	6.67E+07	n/a †
Fusarium proliferatum	NCPF 7484	*Fusarium*	8.10E+04	4.83E+06
Candida auris	NCPF 8971	*Candida auris*	8.08E+06	7.27E+07

† This pathogen was tested twice as enumeration at 27h could not be performed the first time. Enumeration was again unsuccessful, and no growth was observed during repetition. Reduced viability of *S. pneumoniae* is expected at 24+ hours following positivity due to cell autolysis.

13.1.2. Pure colony detection

The Pure colony detection study was executed to verify that the QIAstat-Dx BCID GPF 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 GPF 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, e.g. SDA) 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 GPF 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 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 GPF Plus AMR Panel to demonstrate that it can detect targets at positive bottle concentrations across different bottle types.

Thirteen (13) 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 GPF 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 8.

Table 8. Bottle equivalency results summary

	Proportion of positive calls		
Blood culture bottle information	**Hits**	**N**	**Percentage (%) (2-sided 95% Confidence Interval)**
BD BACTEC Plus Aerobic	199	200	99.5 (97.3–100)
BD BACTEC Plus Anaerobic	150	150	100.0 (97.6–100)
BD BACTEC Standard Aerobic	198	200	99.0 (96.4–99.9)
BD BACTEC Standard Anaerobic	138	143	96.5 (92.0–98.9)
BD BACTEC Peds Plus	198	200	99.0 (96.4–99.9)
BD BACTEC Lytic Anaerobic	154	158	97.5 (93.7–99.3)

Table 8. Bottle equivalency results summary (continued)

	Proportion of positive calls		
Blood culture bottle information	**Hits**	**N**	**Percentage (%) (2-sided 95% Confidence Interval)**
BioMérieux BACT/ALERT SA Standard Aerobic	200	200	100.0 (98.2–100)
BioMérieux BACT/ALERT SN Standard Anaerobic	187	189	98.9 (96.2–99.9)
BioMérieux BACT/ALERT FA PLUS Aerobic	199	200	99.5 (97.2–100)
BioMérieux BACT/ALERT FN PLUS Anaerobic	133	134	99.3 (96.0–100)
BioMérieux BACT/ALERT PF PLUS Peds	201	201	100.0 (98.2–100)
Thermo Scientific Versatrek Redox 1	184	184	100.0 (98.0–100)
Thermo Scientific Versatrek Redox 2 EZ Draw Anaerobic	182	184	98.9 (96.1–99.9)
Overall	2323	2343	99.2
Overall BD BACTEC	1037	1051	98.8
Overall BioMérieux BACT/ALERT	920	924	99.7
Overall Thermo Scientific Versatrek	366	368	99.5

13.1.4. Agar equivalency and interference

The QIAstat-Dx BCID GPF 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 9.

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 GPF Plus AMR Panel performance.

Table 9. Agar equivalency results summary

		Percentage hit rate summary (%)						
Pathogen (Source ID)	**Target(s)**	**Columbia blood agar**	**Rice agar**	**Chocolate agar & 1% polyvitex**	**TSA II**	**Fastidious anaerobe Agar**	**Chromagar candida**	**Sabouraud dextrose agar**
Streptococcus agalactiae (ATCC 12401)	*Streptococcus agalactiae*	100	N/A	100	N/A	100	N/A	N/A
Streptococcus anginosus (CCUG 27298)	*Streptococcus anginosus*	100	N/A	100	N/A	100	N/A	N/A
Enterococcus faecalis (ATCC 51299)	*Enterococcus faecalis* *aac(6')-aph(2")* *vanB*	100	N/A	100	100	100	N/A	N/A
Enterococcus faecium (NCTC 12204)	*Enterococcus faecium* *vanA* *tetM*	100	N/A	100	100	100	N/A	N/A
Staphylococcus lugdunensis (CCUG 71098)	*Staphylococcus lugdunensis*	100	N/A	100	100	100	N/A	N/A
Listeria monocytogenes (CCUG 67296)	*Lysteria monocytogenes*	100	N/A	100	100	100	N/A	N/A
Candida albicans (ATCC 10231)	*Candida* Group 1	100	100	N/A	N/A	N/A	100	100%
Candida auris (NCPF 8971)	*Candida auris*	100	100	N/A	N/A	N/A	100	100%

Table 9. Agar equivalency results summary (continued)

		Percentage hit rate summary (%)						
Pathogen (Source ID)	**Target(s)**	**Columbia blood agar**	**Rice agar**	**Chocolate agar & 1% polyvitex**	**TSA II**	**Fastidious anaerobe Agar**	**Chromagar candida**	**Sabouraud dextrose agar**
Staphylococcus capitis CCUG 42761)	*Staphylococcus capitis/hominis*	100	N/A	100	100	100	N/A	N/A
Corynebacterium striatum (ATCC 43735)	*Corynebacterium*	100	N/A	100	100	N/A	N/A	N/A
Staphylococcus aureus (ATCC BAA-1556)	*Staphylococcus aureus* *mecA* *ermC* *tetK*	100	N/A	100	100	100	N/A	N/A
Staphylococcus epidermis (ATCC 35984)	*Staphylococcus epidermis*	100	N/A	100	100	100	N/A	N/A
Streptococcus pyogenes (ATCC 12384)	*Streptococcus pyogenes*	100	N/A	100	N/A	100	N/A	N/A
Acinetobacter baumanii (NCTC13302)	Pan Gram Neg	100	N/A	100	100	100	N/A	N/A
Staphylococcus aureus (t011-ST398/CC398)	*Staphylococcus aureus* *cfr* *tetM* *tetK* *mecA*	100	N/A	100	100	100	N/A	N/A
Staphylococcus aureus (ATCC BAA-2313)	*Staphylococcus aureus* *mecC*	100	N/A	100	100	100	N/A	N/A

Table 9. Agar equivalency results summary (continued)

		Percentage hit rate summary (%)						
Pathogen (Source ID)	**Target(s)**	**Columbia blood agar**	**Rice agar**	**Chocolate agar & 1% polyvitex**	**TSA II**	**Fastidious anaerobe Agar**	**Chromagar candida**	**Sabouraud dextrose agar**
Bacillus cereus (ATCC21769)	*Bacillus cereus* group	100	N/A	100	100	100	N/A	N/A
Micrococcus luteus (CCUG 48508)	*Micrococcus* spp.	100	N/A	100	100	N/A	N/A	N/A
Cryptococcus gattii (ATCC MYA-4071)	*Cryptococcus* spp.	100	100	N/A	N/A	N/A	100	100
Streptococcus pneumoniae (CCUG 70149)	*Streptococcus pneumoniae*	100	N/A	100	N/A	100	N/A	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 GPF Plus AMR Panel target pathogenic organisms was assessed, using a total of 56 pathogen strains, by analyzing serial dilutions of analytical samples prepared from culture isolates from commercial suppliers (e.g., ATCC, NCTC, CCUG), or confirmed clinical isolates.

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 also tested in 20 replicates and was required to result in less than 95% positivity.

Individual LoD values for each QIAstat-Dx BCID GPF Plus AMR Panel target are shown in Table 10.

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 10. Limit of Detection results summary

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
		Microorganism		
Bacillus cereus	*Bacillus cereus*	ATCC 21769	6.11E+05	1.50E+06
	Bacillus thuringiensis	ATCC 35646	1.54E+04	1.50E+05
Candida auris	*Candida auris*	NCPF 8971	1.74E+06	1.00E+07
	Candida auris	CBS 14144	2.17E+06	N/A
	Candida auris	NCPF 8977	N/A	1.00E+07
Candida spp. Group 1	*Candida tropicalis*	ATCC 750	8.50E+04	1.50E+06
	Candida dublinensis	NCPF 8516	3.88E+06	1.58E+06
	Candida famata	CBS 767	6.25E+06	1.58E+06
	Candida guillermondi	NCPF 3896	4.75E+05	1.00E+06
	Candida kefyr	NCPF 8343	1.25E+06	4.74E+05
	Candida albicans	ATCC 10231	6.74E+05	1.58E+06

Table 10. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
Candida spp. Group 2	*Candida lusitaniae*	NCPF 3968	4.83E+06	1.50E+06
	Candida glabrata	ATCC 15126	2.07E+05	1.50E+05
	Candida krusei	ATCC 32196	4.37E+04	1.50E+05
	Candida parapsilosis	ATCC 58895	1.55E+05	1.50E+04
Corynebacterium	*Corynebacterium striatum*	ATCC 43735	7.12E+05	3.00E+07
	Corynebacterium jeikeium	ATCC BAA-949	3.84E+06	1.64E+08
Cryptococcus	*Cryptococcus neoformans*	ATCC 208821	1.00E+03	1.00E+04
	Cryptococcus gattii	ATCC MYA-4071	1.00E+04	1.00E+03
Enterococcus faecalis	*Enterococcus faecalis*	ATCC 51299	5.00E+05	4.50E+06
	Enterococcus faecalis	NCTC 13780	5.03E+04	3.63E+05
Enterococcus faecium	*Enterococcus faecium*	NCTC 12204	4.30E+04	4.00E+05
	Enterococcus faecium	ATCC 51858	1.36E+04	4.00E+05
	Enterococcus faecium	ATCC BAA-2316	N/A	4.00E+04
Fusarium	*Fusarium oxysporum*	CBS 267.50	4.83E+03	N/A
	Fusarium proliferatum	NCPF 7484	1.06E+04	N/A
Listeria monocytogenes	*Listeria monocytogenes*	ATCC 19115	6.50E+03	6.50E+03
	Listeria monocytogenes	CCUG 67296	3.58E+04	3.25E+04

Table 10. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
Micrococcus spp.	*Micrococcus yunnanensis*	CCUG 59864	5.50E+05	9.51E+06
	Micrococcus luteus	NCTC 2665	2.89E+04	N/A
	Micrococcus luteus	NCTC 7011	N/A	3.00E+07
Pan Gram Neg	*Acinetobacter baumannii*	NCTC 13302	1.39E+06	5.25E+05
	Eschericchia coli	ATCC BAA 196	4.04E+06	5.25E+06
Streptococcus agalactiae	*Streptococcus agalactiae*	ATCC 12401	3.00E+05	6.00E+04
	Streptococcus agalactiae	NCTC 8181	1.50E+05	≤6.00E+05*
Streptococcus anginosus group	*Streptococcus anginosus*	CCUG 27298	4.81E+04	9.50E+04
	Streptococcus intermedius	ATCC 27335	8.76E+02	9.50E+05
Staphylococcus capitis/hominis	*Staphylococcus capitis*	CCUG 42761	7.70E+04	4.00E+06
	Staphylococcus hominis	CCUG 42399T	3.87E+03	4.00E+05
Staphylococcus epidermidis	*Staphylococcus epidermidis*	ATCC 35983	1.00E+04	1.00E+06
	Staphylococcus epidermidis	NCTC 13360	2.41E+04	3.00E+05
	Staphylococcus epidermidis	ATCC 35984	3.41E+04	3.00E+06
	Staphylococcus epidermidis	PA212221	1.32E+05	3.00E+06
Staphylococcus lugdunensis	*Staphylococcus lugdunensis*	CCUG 71098	1.50E+03	2.00E+06
	Staphylococcus lugdunensis	ATCC 49576	1.00E+05	2.00E+05

Table 10. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
Streptococcus pneumoniae	*Streptococcus pneumoniae*	ATCC 700672	7.00E+02	7.00E+04
	Streptococcus pneumoniae	CCUG 70149	7.00E+03	7.00E+04
Streptococcus pyogenes	*Streptococcus pyogenes*	ATCC 12384	1.00E+05	1.00E+05
	Streptococcus pyogenes	CCUG 74645	1.00E+04	1.00E+05
Staphylococcus aureus	*Staphylococcus aureus*	t011-ST398/CC398	4.75E+03	1.65E+05
	Staphylococcus aureus	ATCC BAA-2313	4.75E+03	1.65E+05
	Staphylococcus aureus	ATCC 33591	4.75E+02	6.25E+05
	Staphylococcus aureus	NCTC 13552	4.75E+02	1.00E+05
	Staphylococcus aureus	ATCC 43300	N/A	9.00E+05
	Staphylococcus aureus	ATCC BAA-1556	N/A	2.48E+07
Antimicrobial Resistance Marker				

Table 10. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
aac (6')-aph(2")	*Enterococcus. faecalis*	ATCC 51299	5.00E+05	4.50E+06
	Enterococcus faecalis	NCTC 13780	5.03E+04	3.63E+05
	Enterococcus faecalis	ATCC BAA-2365	N/A	3.63E+05
	Enterococcus faecium	ATCC BAA-2316	N/A	4.00E+05
	Enterococcus faecium	ATCC 51858	N/A	4.00E+05
	Staphylococcus aureus	ATCC 43300	N/A	9.00E+05
	Streptococcus epidermidis	PA212221	1.32E+05	3.00E+06
	Streptococcus epidermidis	ATCC 35984	3.41E+04	3.00E+06
	Streptococcus epidermidis	ATCC 35983	1.00E+04	1.00E+06
	Staphylococcus hominis	CCUG 42399T	3.87E+04	4.00E+05
cfr	*Staphylococcus aureus*	t011-ST398/CC398	4.75E+03	1.65E+05
	Streptococcus epidermidis	PA212221	1.32E+05	3.00E+06
ermA	*Staphylococcus aureus*	ATCC 33591	4.75E+02	6.25E+05
	Staphylococcus aureus	ATCC 43300	N/A	9.00E+05
	Streptococcus epidermis	ATCC 35984	3.41E+04	3.00E+06

Table 10. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
ermC	*Staphylococcus aureus*	ATCC BAA-1556	N/A	3.71E+07
	Streptococcus epidermidis	ATCC 35983	1.00E+04	1.00E+07
	Staphylococcus hominis	CCUG 42399T	3.87E+03	4.00E+06
mecA	*Staphylococcus aureus*	t011-ST398/CC398	4.75E+03	1.65E+05
	Staphylococcus aureus	ATCC 33591	4.75E+03	6.25E+05
	Staphylococcus aureus	ATCC 43300	N/A	9.00E+05
	Streptococcus epidermidis	ATCC 35983	1.00E+04	1.00E+06
	Streptococcus epidermidis	ATCC 35984	3.41E+04	3.00E+06
	Streptococcus epidermidis	PA212221	1.32E+05	3.00E+06
	Staphylococcus hominis	CCUG 42399T	3.87E+04	4.00E+05
mecC	*Staphylococcus aureus*	ATCC BAA-2313	4.75E+03	1.65E+06
	Staphylococcus aureus	NCTC 13552	4.75E+02	1.00E+05
tetK	*Staphylococcus aureus*	t011-ST398/CC398	4.75E+03	1.65E+05
	Staphylococcus aureus	ATCC 33591	4.75E+03	6.25E+05
	Streptococcus epidermidis	NCTC 13360	2.41E+04	3.00E+05

Table 10. Limit of Detection results summary (continued)

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)	LoD concentration PC (CFU/mL)
tetM	*Enterococcus faecalis*	NCTC 13780	5.03E+05	3.63E+05
	Enterococcus faecium	ATCC BAA-2316	N/A	4.00E+05
	Staphylococcus aureus	t011-ST398/CC398	1.50E04	1.65E+06
	Staphylococcus aureus	ATCC 33591	4.75E+03	6.25E+06
	Streptococcus pneumoniae	ATCC 700672	N/A	2.21E+06
vanA	*Enterococcus faecalis*	NCTC 13780	5.03E+04	3.63E+05
	Enterococcus faecium	NCTC 12204	4.30E+04	4.00E+05
	Enterococcus faecium	ATCC BAA-2316	N/A	4.00E+04
vanB	*Enterococcus faecalis*	ATCC 51299	5.00E+05	4.50E+06
	Enterococcus faecalis	ATCC BAA-2365	N/A	3.63E+05
	Enterococcus faecium	ATCC 51858	1.36E+05	4.00E+05

* LoD could not be established for this strain. LoD is determined to be equal or lower than 6.00E+05 CFU/mL

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 GPF 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 >8.0E+06 CFU/mL.

Cross-reactivity with the on-panel targets was observed for *Micrococcus luteus* (NCTC 2665) in the *Corynebacterium* assay. The on-panel organisms tested are shown in Table 7 and Table 13, tested as part of the Growth and Detection and Analytical Reactivity respectively.

Several off-panel microorganisms showed cross-reactivity with the *Corynebacterium, Enterococcus faecium,* and *Staphylococcus capitis/hominis* assay. The off-panel organisms tested are shown in Table 11 (see footnotes for further information regarding cross-reactions).

Table 11. Summary of cross-reactivity results of off-panel targets

Pathogen	Source ID	Pathogen	Source ID
Acinetobacter junii	CCUG 889	*Neisseria lactamica*	CCUG 5853
Actinomyces odontolyticus	CCUG 20536	*Neisseria mucosa*	CCUG 26877
Aerococcus sanguinicola	CCUG 43001	*Ochrobactrum anthropi**	CCUG 64950
Aerococcus urinae	ATCC 51268	*Pediococcus acidilactici*	CCUG 32235
Aerococcus viridans	CCUG 4311	*Pediococcus pentosaceus*	CCUG 32205
Anaerococcus prevotii	NCTC 11806	*Penicillium/ Talaromyces marneffei* (gDNA ONLY)	CBS 549.77
Arcanobacterium haemolyticum	NCTC 8452	*Peptostreptococcus anaerobius*	CCUG 7835
Bacillus amyloliquefaciens	CCUG 28519	*Prevotella oralis*	CCUG 15408
Bacillus atrophaeus	CCUG 11738	*Propionibacterium propionicum*	CCUG 4939
Bacillus badius	CCUG 7412	*Providencia rettgeri*	CCUG 14804
Bacillus licheniformis	CCUG 7422	*Pseudomonas putida*	NCTC 10936
Bacillus pumilus	CCUG 3273	*Raoultella ornithinolytica*	NCTC 13096
Bacillus subtilis	ATCC 6051	*Rhodococcus equi*†	CCUG 892
Bacteroides distasonis (Parabacteroides)	CCUG 4941	*Rhodococcus fascians*†	CCUG 51073T
Bacteroides eggerthii	CCUG 9559	*Rhodotorula glutinis*	CCUG 53432
Bacteroides ovatus	CCUG 4943	*Rhodotorula minuta*	NCPF 8736
Bacteroides ureolyticus (aka. *Campylobacter ureolyticus*)*	CCUG 59288	*Rhodotorula mucilaginosa*	NCPF 8529
Brochothrix thermosphacta	CCUG 35132	*Rothia dentocariosa*†	CCUG 35437
Burkholderia cepacian	NCTC 10743	*Rothia mucilaginosa*†	CCUG 20962

Table 11. Summary of cross-reactivity results of off-panel targets (continued)

Pathogen	Source ID	Pathogen	Source ID
Candida lambica	NCPF 8835	*Saccharomyces cerevisiae*	NCPF 8313
Candida lipolytica	NCPF 8722	*Shigella boydii*	CCUG 49022
Candida metapsilosis	NCPF 8791	*Shigella sonnei*	CCUG 68726
Candida orthopsilosis	NCPF 8804	*Staphylococcus arlettae*	CCUG 32416
Candida pelliculosa/Wickerhamomyces	CBS 605	*Staphylococcus auricularis*	CCUG 15601
Candida/Wickerhamiella rugosa	CBS 1948	*Staphylococcus carnosus*	CCUG 15605
Candida sake	CCUG 28104	*Staphylococcus chromogenes*	CCUG 4319
Candida utilis	NCPF 8743	*Staphylococcus cohnii*	CCUG 35144
Carnobacterium divergens	CCUG 30094	*Staphylococcus gallinarum*	CCUG 28809
Carnobacterium maltaromaticum	CCUG 30142	*Staphylococcus haemolyticus*	CCUG 7323
Cellulosimicrobium cellulans	CCUG 50776	*Staphylococcus hycius*	CCUG 6509
Cellulomonas turbata	LMG 4072	*Staphylococcus intermedius*	CCUG 6520
Clostridium clostridioforme	ATCC 25537	*Staphylococcus lentus*	CCUG 15599
Clostridium perfringens	NCTC 6719	*Staphylococcus muscae*	CCUG 36972
Propionibacterium/Cutibacterium acnes†	NCTC 737	*Staphylococcus pasteuri*	CCUG 32420
Priopionibacterium/Cutibacterium granulosum†	CCUG 32987	*Staphylococcus pettenkoferi*	CCUG 51270
Enterobacter cowanii	CCUG 45998	*Staphylococcus pseudintermedius*	ATCC 49051
Enterococcus avium	CCUG 7983	*Staphylococcus saccharolyticus*	CCUG 24040
Enterococcus casseliflavus	CCUG 18657	*Staphylococcus saprophyticus*	CCUG 3706
Enterococcus cecorum	CCUG 27299	*Staphylococcus schleiferi*	CCUG 37248
Enterococcus dispar	CCUG 33309	*Staphylococcus sciuri*	CCUG 15598
Enterococcus durans	CCUG 7972	*Staphylococcus simulans*	CCUG 7327
Enterococcus gallinarum	CCUG 18658	*Staphylococcus vitulinus*	CCUG 33938
Enterococcus hirae	CCUG 18659	*Staphylococcus warneri*	CCUG 7325
Enterococcus italicus	CCUG 47860	*Staphylococcus warneri*	NCTC 11044

Table 11. Summary of cross-reactivity results of off-panel targets (continued)

Pathogen	Source ID	Pathogen	Source ID
Enterococcus lactis‡	LMG 25958	*Staphylococcus xylosus*	CCUG 70257
Enterococcus malodoratus	CCUG 30572	*Streptococcus canis*	CCUG 27661
Enterococcus pseudoavium	CCUG 33310T	*Streptococcus criceti*	CCUG 27300
Enterococcus raffinosus	ATCC 49427	*Streptococcus dysgalactiae*	LMG 16026
Enterococcus saccharolyticus	CCUG 27643	*Streptococcus equi*	CCUG 23256
Erysipelothrix rhusiopathiae	CCUG 221	*Streptococcus equinus*	CCUG 27302
Gemella haemolysans	CCUG 37985	*Streptococcus gallolyticus*	CCUG 46101
Gemella morbillorum	CCUG 15561	*Streptococcus gordonii*	CCUG 33482
Geotrichum capitatum (Blastoschizomyces capitatus)	NCPF 3417	*Streptococcus infantarius*	CCUG 43820
Granulicatella adiacens	CCUG 27809	*Streptococcus infantis*	CCUG 39817
Granulicatella elegans	CCUG 38949	*Streptococcus mitis*	CCUG 31611
Kingella kingae	CCUG 352	*Streptococcus oralis*	CCUG 13229
Kocuria kristinae	CCUG 33026	*Streptococcus parasanguinis*	CCUG 30417
Kocuria rhizophila	LMG 8816	*Streptococcus peroris*	CCUG 39814
Kytococcus sedentarius	CCUG 33030	*Streptococcus pseudopneumoniae*	CCUG 49455
Lactobacillus zeae	CCUG 35515	*Streptococcus salivarius*	CCUG 50207T
Lactococcus garvieae	CCUG 32208	*Streptococcus sanguinis*	CCUG 17826
Lactococcus lactis subsp.	CCUG 31342	*Streptococcus thoraltensis*	CCUG 32906
Lawsonella clevelandensis†	CCUG 66657	*Trichosporon asahii* (mould)	CCUG 57655
Leuconostoc carnosum	CCUG 30059	*Trueperella bernardiae*	CCUG 33420
Leuconostoc citreum	CCUG 30058	*Vagococcus fluvialis*	CCUG 32704
Leuconostoc mesenteroides	CCUG 30066	*Vibrio parahaemolyticus*	NCTC 10903
Listeria ivanovii	CCUG 37344	*Weissella paramesenteroides*	CCUG 30068
Macrococcus caseolyticus (subsp. *Hominis*)	CCUG 15606 B	*Corynebacterium simulans*	CCUG 43305T

Table 11. Summary of cross-reactivity results of off-panel targets (continued)

Pathogen	Source ID	Pathogen	Source ID
Mycobacterium tuberculosis (gDNA ONLY)†	ATCC-25177	*Staphylococcus caprae*§	NCTC 12196

* Cross -reaction observed with the *Corynebacterium* assay, but not predicted in silico.

† Cross-reaction observed with the *Corynebacterium* assay and predicted in silico.

‡ Cross-reaction observed with the *Enterococcus faecium*assay and predicted in silico.

§ Cross-reaction observed with the *Staphylococcus capitis/hominis* assay and predicted in silico.

In addition, apart from the cross-reactions detected in vitro, in silico predictions showed that the following cross-reactions may occur (organisms not tested in vitro) (see Table 12).

Table 12. Potential cross-reactions based on in silico analysis

Potential cross-reactive organisms	Target in the QIAstat-Dx BCID GPF Plus AMR Panel
Listeria innocua	*Listeria monocytogenes*
Streptococcus periodonticum	*Streptococcus anginosus*
Staphylococcus debuckii, *Staphylococcus piscifermentans*	*Staphylococcus capitis/hominis*

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 GPF 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 GPF 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 *(Bacillus cereus* group, *Corynebacterium, Candida groups, Fusarium, Micrococcus* spp, *Staphylococcus hominis/capitis, Streptococcus anginosus* group and Pan Gram Negative assay), at least 5 strains were tested in total. As an exception, AMR genes *cfr, ermC,* and *vanB* were tested in less than 5 strains because of samples availability. By default, testing was performed by spiking 5 pathogens in the same sample mix. First, all assays included in the QIAstat-Dx BCID GPF Plus AMR Panel intended to detect presence of organisms were evaluated. All strains

described in Table 13 were tested in triplicates at the initial concentration near LoD. 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 13. Summary of pathogen inclusivity results

Target	Species	Source ID	Strain name/ Designation	Result
Bacillus cereus group	*Bacillus cereus*	ATCC 21769 *	Frankland and Frankland. SP-2	Detected
	Bacillus thuringiensis	ATCC 35646 *	Berliner. USDA HD522	
	Bacillus cereus	NCTC 10320	Frankland and Frankland 1887 (AL). PCI 213	
	Bacillus cereus	NCTC 2599	Frankland and Frankland 1887 (AL). 13, 971, Ford 13, Gibson 971	
	Bacillus thuringiensis	CCUG 7429T	Berliner. NRS-996	
	Bacillus cereus	CCUG 36593	N/A	Not detected. Predicted to be detected in silico.
	Bacillus mycoides	NCTC 926	FLUGGE 1886. CR ii Rothamsted	Not detected. In silico analysis predicted only a 18.33% of detection.
Candida auris	*Candida auris*	CBS 12372	N/A	Detected
	Candida auris	CBS 14144*	N/A	
	Candida auris	NCPF 8971*	N/A	
	Candida auris	NCPF 8977	N/A	
	Candida auris	NCPF 8984	N/A	Detected with reduced sensitivity (5.22E+07 CFU/mL) †

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Candida spp. Group 1	*Candida dubliensis*	NCPF 8516*	N/A	Detected
	Candida kefyr	NCPF 8343*	(Beijerinck) van Uden et Buckley	
	Candida albicans	ATCC 10231*	(Robin) Berkhout. 3147	
	Candida guilliermondii	NCPF 3896*	N/A	
	Candida tropicalis	ATCC 750*	(Castellani) Berkhout. [1909, ATCC 4563, ATCC 7349, CBS 94, CCRC 20520, IFO 1070, IFO 1400, JCM 1541, NRRL Y-12699, NRRL Y-12968, NRRL Y-607]	
	Candida famata (Debaryomyces. hansenii)	CBS 767*	(Zoph) Lodder et Kreger-van Rij	Detected with reduced sensitivity (6.25E+06 CFU/mL) §

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Candida spp. Group 2	*Candida glabrata*	ATCC 15126*	(Anderson) Sugita et Takash. Mutant TMAGR-23 [CBS 15126, NRRL Y-17770]	Detected
	Candida glabrata	ATCC 2001	(Anderson) Sugita et Takash. CBS 138	
	Candida krusei	ATCC 32196*	(Castellani) Berkhout. RIFY E-17 [CBS 6799, CCY 29-109-1, IFO 1664, NBRC 1664, VTT C-79090]	
	Candida krusei	NCPF 3930	N/A	
	Candida lusitaniae	CCUG 69483	N/A	
	Candida lusitaniae	NCPF 3968*	N/A	
	Candida parapsilosis	ATCC 58895*	(Ashford) Langeron et Talice. IJFM 6044 [CBS 8181]	
	Candida parapsilosis	NCPF 3207	N/A	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Corynebacterium spp.	*Corynebacterium striatum*	ATCC 43735*	(Chester) Eberson. CDC E3794	Detected
	Corynebacterium amycolatum	CCUG 57527	Collins et al. 1988. CCUG 57527	
	Corynebacterium diphtheriae	CCUG 33629	(Kruse) Lehmann and Neumann. 48255	
	Corynebacterium falseni	ATCC BAA-596	Sjoden et al. BL 8171	
	Corynebacterium imitans	CCUG 36877	Funke et al. DMMZ 2023	
	Corynebacterium jeikeium	ATCC BAA-949*	Jackman et al. CJ12	
	Corynebacterium jeikeium	NCTC 11913	Jackman et al. 1988. D1076	
	Corynebacterium pseudotuberculosis	ATCC 43924	(Buchanan) Eberson. 2804	
	Corynebacterium ulcerans	ATCC 51799	Riegel et al. CCUG 2708 [NCTC 7910]	
	Corynebacterium urealyticum	ATCC 43044	Pitcher et al. 3 [Garcia strain]	
	Corynebacterium afermentans subsp. *Afermentans*	CCUG 32103	Riegel et al. 1993. CIP 103499 [LCDC 88199]	Detected with reduced sensitivity (1.52E+08 CFU/mL) †
	Corynebacterium coyleae	N/A	N/A	In vitro testing not performed. Predicted to be detected in silico

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Cryptococcus gattii/neoformans	*Cryptococcus gattii*	ATCC MYA-4071*	(Vanbreuseghem et Takashio) Kwon-Chung et Boekhout. WM 276	Detected
	Cryptococcus gattii	CCUG 43335	(Vanbreus. & Takashio) Kwon-Chung & Boekhout 2002	
	Cryptococcus neoformans	ATCC 208821*	(Sanfelice) Vuillemin by Hagen et al. (2015). H99 [H99JP, NYSD 1649, CBS8710]	
	Cryptococcus neoformans	ATCC 90112	Franzot et al. 7588/9.854 MCV 3 [NCCLS 88]	
	Cryptococcus neoformans	CCUG 23479	N/A	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Enterococcus faecalis	*Enterococcus faecalis*	NCTC 13780*	(Andrewes and Horder 1906) Schleifer and Kilpper-Bälz 1984. EC0014	Detected ¶
	Enterococcus faecalis	CCUG 19916	(Andrewes and Horder 1906) Schleifer and Kilpper-Bälz 1984. Tissier	
	Enterococcus faecalis	NCTC 12203	(Andrewes and Horder 1906) Schleifer and Kilpper-Bälz 1984. Original strain reference: No. 10	
	Enterococcus faecalis	ATCC 51299*	(Andrewes and Horder) Schleifer and Kilpper-Balz. NJ-3	
	Enterococcus faecalis	ATCC BAA-2365	(Andrewes and Horder) Schleifer and Kilpper-Balz	
	Enterococcus faecalis	ATCC 51575	(Andrewes and Horder) Schleifer and Kilpper-Balz. Taxo 239	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Enterococcus faecium	*Enterococcus faecium*	ATCC 51858*	(Orla-Jensen) Schleifer and Kilpper-Balz. Vancomycin-dependent #4	Detected**
	Enterococcus faecium	NCTC 12204*	(Orla-Jensen 1919) Schleifer and Kilpper-Bälz 1984. No. 14	
	Enterococcus faecium	JMI 1031982	N/A	
	Enterococcus faecium	CCUG 68933	N/A	
	Enterococcus faecium	ATCC BAA-2316	(Orla-Jensen) Schleifer and Kilpper-Balz	
	Enterococcus faecium	ATCC 51559	(Orla-Jensen) Schleifer and Kilpper-Balz. MMC4	
Fusarium	*Fusausarium oxysporum*	CBS 267.50*	Snyder et Hansen. CR 9	Detected
	Fusarium proliferatum	NCPF 7484*	N/A	
	Fusarium verticillioides	CBS 115135	(Saccardo) Nirenberg	
	Fusarium sacchari	CBS 134.73	(E.J. Butler) W. Gams	Detected with reduced sensitivity (1.44E+05 CFU/mL) ††
	Fusarium solani	NCPF 7483	N/A	Detected with reduced sensitivity (2.32E+05 CFU/mL) ††

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Listeria monocytogenes	*Listeria monocytogenes*	ATCC 19111	(Murray et al.) Pirie. Li 20	Detected ‡‡
	Listeria monocytogenes	ATCC 19115*	(Murray et al.) Pirie. Li 2	
	Listeria monocytogenes	CCUG 67296*	N/A	
	Listeria monocytogenes	NCTC 5105	(Murray et al. 1926) Pirie 1940 (AL). Li 22	
	Listeria monocytogenes	NCTC 5348	(Murray et al. 1926) Pirie 1940 (AL). Li 21	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Micrococcus spp	*Micrococcus luteus*	NCTC 196	(SCHROETER 1872) COHN 1872 (AL). Lister (Sarcina lutea)	Detected
	Micrococcus luteus	NCTC 2665*	(Schroeter 1872) Cohn 1872 (AL). [ATCC 15307, CCM 169, CIP A-270, IAM 1056, IFO 3333, NCIB 9278, NCTC 2665, NRRL B-287]	
	Micrococcus luteus	NCTC 7743	(Schroeter 1872) Cohn 1872 (AL). 130.21, FDA 16	
	Micrococcus yunnanensis	CCUG 59864*	(Schroeter 1872) Cohn 1872 (Approved Lists 1980).	
	Micrococcus luteus	NCTC 7011	(Schroeter 1872) Cohn 1872 (AL). HUTNER 2	Detected with reduced sensitivity (1.26E+07 CFU/mL) ‡
	Micrococcus lylae	CCUG 44721	N/A	Not detected §§
Pan Gram Neg	*Acinetobacter baumannii*	NCTC 13302*	N/A	Detected
	Bacteroidis fragilis	NCTC 8560	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL). WPMH 1	
	Brenneria alni	CCUG 48887T	(Surico et al. 1996) Hauben et al. 1999. PVFi20	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Cedecea davisae	NCTC 13724	Grimont et al. 1981 (VP). 005, CDC 3278-77	
	Chania multitudinisentens	LMG 28304	Ee et al. 2016. DSM 28811	
	Citrobacter koseri	ATCC 27156	Frederiksen. CDC 3613-63	
	Cronobacter sakazakii	ATCC 29004	(Farmer et al.) Iversen et al. CDC 3225-73 [ATCC 29003, CDC 74-011306]	
	Dickeya dadantii	LMG 25991	Samson et al. 2005. CFBP 1269; DSM 18020; Hayward B374; ICMP 1544; LMG 25991; NCPPB 898	
	Escherichia coli	CCUG 67180	NCTC 13476	
	Edwardsiella tarda	NCTC 10396	Ewing and McWhorter 1965 (AL). K 349, NCDC 1483-59	
	Enterobacter asburiae	ATCC 35955	Brenner et al. CDC 14-81	
	Erwinia aphidicola	ATCC 29919	Harada et al. CDC 5422-69	
	Erwinia billingiae	CCUG 50417	Mergaert et al. 1999	
	*Escherichia coli**	ATCC BAA 196	(Migula) Castellani and Chalmers. J53 pMG223	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Haemophilus influenzae	CCUG 33775	(Lehmann and Neumann) Winslow et al. AMC 36-A-1 [572]	
	Hafnia alvei	CCUG 59411	Møller 1954	
	Izhakiella capsodis	LMG 28431	Aizenberg-Gershtein et al. 2016. DSM 29292	
	Klebsiella pneumoniae	CCUG 68728	(Schroeter 1886) Trevisan 1887	
	Kluyvera cryocrescens	NCTC 10483	Farmer et al. 1981. 2367, No.4	
	Kosakonia quasisacchari	NCTC 14272	C. Wang et al. 2019. Original strain reference: WCHEs120001	
	Leclercia adecarboxylata	NCTC 13032	(Leclerc 1962) Tamura et al. 1987. 1783	
	Lelliota nimipressuralis	CCUG 69901	(Carter 1945) Brady et al. 2013	
	Neisseria meningitidis	CCUG 27650	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980). LNP 638	
	Obesubacterium proteus strain	CCUG 26658	(Shimwell and Grimes 1936) Shimwell 1963 (Approved Lists 1980)	
	Phytobacter diazotrophicus	CCUG 74074	N/A	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Phytobacter/ Metakosakonia massiliensis	CCUG 75195T	N/A	
	Phytopthora /Pectobacterium/Dickeya chrysanthemi	CCUG 47021	(Burkholder et al. 1953) Samson et al. 2005	
	Pluralibacter gergoviae	CCUG 33719	(Brenner et al. 1980) Brady et al. 2013	
	Pragia fontium	CCUG 23265	Aldová et al. 1988. CNCTC Eb11/82	
	Proteus mirabilis	ATCC BAA-2792	Hauser. 1104843	
	Providencia stuartii	CCUG 74678	N/A	
	Pseudomonas aeruginosa	ATCC BAA-2794	(Schroeter) Migula. 1079232	
	Rahnella aquatilis	CCUG 52909	Izard et al. 1981	
	Raoultella terrigena	NCTC 13038	Izard et al. 1981. CUETM 77.176	
	Salmonella enterica	ATCC 6962	(ex Kauffmann and Edwards) Le Minor and Popoff serovar Newport. NCTC 129	
	Scandinavium goeteborgensis	NCTC 14286	Type 2	
	Serratia liquefaciens	ATCC 27592	(Grimes and Hennerty) Bascomb et al. CDC 1284-57 [ATCC 12926]	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
	Shigella sonnei	CCUG 68726	(Levine 1920) Weldin 1927. I virulent	
	Shimwellia blattae	NCTC 12127	Burgess et al. 1973 (AL). CDC 9005-74	
	Stenotrophomonas maltophilia	NCTC 10498	(Hugh 1981) Palleroni and Bradbury 1993. RH 661-1	
	Tatumella ptyseos	NCTC 11468	Hollis et al. 1982. H36	
	Xenorhabdus nematophila	CCUG 14189T	(Poinar and Thomas) Thomas and Poinar	
	Yersinia enterocolitica subsp *enterocolitica*	NCTC 12982	(Schleifstein and Coleman 1939) Neubauer et al. 2000. 33114	
	Yokenella regensburgei	NCTC 12131	Kosako et al. 1985. CDC 3349-72	
	Pseudoescherichia, Sodalis, Gibbsiella, Limnobaculum, Lonsdalea, Chimaeribacter/Nissabacter and Obesumbacterium proteus	N/A	N/A	In vitro testing not performed. Predicted to be detected in silico
	Morganella morganii	ATCC 25829	(Winslow et al.) Fulton. M4 [ATCC 8076d, DSM 6675, NCTC 417; AMNH 692]	Detected with reduced sensitivity (8.16E+07 CFU/mL)

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Staphylococcus aureus	*Staphylococcus aureus*	ATCC 700698	Rosenbach. Mu3 [NRS2]	Detected
	Staphylococcus aureus	ATCC BAA-977	Rosenbach. UT 32	
	Staphylococcus aureus	ATCC 33591*	Rosenbach. 328	
	Staphylococcus aureus	ATCC BAA-2313*	Rosenbach. M10/0148	
	Staphylococcus aureus	NCTC 13552*	Rosenbach. LGA 251	
	Staphylococcus aureus	NR-10187/HFH-29994	HFH-29994	
	Staphylococcus aureus	ATCC BAA-1707	Rosenbach. MW2 [HIP08270]	
	Staphylococcus aureus	CC398 / t011-ST398	N/A - clinical sample	
	Staphylococcus aureus	ATCC BAA-1556	Rosenbach. FPR3757	
	Staphylococcus aureus	CCUG 74989	N/A	
	Staphylococcus aureus	NCTC 13140	M274	
	Staphylococcus aureus	NR-10189/HFH-30364	HFH-30364 (MRSA)	Detected with reduced sensitivity (1.87E+05 CFU/mL) ‡
	Staphylococcus aureus	NR-46070/USA300-0114	USA300-0114	
	Staphylococcus aureus	NR-46069	96758	
	Staphylococcus aureus	ATCC BAA-2312	Rosenbach. M10/0061	
	Staphylococcus aureus	NCTC 14457	Rosenbach 1884. Ca155	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Staphylococcus epidermidis	*Staphylococcus epidermidis*	ATCC 35983*	(Winslow and Winslow) Evans. RP12 [CIP 106510]	Detected
	Staphylococcus epidermidis	ATCC 35984*	(Winslow and Winslow) Evans. RP62A	
	Staphylococcus epidermidis	PA212221*	N/A - clinical sample	
	Staphylococcus epidermidis	JMI 1090853	N/A	
	Staphylococcus epidermidis	JMI 1151922	N/A	
	Staphylococcus epidermidis	JMI 1171320	N/A	
	Staphylococcus epidermidis	NCTC 13360*	(Winslow and Winslow 1908) Evans 1916. PCI 1200	
	Staphylococcus epidermidis	NCTC 13924	(Winslow and Winslow 1908) Evans 1916 (AL)	
Staphylococcus hominis/capitis	*Staphylococcus capitis*	ATCC 27840	Kloos and Schleifer. LK 499	Detected
	Staphylococcus capitis	CCUG 42761*	Kloos and Schleifer 1975	
	Staphylococcus capitis subsp. *urealyticus*	CCUG 35142T	Bannerman and Kloos 1991. MAW 8436	
	Staphylococcus hominis	CCUG 35516	Kloos and Schleifer. DM 122	
	Staphylococcus hominis subsp. *hominis*	ATCC 25615	Kloos and Schleifer. X300	
	Staphylococcus hominis subsp. *Novobiosepticus*	CCUG 42399T*	Kloos et al. 1998. R22	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Staphylococcus lugdunensis	*Staphylococcus lugdunensis*	CCUG 71098*	N/A	Detected
	Staphylococcus lugdunensis	ATCC 49576*	Freney et al. LRA 260.05.79	
	Staphylococcus lugdunensis	CCUG 74993	N/A	
	Staphylococcus lugdunensis	NCTC 7990	Freney et al. 1988. Kelly	
	Staphylococcus lugdunensis	CCUG 66510	N/A	Detected with reduced sensitivity (2.63E+06 CFU/mL) ‡
Streptococcus agalactiae (GBS)	*Staphylococcus agalactiae*	NCTC 8181*	Lehmann and Neumann. G19	Detected ¶¶
	Staphylococcus agalactiae	ATCC 12401*	Lehmann and Neumann. Typing strain H36B [ATCC 8057, J. Brown strain Baby B]	
	Staphylococcus agalactiae	CCUG 62211	N/A	
	Staphylococcus agalactiae	NCTC 9410	Lehmann and Neumann 1896 (AL). 758 Cole	
	Staphylococcus agalactiae	NCTC 9412	Lehmann and Neumann 1896 (AL). 906 Irene Morris	

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Streptococcus anginosus Group	*Streptococcus anginosus*	ATCC 9895	(Andrewes and Horder) Smith and Sherman emend. Whiley and Beighton. 9 [SK 57]	Detected with reduced sensitivity (8.52E+07 CFU/mL)***
	Streptococcus anginosus	CCUG 27298*	(Andrewes and Horder) Smith and Sherman emend. Whiley and Beighton. F68A Havill III	Detected ¶¶
	Streptococcus constellatus	CCUG 67510	N/A	
	Streptococcus constellatus	NCTC 11325	Prévot 1924 emend. Whiley and Beighton 1991. 4055, VPI 3810	
	Streptococcus intermedius	ATCC 27335*	Prevot emend. Whiley and Beighton. VPI 3372A [1877, SK 54]	
Streptococcus pneumoniae	*Streptococcus pneumoniae**	ATCC 700672	(Klein) Chester. VH14	Detected
	Streptococcus pneumoniae	ATCC BAA-334	(Klein) Chester. TIGR4 [JNR.7/87]	
	Streptococcus pneumoniae	CCUG 70149*	N/A	
	Streptococcus pneumoniae	ATCC 10357	(Klein) Chester	
	Streptococcus pneumoniae	CCUG 71170	N/A	Detected with reduced sensitivity (2.78E+08 CFU/mL) †

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result
Streptococcus pyogenes (GAS)	*Streptococcus pyogenes*	ATCC 12384*	Rosenbach. Typing strain C203 [Dochez 1708]	Detected
	Streptococcus pyogenes	CCUG 74645*	N/A	
	Streptococcus pyogenes	CCUG 58107	Rosenbach 1884	
	Streptococcus pyogenes	NCTC 12696	Rosenbach 1884 (AL). Original strain reference: BRUNO	
	Streptococcus pyogenes	NCTC 5163	Rosenbach 1884 (AL). NY 5 Bergey	

* These strains were evaluated during the LoD study (Section 13.1.5).

N/A: Information not available.

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

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

§ *Candida famata* detected in LoD has not been able to be grown to bottle positivity, so it is not known if it would be detected below bottle positivity.

¶ *Enterococcus faecalis* (ATCC 51575), *Enterococcus faecalis* (CCUG 19916), and *Enterococcus faecalis* (NCTC 12203) were detected (3/3 hits obtained) at ≥ 1.10E+07 CFU/mL (≥ 10x LoD) but below the mean concentration at bottle positivity determined for *Enterococcus faecalis*. Lower concentrations of these strains were not tested.

** *Enterococcus faecium* (ATCC 51559), *Enterococcus faecium* (CCUG 68933) and *Enterococcus faecium* (JMI 1031982) were detected (3/3 hits obtained) at ≥ 2.10E+05 mL (≥ 10x LoD) but below the mean concentration at bottle positivity determined for *Enterococcus faecium*. Lower concentrations of these strains were not tested.

†† *Fusarium sacchari* (CBS 134.73) and *Fusarium solani*(NCPF 7483) were detected with reduced sensitivity (3/3 hits obtained) at ≥ 1.44E+05 CFU/mL (≥ 10x LoD) and above the mean concentration at bottle positivity determined for Fusarium. Lower concentrations of these strains were not tested.

‡‡ All *Listeria. monocytogenes* strains were detected at 5.46E+06 CFU/mL, which is 257.5 x the LoD established for Listeria monocytogenes. However, they were detected below the mean concentration at bottle positivity determined for Listeria monocytogenes. Lower concentrations of these strains were not tested.

§§ *Micrococcus. lylae* CCUG 44721 was not detected in this study at 4.4xLoD. Testing at higher concentrations was not performed as *Micrococcus lylae* was previously tested in the LoD study at a 1.0 McFarland stock concentration, where it was not detected. In silico analyses based on the single available genome confirmed that it is not detected.

Table 13. Summary of pathogen inclusivity results (continued)

Target	Species	Source ID	Strain name/ Designation	Result

¶¶ *Streptococcus anginous* (ATCC 27335), *Streptococcus anginous* (CCUG 67510), and *Streptococcus anginous* (NCTC 11325) were detected (3/3 hits obtained) at 8.52E+05 CFU/mL (≥ 10x LoD), but below the mean concentration at bottle positivity determined for *Streptococcus anginosus*. Lower concentrations of these strains were not tested.

*** *Streptococcus anginous* (ATCC 9895) was detected at 8.52E+07CFU/mL, which was 3479x the mean LoD. This was above the mean concentration obtained at bottle positivity of 4.38E+07 CFU/mL. Whilst this strain was not tested at concentrations close to LoD, it was tested at lower concentrations within this study and was not 100% detected and therefore, is reported as detected with reduced sensitivity.

In addition, all the assays included in the QIAstat-Dx BCID GPF Plus AMR Panel intended to detect AMRs were also evaluated. Table 14 summarizes all results obtained.

Table 14. Summary of AMR markers inclusivity results

Target	Species	Catalog number	Strain designation	Result
aac(6')-aph(2")	*Staphylococcus epidermidis*	ATCC 35983*	RP12 [CIP 106510]	Detected §
	Staphylococcus epidermidis	ATCC 35984*	RP62A	
	Enterococcus faecalis	NCTC 13780*	EC0014	
	Enterococcus faecium	ATCC 51559	MMC4	
	Enterococcus faecalis	ATCC 51299#	NJ-3	
	Staphylococcus epidermidis	NCTC 13924	N/A	
	Enterococcus faecalis	NCTC 12203	Original strain reference: No. 10	
	Staphylococcus epidermidis	PA212221*	N/A - clinical sample	
	Enterococcus faecalis	ATCC BAA-2365	N/A	
	Staphylococcus aureus	NR-46069	96758	
	Staphylococcus aureus	ATCC 700698	Mu3 [NRS2]	
	Enterococcus faecalis	ATCC 51575	Taxo 239	
	Staphylococcus epidermidis	JMI 1090853	N/A	
	Staphylococcus epidermidis	JMI 1151922	N/A	
	Staphylococcus hominis subsp. *Novobiosepticus*	CCUG 42399T*	R22	
	Enterococcus faecium	ATCC BAA-2316	N/A	Detected with reduced sensitivity (8.16E+06 CFU/mL) ‡,¶

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
	Staphylococcus aureus	NCTC 13140	M274	Detected with reduced sensitivity (1.87E+06 CFU/mL) †,**
	Staphylococcus epidermidis	JMI 1171320	N/A	Detected with reduced sensitivity (4.66E+06 CFU/mL) ‡,***
cfr	*Staphylococcus epidermidis*	PA212221*	N/A - clinical sample	Detected
	Staphylococcus aureus	CC398 / t011-ST398*	N/A - clinical sample	
	Staphylococcus epidermidis	JMI 1090853	N/A	
	Staphylococcus epidermidis	JMI 1151922	N/A	Detected with reduced sensitivity (3.81E+06 CFU/mL) ‡
	Staphylococcus epidermidis	JMI 1171320	N/A	
ermA	*Staphylococcus aureus*	ATCC 33591*	328	Detected
	Staphylococcus epidermidis	ATCC 35984*	RP62A	
	Staphylococcus aureus	ATCC BAA-977	UT 32	
	Staphylococcus aureus	ATCC 700698	Mu3 [NRS2]	
	Staphylococcus aureus	NR-10187/HFH-29994	HFH-29994	Detected with reduced sensitivity (1.87E+06 CFU/mL) †
	Staphylococcus aureus	NR-46069	96758	Detected with reduced sensitivity (1.87E+05 CFU/mL) ‡

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
ermC	*Staphylococcus epidermidis*	ATCC 35983*	RP12 [CIP 106510]	Detected
	Staphylococcus epidermidis	NCTC 13924	N/A	
	Staphylococcus hominis subsp. *novobiosepticus*	CCUG 42399T*	R22	
	Staphylococcus aureus	ATCC BAA-1556	FPR3757	Detected with reduced sensitivity (3.93E+05 CFU/mL) ‡
	Staphylococcus epidermidis	JMI 1090853	N/A	Detected with reduced sensitivity (3.81E+06 CFU/mL) ‡
	Staphylococcus epidermidis	JMI 1171320	N/A	
	Staphylococcus epidermidis	JMI 1151922	N/A	Not Detected

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
mecA	*Staphylococcus aureus*	ATCC 33591*	328	Detected
	Staphylococcus epidermidis	ATCC 35983*	RP12 [CIP 106510]	
	Staphylococcus epidermidis	ATCC 35984*	RP62A	
	Staphylococcus epidermidis	CCUG 42399T*	R22	
	Staphylococcus epidermidis	NCTC 13924	N/A	
	Staphylococcus epidermidis	PA212221*	N/A - clinical sample	
	Staphylococcus aureus	CC398 / t011-ST398*	N/A - clinical sample	
	Staphylococcus aureus	ATCC BAA-1556	FPR3757	
	Staphylococcus aureus	ATCC BAA-1707	MW2 [HIP08270]	
	Staphylococcus aureus	ATCC 700698	Mu3 [NRS2]	
	Staphylococcus epidermidis	JMI 1090853	N/A	
	Staphylococcus epidermidis	JMI 1151922	N/A	
	Staphylococcus epidermidis	JMI 1171320	N/A	
	Staphylococcus aureus	NR-46069	96758	Detected with reduced sensitivity (1.87E+05 CFU/mL) ‡

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
	Staphylococcus aureus	NCTC 13140	M274	Detected with reduced sensitivity (1.87E+06 CFU/mL) †
	Staphylococcus aureus	NR-10189/HFH-30364	HFH-30364 (MRSA)	
	Staphylococcus aureus	NR-10187/HFH-29994	HFH-29994	
	Staphylococcus aureus	NR-46070/USA300-0114	USA300-0114	
mecC	*Staphylococcus aureus*	CCUG 74989	N/A	Detected
	Staphylococcus aureus	ATCC BAA-2313*	M10/0148	
	Staphylococcus aureus	NCTC 13552*	LGA 251	
	Staphylococcus aureus	ATCC BAA-2312	M10/0061	Detected with reduced sensitivity (1.87E+05 CFU/mL) ‡
	Staphylococcus aureus	NCTC 14457	Ca155	Detected with reduced sensitivity (1.87E+05 CFU/mL) ‡

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
tetK	*Staphylococcus aureus*	CC398 / t011-ST398*	N/A - clinical sample	Detected
	Staphylococcus aureus	ATCC 33591*	328	
	Staphylococcus aureus	NCTC 13360*	PCI 1200	
	Staphylococcus aureus	ATCC BAA-1556	FPR3757	
	Staphylococcus aureus	ATCC BAA-1707	MW2 [HIP08270]	
	Staphylococcus aureus	NR-10189/HFH-30364	HFH-30364 (MRSA)	Detected with reduced sensitivity (1.87E+06 CFU/mL) ‡
	Staphylococcus aureus	NR-46070/USA300-0114	USA300-0114	Detected with reduced sensitivity (1.87E+06 CFU/mL) †

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
tetM	*Staphylococcus aureus*	ATCC 33591*	328	Detected §§,¶¶
	Enterococcus faecalis	NCTC 13780*	EC0014	
	Enterococcus faecalis	NCTC 12203	Original strain reference: No. 10	
	Streptococcus constellatus	NCTC 11325	4055, VPI 3810	
	Streptococcus agalactiae	CCUG 62211	N/A	
	Staphylococcus aureus	CC398 / t011-ST398*	N/A - clinical sample	
	Staphylococcus aureus	NCTC 13140	M274	
	Enterococcus faecium	ATCC BAA-2316	N/A	
	Enterococcus faecalis	ATCC 51575	Taxo 239	
	Enterococcus faecium	CCUG 68933	N/A	
	Staphylococcus epidermidis	JMI 1171320	N/A	
	Staphylococcus aureus	ATCC 700698	Mu3 [NRS2]	Detected with reduced sensitivity (1.87E+05 CFU/mL) ‡
	Staphylococcus aureus	NCTC 13140	M274	Detected with reduced sensitivity (1.87E+06 CFU/mL) †
	Enterococcus faecium	ATCC BAA-2316	N/A	Detected with reduced sensitivity (4.08E+06 CFU/mL) ‡,§§

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result
	Enterococcus faecium	CCUG 68933	N/A	Detected with reduced sensitivity (5.00E+06 CFU/mL) ‡,§§
vanA	*Enterococcus faecium*	NCTC 12204*	No. 14	Detected ††,¶¶
	Enterococcus faecalis	NCTC 13780*	EC0014	
	Enterococcus faecium	ATCC 51559	MMC4	
	Enterococcus faecalis	NCTC 12203	Original strain reference: No. 10	
	E. faecium	ATCC BAA-2316*	N/A	
vanB	*Enterococcus faecalis*	ATCC 51299*	NJ-3	Detected ‡‡
	Enterococcus faecalis	ATCC BAA-2365	N/A	
	Enterococcus faecalis	ATCC 51575	Taxo 239	
	Enterococcus faecium	JMI 1031982	N/A	
	Enterococcus faecium	ATCC 51858*	Vancomycin-dependent No. 4	

* These AMRs were evaluated during the LoD study (Section 13.1.5 on page 73).

N/A: Information not available.

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

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

§ In *Enterococcus faecalis* (NCTC 12203), *E. faecalis*(ATCC 51299), *Enterococcus faecalis* (ATCC 51575) and *Enterococcus faecium* (ATCC 51559), *aac(6')-aph(2")* was detected at a concentration which was >10x combined pathogen LoD, but that was less than the mean concentration obtained at bottle positivity for these species. Lower concentrations of these strains were not tested.

¶ *Enterococcus faecium* (ATCC BAA-2316) was manufactured incorrectly and was not re-tested at a lower concentration within the study. It is unknown whether inclusivity for *aac(6')-aph(2")* would be confirmed at a lower concentration if evaluated.

Table 14. Summary of AMR markers inclusivity results (continued)

Target	Species	Catalog number	Strain designation	Result

** In *Staphylococcus aureus* (NCTC 13140), *aac(6')-aph(2")*was detected at a concentration which was >10x combined pathogen LoD, and was also above the mean concentration obtained at bottle positivity for *Staphylococcus aureus*.

†† In *Enterococccus faecalis* (NCTC 12203), *vanA* was detected at a concentration which was >10x combined pathogen LoD, but that was less than the mean concentration obtained at bottle positivity for *E. faecalis*. Lower concentrations of this strain were not tested.

‡‡ *Enterococcus faecalis* (ATCC 51575) and *Enterococcus faecium* (JMI 1031982), *vanB* was detected at a concentration which was >10x combined pathogen LoD, but that was less than the mean concentration obtained at bottle positivity for these strains. Lower concentrations of this strain were not tested.

§§ In *Streptococcus constellatus* (NCTC 11325) and *E. faecalis* (ATCC 51575), tet(M) was detected at a concentration which was >10x combined pathogen LoD, but that was less than the mean concentration obtained at bottle positivity for these strains. Lower concentrations of this strain were not tested.

¶¶ Lowest detectable concentration for *vanA* and *tetM*harboured by *Enterococcus faecalis* (ATCC BAA-2316) reported was determined separately.

*** In *Staphylococcus epidermidis* (JMI 1171320) *aac(6')-aph(2")*was detected at a concentration which was >10x combined pathogen LoD determined for this species, but was below the mean concentration obtained at bottle positivity for *Staphylococcus epidermidis*.

In parallel, the bioinformatic prediction of the inclusivity assessment of the QIAstat-Dx BCID GPF 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 GPF 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 GPF 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 1 Forward, 1 Probe, and 1 Reverse primer from the same assay included in the QIAstat-Dx BCID GPF 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 1 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 15) 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 GPF 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 15) showed perfect inclusivity levels for all the AMR genes targeted by the panel with few observations.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
Organism-PCR assays	*Listeria monocytogenes*	595 (100.00%)	Inclusivity determined for *L. monocytogenes* (including serotypes 1/2a,1/2b, 1/2c, 3a, 3b, 3c, 4a, 4b, 4c, 4d, 4e, 7)
	Streptococcus pyogenes	407 (99.75%)	Only a single sequence (LS483520) was not detected.
	Bacillus cereus group	646 (93.34%)	Inclusivity determined for *B. cereus, B. thuringiensis, B. albus, B, anthracis, B. bombysepticus, B. mobilis, B. nitratireducens, B. pacificus, B. paramobilis, B. paranthracis, B. shihchuchen, B. tropicus, B. wiedmannii.* Partial inclusivity determined for *B. mycoides, B. weihenstephanensis.* **Note**: • 5/216 and 4/134 not detected sequences for *B. cereus and B. thuringiensis*respectively. • *B. mycoides* only 18.33% detected. • 1/27 not detected sequence of *B. paranthracis.* • 1/2 not detected sequences of *B. weihenstephanensis.*

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Corynebacterium	702 (100.00%)	Inclusivity determined for all 131 *Corynebacterium species described (C. diphtheriae, C. ulcerans, C. pseudotubercolosis, C. urealyticum, C. argentoratense, C. flavum, C. accolens, C. afermentans, C. ammoniagenes, C. amycolatum, C. anserum, C. appendicis, C. aquatimens, C. aquilae, C. atrinae, C. atypicum, C. aurimucosum, C. auris, C. auriscanis, C. belfantii, C. bovis, C. breve, C. callunae, C. camporealensis, C. canis, C. capitovis, C. casei, C. caspium, C. choanae, C. ciconiae, C. comes, C. confusum, C. coyleae, C. crudilactis, C. cystitidis, C. dentalis, C. deserti, C. doosanense, C. durum, C. efficiens, C. endometrii, C. epidermidicanis, C. faecale, C. falsenii, C. felinum, C. flavescens, C. fournieri, C. frankenforstense, C. freiburgense, C. freneyi, C. genitalium, C. gerontici, C. glaucum, C. glucuronolyticum, C. glutamicum, C. glyciniphilum, C. gottingense, C. guangdongense, C. hadale, C. haemomassiliense, C. halotolerans, C. hansenii, C. heidelbergense, C. hesseae, C. hindlerae, C. humireducens, C. ihumii, C. imitans, C. incognita, C. jeddahense, C. jeikeium, C. kalinowskii, C. kefirresidentii, C. kroppenstedtii, C. kutscheri, C. lactis, C. liangguodongii, C. lizhenjunii, C. lujinxingii, C. macclintockiae, C. macginleyi, C. marinum, C. maris, C. marquesiae, C. massiliense, C. matruchotii, C. mayonis, C. minutissimum, C. mustelae, C. mycetoides, C. nuruki, C. occultum, C. pelargi, C. phocae, C. poyangense, C. propinquum, C. provencense, C. pseudodiphtheriticum, C. pseudogenitalium,*

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			C. pseudokroppenstedtii, C. pseudopelargi, C. pyruviciproducens, C. qintianiae, C. renale, C. resistens, C. rhinophilum, C. riegelii, C. rouxii, C. sanguinis, C. segmentosum, C. silvaticum, C. simulans, C. singulare, C. sphenisci, C. stationis, C. striatum, C. suedekumii, C. terpenotabidum, C. testudinoris, C. timonense, C. tuberculostearicum, C. uberis, C. ureicelerivorans, C. urogenitale, C. uterequi, C. variabile, C. vitaeruminis, C. wankanglinii, C. xerosis, C. yudongzhengii, C. zhongnanshanii)
	Staphylococcus epidermidis	328 (98.00%)	Inclusivity determined for *Staphylococcus epidermidis*. **Note**: 5/328 sequences was not detected.
	Streptococcus pneumoniae	355 (100.00%)	Inclusivity determined for *Streptococcus pneumoniae*.
	Staphylococcus lugdunensis	42 (100.00%)	Inclusivity determined for *Streptococcus lugdunensis*.
	Cryptococcus neoformans/gatti	66 (100.00%)	Inclusivity determined for *Cryptococcus neoformans/gatti*(including serotype A (*C. neoformans var neoformans*), serotype D (*C. neoformans var grubii*), serotypesB and C (*C. gattii* including all VGI,VGII, VGIII, VGIV molecular types))
	Enterococcus faecalis	792 (99.87%)	Inclusivity determined for *Enterococcus faecalis*. **Note**: Only a single sequence (CP022312) was not detected.
	Enterococcus faecium	951 (99.89%)	Inclusivity determined for *Enterococcus faecium*. **Note**: Only a single sequence (CP175041) was not detected.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Streptococcus anginosus group	56 (96.43%)	Inclusivity determined for the 3 major species in the group, including *Streptococcus anginosus*, *Streptococcus constellatus* and *Streptococcus intermedius*. **Note**: Only 2/32 sequences of *Streptococcus anginosus*(CP088916.1 and CP186002.1) were not detected, both collected in urogenital samples.
	Staphylococcus capitis / hominis	71 (100.00%)	Inclusivity determined for *Staphylococcus capitis* and *Staphylococcus hominis*.
	Staphylococcus aureus	2971 (99.97%)	Inclusivity determined for *Staphylococcus aureus*. **Note**: Only a single sequence (AP020315) was not detected.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Fusarium group	8726 (99.00%)	Inclusivity determined for *Fusarium solani species complex including at least Fusarium acutisporum, F. addoense, F. akasia, F. ambrosium, F. amplum, F. awan, F. bataticola, F. bomiense, F. borneense, F. bostrycoides, F. brasiliense, F. breve, F. breviconum, F. catenatum, F. crassistipitatum, F. cf. crassum, F. crassum, F. croci, F. cucurbiticola, F. cuneirostrum, F. cyanescens, F. diminutum, F. drepaniforme, F. duplospermum, F. epipeda, F. euwallaceae, F. falciforme, F. ferrugineum, F. floridanum, F. gamtoosense, F. gannanense, F. haematococcum, F. helgardnirenbergiae, F. hengyangense, F. hypothenemi, F. keratoplasticum, F. kuroshium, F. kurunegalense, F. lerouxii, F. lichenicola, F. liriodendri, F. macrosporum, F. martii, F. mekan, F. merkxianum, F. metavorans, F. mori, F. neerlandicum, F. neocosmosporiellum, F. ngaiotongaense, F. noneumartii, F. obliquiseptatum, F. oblongum, F. oligoseptatum, F. papillatum, F. paraeumartii, F. paranaense, F. parceramosum, F. paulenelsonii, F. perseae, F. petroliphilum, F. phaseoli, F. piperis, F. populicola, F. protoensiforme, F. pseudensiforme, F. pseudopisi, F. pseudoradicicola, F. quercinum, F. rectiphorum, F. regulare, F. rekanum, F. riograndense, F. samuelsii, F. silvicola, F. solani, F. solani f. radicicola, F. solani f. sp. eumartii, F. solani f. sp. passiflorae, F. solani-melongenae, F. spathulatum, F. stercicola, F. suttonianum, F. tenuicristatum, F. tonkinense, F. tuaranense, F. tucumaniae, F. tumidispermum, F. vanettenii, F. variasi, F. virguliforme, F. waltergamsii, F. warna,*

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			F. witzenhausenense, F. yamamotoi, Neocosmospora alboflava, N. anhuiensis, N. aquatica, N. australiana, N. australpacifica, N. caricae, N. citricola, N. dimorpha, N. easleyae, N. fangfangiae, N. fungicola, N. galbana, N. gerryae, N. guangdongensis, N. lechatii, N. lithocarpi, N. macnamarae, N. magnoliae, N. myrtaceicola, N. paphiopedili, N. paramacrospora, N. queenslandica, N. sorabjiae, N. striatispora, N. thailandica, N. wangariae. Inclusivity determined for other *Fusarium* species including at least *F. arbusti, F. aurantii, F. babinda, F. camelliae, F. algeriense, F. beomiforme, F. burgessii, F. cartwrightiae, F. aseptatum, F. atrovinosum, F. aywerte, F. chlamydosporum, F. humicola, F. microconidium, F. nelsonii, F. peruvianum, F. spinosum, F. sporodochiale, F. tjaynera, F. cili, F. coffeibaccae, F. anguioides, F. austroafricanum, F. bambusarum, F. concolor, F. verrucosum, F. echinatum, F. endophyticum, F. erosum, F. falsibabinda, F. acutatum, F. agapanthi, F. aglaonematis, F. ananatum, F. andiyazi, F. annulatum, F. anthophilum, F. aquaticum, F. awaxy, F. bactridioides, F. begoniae, F. bilaiae, F. brachiariae, F. brevicatenulatum, F. cf. brevicatenulatum, F. bulbicola, F. caapi, F. casha,*

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			F. chinhoyiense, F. chuoi, F. circinatum, F. coicis, F. concentricum, F. concentricum x F. mangiferae, F. curculicola, F. cymbidii, F. dendrobii, F. denticulatum, F. dhileepanii, F. dlaminii, F. ednaryaniae, F. elaeagni, F. ficicrescens, F. fracticaudum, F. fractiflexum, F. fredkrugeri, F. fujikuroi, F. fujikuroi IMI 58289, Gibberella fujikuroi var. moniliformis, F. giganteum, F. globosum, F. guangdongense, F. guttiforme, F. hechiense, F. konzum, F. lactis, F. lumajangense, F. madaense, F. mangiferae, F. marasasianum, F. mexicanum, F. mirum, F. mundagurra, F. napiforme, F. nygamai, F. ophioides, F. panlongense, F. parvisorum, F. phyllophilum, F. pilosicola, F. pininemorale, F. prieskaense, F. proliferatum, F. proliferatum ET1, F. pseudoanthophilum, F. pseudocircinatum, F. pseudonygamai, F. purpureum, F. ramigenum, F. sacchari, F. secorum, F. sororula, F. sterilihyphosum, F. subglutinans, F. succisae, F. sudanense, F. temperatum, F. thapsinum, F. tjaetaba, F. cf. tjaetaba, F. tupiense, F. udum, F. verticillioides, F. verticillioides 7600, F. volatile, F. xylarioides, F. xyrophilum, F. hanswilhelmii, F. idabrowneae, F. compactum, F. irdabamae, F. kazakhstanicum, F. kirstenboschense, F. cassiae, F. citri-sinensis, F. lateritium, F. magnoliae-champaca, F. ramsdenii, F. sarcochroum, F. stilboides, F. stramineum, F. velutinum, F. verruculosum, F. louisalawsoniae, F. malawiense, F. menglaense, F. microcyclum, F. musae, F. nashariae, F. neoglobosum,

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			F. newnesense, F. anoectochili, F. commune, F. gaditjirri, F. miscanthi, F. nisikadoi, F. paranisikadoi, F. oliniae, F. oxysporum species complex, F. callistephi, F. carminascens, F. contaminatum, F. cugenangense, F. curvatum, F. duoseptatum, F. elaeidis, F. fabacearum, F. foetens, F. glycines, F. gossypinum, F. grosmichelii, F. hexaseptatum, F. cf. hexaseptatum/cugenangense, F. hoodiae, F. inflexum, F. kalimantanense, F. languescens, F. libertatis, F. nirenbergiae, F. odoratissimum, F. odoratissimum NRRL 54006, F. oxysporum, F. oxysporum Fo47, F. oxysporum f. sp. asparagi, F. oxysporum f. sp. cepae, F. oxysporum f. sp. ciceris, F. oxysporum f. sp. cubense, F. oxysporum f. sp. cumini, F. oxysporum f. sp. cyclaminis, F. oxysporum f. sp. dianthi, F. oxysporum f. sp. fragariae, F. oxysporum f. sp. koae, F. oxysporum f. sp. lactucae, F. oxysporum f. sp. lycopersici 4287, F. oxysporum f. sp. medicaginis, F. oxysporum f. sp. melonis, F. oxysporum f. sp. niveum, F. oxysporum f. sp. opuntiarum, F. oxysporum f. sp. passiflorae, F. oxysporum f. sp. psidii, F. oxysporum f. sp. quitoense, F. oxysporum f. sp. radicis-cucumerinum, F. oxysporum f. sp. rhois, F. oxysporum f. sp. tulipae, F. oxysporum f. sp. vasinfectum, F. oxysporum f. sp. zingiberi, F. cf. oxysporum, F. pharetrum, F. phialophorum, F. purpurascens, F. sangayamense, F. tardichlamydosporum, F. tardicrescens, F. triseptatum, F. vanleeuwenii, F. veterinarium, F. planum, F. queenslandicum, F. hostae, F. redolens, F. rhizicola, F. rosae-roxburghii, F. rufum, F. asiaticum,

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			F. brachygibbosum, F. brachypes, F. cuspidatum, F. dimorphosporum, F. dolichosporum, F. hamatum, F. magnum, F. minutum, F. platysporum, F. poae, F. sagittatum, F. transvaalense, F. sanyaense, F. siculi, F. spartum, F. terricola, F. continuum, F. torreyae, F. zanthoxyli, F. valentineae, F. werrikimbe, F. wimaladesilvae, F. xishuangbannaense, F. youattiae. **Note**: • 1/2 sequences of *F. acutisporum* not detected. • 1/20 *F. chlamydosporum* sequences not detected. • 1/47 *F. coffeibaccae* sequences not detected. • Only 1/83 *F. compactum* sequences detected. • 1/68 *F. lateritium* sequences not detected. • 1/2 *F. brachypes* sequences detected.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Micrococcus spp.	45 (84.44%)	Inclusivity determined for at least *Micrococcus luteus* and *Micrococcus yunnanensis* **Note**: • All BLAST hit sequences corresponded to *M. luteus*. Some genomes were manually collected from NCBI for species not found in the initial BLAST analysis. • The assay is not expected to detect *Micrococcus porci* (0/1), *Micrococcus antarcticus* (0/1), *Micrococcus terrae* (0/1), *Micrococcus lylae*(0/1), some unclassified *Micrococcus* sp. (1/4) and some *Micrococcus luteus* strains (2/33)
	Streptococcus agalactiae	270 (99.63%)	Inclusivity determined for *Streptococcus agalactiae*. **Note**: Only a single sequence (CP187264) not detected because of 4 mismatches in the probe binding region.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	Pan Gram Negative	10109 (99.98%)	Inclusivity determined for *Bacteroides fragilis*. Inclusivity determined for all capsulated *N. meningitidis*strains (including serotypes A, B, C, D, E, H, I, K, L, NG, W, W135, X, Y, Z, 29E). Inclusivity determined for *S. maltophilia*. Inclusivity determined for all *H. influenzae* strains including all encapsulated serotypes (a, b, c, d, e, f) and unencapsulated strains (nontypable, NTHi) including *var. H. aegyptius*. Inclusivity determined for *Pseudomonas* species including at least *P. aueruginosa group (P. aeruginosa, P. azelaica, P. multiresinivorans, P. nitritireducens, P. nitroreducens, P. paraeruginosa), P. acephalitica, P. alloputida, P. azotoformans, P. baetica, P. brassicacearum, P. brenneri, P. ceruminis, P. chlororaphis, P. donghuensis, P. entomophila, P. extremaustralis, P. fluorescens, P. gessardii, P. grimontii, P. guezennei, P. haemolytica, P. hunanensis, P. khavaziana, P. kielensis, P. kilonensis, P. libanensis, P. lini, P. linyingensis, P. lurida, P. lutea, P. luteola, P. marginalis, P. migulae, P. monteilii, P. mosselii, P. mucidolens, P. nicosulfuronedens, P. oryzihabitans, P. panipatensis, P. paralactis, P. plecoglossicida, P. poae, P. putida, P. quebecensis, P. rhizosphaerae, P. rhodesiae, P. shahriarae, P. sihuiensis, P. synxantha, P. taiwanensis, P. thivervalensis, P. tolaasii, P. trivialis, P. tropicalis, P. yamanorum*.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			Inclusivity determined for *Acinetobacter* species including at least *A. albensis, A. baumannii, A. baylyi, A. beijerinckii, A. bereziniae, A. bohemicus, A. brisouii, A. calcoaceticus, A. celticus, A. colistiniresistens, A. courvalinii, A. dispersus, A. geminorum, A. gyllenbergii, A. haemolyticus, A. halotolerans, A. ihumii, A. indicus, A. johnsonii, A. junii, A. kookii, A. lactucae, A. lwoffii, A. modestus, A. nosocomialis, A. oleivorans, A. parvus, A. pittii, A. plantarum, A. populi, A. proteolyticus, A. psychrotolerans, A. puyangensis, A. radioresistens, A. rhizosphaerae, A. schindleri, A. seifertii, A. septicus, A. soli, A. suaedae, A. tjernbergiae, A. towneri, A. ursingii, A. variabilis, A. venetianus, A. vivianii.*
			Inclusivity determined for *Enterobacterales* genera including at least *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. condimenti, C. malonaticus, C. sakazakii); Dickeya (D. oryzae, D. zeae); Dryocola; 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,*

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			E. coli, E. fergusonii, E. marmotae); 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); Kluyvera (K. intermedia); Kosakonia (K. pseudosacchari, K. radicincitans); Leclercia (L. adecarboxylata, L. pneumoniae); Lelliottia; 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. rettgeri, P. stuartii); Pseudescherichia (P. vulneris), Rahnella (R. bonaserana); Raoultella (R. ornithinolytica, R. planticola, R. terrigena); Salmonella (S. bongori, S. enterica); Scandinavium (S. goeteborgense); Serratia (S. entomophila, S. marcescens, S. rhizosphaerae, S. rubidaea); Shigella (S. boydii, S. dysenteriae, S. flexneri, S. sonnei); Shimwellia (S. blattae); Sodalis (S. glossinidius, S. ligni, S. praecaptivus); Tatumella (T. citrea, T. ptyseos); Yersinia (Y. enterocolitica, Y. frederiksenii, Y. intermedia, Y. massiliensis, Y. mollaretii, Y. pestis, Y. pseudotuberculosis, Y. ruckeri); Yokenella (Y. regensburgei).

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			Note: • 2 sequences (CP078102 & CP133415) of *S. maltophilia* were not detected. • Some genomes were manually collected from NCBI for species not found in the initial BLAST analysis.
	Candida group 1†	21 (95.24%)	Inclusivity determined for *Candida* species included in the *Candida* 1 group *(C. albicans, C. dubliniensis, C. famata, C. guillermondi, C. kefyr, C. tropicalis)*. **Note**: One *C. famata* genome (CP045114) not detected because of Reverse primer binds with 4 mismatches.
	Candida group 2†	36 (100.00%)	Inclusivity determined for *Candida* species in the *Candida*2 group *(C. glabrata, C. krusei, C. lusitaniae, C. parapsilosis)*. **Note**: Some genomes of *C. krusei* contained 2 copies of the target gene within the same chromosome.
	Candida auris	70 (100.00%)	Inclusivity determined for *Candida auris*.

Table 15. Summary and observations found in the In silico prediction of the QIAstat-Dx BCID GPF Plus AMR Panel (continued)

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
AMR- PCR assays	*cfr*	42 (100.00%)	All sequences detected
	vanB	33 (100.00%)	All sequences detected
	tetM	1003 (99.40%)	Six (6) out of 1003 accession numbers were predicted not to be detected (CP059743, CP059819, CP018072, LR135320, LR135327 & LR135256), because of a deletion in the AMR gene.
	vanA	190 (100.00%)	All sequences detected
	mecA	676 (100.00%)	All sequences detected
	tetK	122 (100.00%)	All sequences detected
	ermA	334 (94.61%)	Variant Spyo_ermA_MLSb (18 sequences) which has been found in some *S. pyogenes* is predicted not to be detected.
	ermC	82 (100.00%)	All sequences detected
	aac(6')-aph(2")	460 (100.00%)	All sequences detected
	mecC	3 (100.00%)	All sequences detected

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

† Genomes corresponding to *Candida* species include a total of 7 or 8 different molecules (chromosomes). Numbers described in the table correspond to the total of available genomes analyzed.

13.1.8. Interfering substances

The effect of potentially interfering substances on the detectability of the QIAstat-Dx BCID GPF Plus AMR Panel organisms was evaluated. Thirty-one 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 5 representative organisms also harboring a total of 4 AMR were tested at 3x LoD or lower. The positive mix covered all reaction chambers of the QIAstat-Dx BCID GPF 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.

No interference was observed for the substances tested. Results from the 31 interfering substances that could be present or introduced in a positive blood culture specimen are provided in Table 16.

Table 16. 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/Clavulanate	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) (55.5 mg/mL)	No Interference
Caspofungin Diacetate	0.005 mg/mL	No Interference
Ceftriaxone Disodium Hemiheptahydrate	0.966 mg/mL	No Interference

Table 16. Final highest concentration without observable inhibitory effect (continued)

Substance name	Concentration in blood culture matrix (units/mL)	Result
Ciprofloxacin	0.01 mg/mL	No Interference
Ethanol	5% (v/v) (39.5 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 GPF 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 17.

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 17. Summary of competitive inhibition results

Co-infection pathogens	Organism target [AMR target]	High positive concentration bottle positivity + 24 hours (CFU/mL)	Low positive concentration detected 3xLoD* (CFU/mL)
Candida albicans (ATCC 10231) *Candida glabrata* (ATCC 15126)	*Candida* spp. group 1	1.83E+07	2.04E+06
	Candida spp. group 2	6.21E+07	6.20E+05
Candida albicans (ATCC 10231) *Enterococcus faecalis* (NCTC 12201)	*Candida* spp. group 1	1.83E+07	2.04E+06
	Enterococcus faecalis [aac(6')-aph(2"), tetM, vanA]	4.64E+08	8.25E+05

Table 17. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration bottle positivity + 24 hours (CFU/mL)	Low positive concentration detected 3xLoD* (CFU/mL)
Candida glabrata (ATCC 15126) *Streptococcus pneumoniae* (CCUG 70149)	*Candida* spp. group 2	6.21E+07	6.20E+05
	Streptococcus pneumoniae	n/a§	2.10E+04
Enterococcus faecium (ATCC BAA 2316) *Enterococcus faecalis* (ATCC 51299)	*Enterococcus faecium* *[aac(6')-aph(2"), vanA, tetM]*	8.96E+08	4.08E+04 [4.08+06 (300x LoD) for *tetM*]
	Enterococcus faecalis *[aac(6')-aph(2"), vanB]*	7.25E+08	1.50E+06
Enterococcus faecalis (ATCC 51299) *Staphylococcus aureus* (ATCC BAA 2313)	*Enterococcus faecalis* *[aac(6')-aph(2"), vanB]*	7.25E+08	1.50E+06
	Staphylococcus aureus *[mecC]*	2.09E+08	1.43E+04
Enterococcus faecalis (ATCC 51299) *Streptococcus pneumoniae* (CCUG 70149)	*Enterococcus faecalis* *[aac(6')-aph(2"), vanB]*	7.25E+08	1.50E+06
	Streptococcus pneumoniae	n/a§	2.10E+04
Streptococcus agalactiae (ATCC 12401) *Streptococcus anginosus* (CCUG 27298)	*Streptococcus agalactiae* (gbs)	4.16E+08	9.00E+05
	Streptococcus anginosus group	3.80E+07	1.45E+05
Staphylococcus aureus (ATCC BAA 2313) *Staphylococcus epidermidis* (ATCC 35984)	*Staphylococcus aureus* *[mecC]*	2.09E+08	1.43E+04
	Staphylococcus epidermidis *[aac(6')-aph(2"), ermA, mecA]*	7.29E+08	1.03E+05

Table 17. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration bottle positivity + 24 hours (CFU/mL)	Low positive concentration detected 3xLoD* (CFU/mL)
Staphylococcus epidermidis (ATCC 35984) *Staphylococcus capitis* (CCUG 427610)	*Staphylococcus epidermidis* *[aac(6')-aph(2"), ermA, mecA]*	7.29E+08	1.03E+05
	Staphylococcus capitis/hominis	2.86E+09	2.31E+06 (30x LoD)
Micrococcus luteus (NCTC 7011) *Streptococcus pyogenes* (ATCC 12384)	*Micrococcus* spp.	2.13E+08	8.65E+05
	Streptococcus pyogenes (gas)	9.45E+07	3.00E+05
Staphylococcus lugdunensis (CCUG 71098) *Corynebacterium striatum* (ATCC 43735)	*Staphylococcus lugdunensis*	1.96E+08	4.50E+03
	Corynebacterium	9.54E+08	2.14E+06
Staphylococcus aureus (ATCC BAA 2313) *Streptococcus agalactiae* (ATCC 12401)	*Staphylococcus aureus* *[mecC]*	2.09E+08	1.43E+0 6 (300x LoD)
	Streptococcus agalactiae (gbs)	4.16E+08	9.00E+05
Streptococcus pneumoniae (CCUG 70149) *Escherichia coli* (ATCC BAA 196)	*Streptococcus pneumoniae*	n/a§	2.10E+04
	Pan Gram negative	4.16E+08	1.21E+07
Staphylococcus aureus (ATCC BAA 2313) *Acinetobacter baumannii* (NCTC 13302)	*Staphylococcus aureus* *[mecC]*	2.09E+08	1.43E+04
	Pan Gram-negative	2.72E+08	4.17E+05‡
Micrococcus luteus (NCTC 7011) *Pseudomonas aeruginosa* (NCTC 13921)	*Micrococcus* spp.	Not tested	8.65E+05
	Pan Gram-negative	1.41E+09	Not tested

Table 17. Summary of competitive inhibition results (continued)

Co-infection pathogens	Organism target [AMR target]	High positive concentration bottle positivity + 24 hours (CFU/mL)	Low positive concentration detected 3xLoD* (CFU/mL)
Bacillus cereus (ATCC 21769)	*Bacillus cereus* group	Not tested	1.84E+06
Cutibacterium acnes (NCTC 737)	*Corynebacterium*†	1.71E+08	Not tested
Staphylococcus aureus (ATCC BAA 2313)	*Staphylococcus aureus [mecC]*	Not tested	1.43E+04
Klebsiella pneumoniae (CCUG 68728)	Pan Gram-negative	1.40E+09	Not tested
Enterococcus faecalis (NCTC 12201)	*Enterococcus faecalis [aac(6')-aph(2"), tetM, vanA]*	Not tested	8.25E+05 [8.25E+06 for *aac(6')-aph(2")*]
Serratia marcescens (ATCC 14041)	Pan Gram negative	4.82E+08	Not tested
Staphylococcus aureus (ATCC BAA 2313)	*Staphylococcus aureus [mecC]*	Not tested	1.43E+04
Proteus mirabilis (ATCC BAA 2792)	Pan Gram negative	3.17E+09	Not tested
Streptococcus anginosus (CCUG 27298)	*Streptococcus anginosus* group	Not tested	1.45E+05
Bacteroides fragilis (CCUG 4856T)	Pan Gram negative	2.27E+09	Not tested
Candida albicans (ATCC 10231)	*Candida* spp. group 1	Not tested	2.04E+06
Enterobacter cloacae (NCTC 14326)	Pan Gram negative	1.08E+09	Not tested

* The concentration annotated is the lowest tested concentration at which 100% hit rate was observed. When this concentration was higher than 3x LoD for any of the targets, the concentration has been reported, including the xLoD.

† *Cutibacterium acnes* cross-reacts with the *Corynebacterium* assay, giving false positives for *Corynebacterium* (see Exclusivity (analytical specificity) section).

‡Tested by mistake at 0.3xLoD, detection rate was 3/3.

§ n/a, strain could not be enumerated.

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 GPF 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 GPF 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 Analyzer 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: 1 combined sample taken at the time of bottle positivity, another at bottle positivity plus 24 hours of incubation, and 1 negative control sample containing an off-panel organism (*Streptococcus peroris,* CCUG 39814) incubated at 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 (*Streptococcus peroris* CCUG 39814) at 1.0 McFarland unit.

Table 18 and Table 19 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 18. Reproducibility hit rate results and confidence intervals established for all targets

			Agreement with expected results			
Target (Pathogen)	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All sites (95% Confidence Interval)**
aac(6')-aph(2") (*Enterococcus faecalis* ATCC 51299)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
Cryptococcus neoformans/gattii (*Cryptococcus gattii* ATCC MYA 4071)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
Enterococcus faecalis (*Enterococcus faecalis* ATCC 51299)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)

Table 18. Reproducibility hit rate results and confidence intervals established for all targets (continued)

			Agreement with expected results			
Target (Pathogen)	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All sites (95% Confidence Interval)**
Listeria monocytogenes (*L. monocytogenes* NCTC 5105)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
mecC (*Staphylococcus aureus* ATCC BAA2313)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
Staphylococcus aureus (*Staphylococcus aureus* ATCC BAA2313)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)

Table 18. Reproducibility hit rate results and confidence intervals established for all targets (continued)

			Agreement with expected results			
Target (Pathogen)	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All sites (95% Confidence Interval)**
Streptococcus anginosus group (*Streptococcus anginosus* CCUG 27298)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
vanB (*Enterococcus faecalis* ATCC 51299)	Positive (Bottle positivity)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	High Positive (Bottle positivity plus 24 hours incubation)	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)
	Negative (Bottle positive for off-panel target)	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6–100%)

Table 19. Reproducibility hit rate results and confidence intervals established for all targets for PC samples

			Agreement with expected results			
Target (Pathogen)	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All sites {95% Confidence Interval)**
aac(6')-aph(2") (*E. faecalis* ATCC 51299)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
Cryptococcus neoformans/gattii (*C. gattii* ATCC MYA 4071)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)

Table 19. Reproducibility hit rate results and confidence intervals established for all targets for PC samples (continued)

			Agreement with expected results			
Target (Pathogen)	**Sample (Concentration tested)**	**Expected**	**Site A**	**Site B**	**Site C**	**All sites (95% Confidence Interval)**
Enterococcus faecalis (*E. faecalis* ATCC 51299)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
Listeria monocytogenes (*L. monocytogenes* NCTC 5105)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
mecC (*S. aureus* ATCC BAA2313)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
Staphylococcus aureus (*S. aureus* ATCC BAA2313)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
Streptococcus anginosus group (*S. anginosus* CCUG 27298)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
vanB (*E. faecalis* ATCC 51299)	Positive	Positive	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)
	Negative	Negative	36 / 36	36 / 36	36 / 36	108 / 108 (96.6 – 100%)

13.1.12. Repeatability

A repeatability study was conducted for both sample types on a QIAstat-Dx Analyzer. For the blood culture sample type, test samples were contrived by inoculating blood culture bottles

with whole blood and the pathogenic material, incubated in a blood culture instrument until positive ring to obtain positive samples and negative sample containing an off-panel organism *(Streptococcus peroris,* CCUG 39814) incubated at bottle positivity. 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 *(Streptococcus peroris,* CCUG 39814) at 1 McFarland. For both sample types, the QIAstat-Dx BCID GPF Plus AMR Panel detected pathogens included in the positive samples were *S. aureus, mecC* (ATCC BAA-2313), *E.faecalis, vanB, aac(6')-aph (2")* (ATCC 51299), *L. monocytogenes* (NCTC 5105), *S. anginosus* (CCUG 27298), and *C. gattii* (ATCC MYA 4071). Negative samples included *S. peroris* (CCUG 39814). 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 GPF Plus AMR Panel was assessed by a multi-centre, 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 1024 prospective residual gram-positive by staining PBCM and a total of 1005 prospective PC were enrolled for the clinical performance evaluation study of the QIAstat-Dx BCID GPF Plus AMR Panel. The final dataset for the clinical performance evaluation study of the QIAstat-Dx BCID GPF Plus AMR Panel consisted of 976 and 1003 prospective specimens for PBMC 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 missing data.

The demographic information for the 976 PBCM specimens evaluated in the prospective study is summarized in Table 20.

Table 20. Demographic summary for prospective PBCM samples for QIAstat-Dx BCID GPF Plus AMR Panel clinical evaluation

Sample Type	Variable	Subgroup	N	%
Prospective Fresh	Age group	<1 year	15	1.7
		1–17 years	16	1.8
		18–44 years	140	15.4
		45–64 years	262	28.9
		65–89 years	434	47.9
		90+ years	40	4.4
	Sex	Female	387	42.7
		Male	519	57.2
		Not Reported	1	0.1
Prospective Frozen	Age group	1–17 years	1	1.4
		18–44 years	8	11.6
		45–64 years	18	26.1
		65–89 years	39	56.5
		90+ years	3	4.3
	Sex	Female	40	58.0
		Male	29	42.0

Table 20. Demographic summary for prospective PBCM samples for QIAstat-Dx BCID GPF Plus AMR Panel clinical evaluation (continued)

Sample Type	Variable	Subgroup	N	%
Prospective Total	Age group	<1 year	15	1.5
		1–17 years	17	1.7
		18–44 years	148	15.2
		45–64 years	280	28.7
		65–89 years	473	48.5
		90+ years	43	4.4
	Sex	Female	427	43.8
		Male	548	56.1
		Not Reported	1	0.1

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

Discordant testing for pathogens was carried out using an additional FDA-cleared, CE-marked test, and validated single PCR assays followed by Bidirectional sequencing which was not used as part of SoC.

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

Phenotypic AST results were also collected, if performed as part of the SoC procedure. Correlation of the QIAstat-Dx BCID GPF 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 GPF 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 GPF Plus AMR Panel and the comparator method have negative results for the specific pathogen. False positive (FP) indicates that the QIAstat-Dx BCID GPF Plus AMR Panel result is positive for the specific pathogen, but the comparator result is negative. The 2-sided 95% Confidence Intervals were calculated.

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

The QIAstat-Dx BCID GPF Plus AMR Panel prospective data for Positive Percent Agreement and Negative Percent Agreement against the comparator methods are presented by analyte in Table 21 and Table 22 for pathogens and AMRs respectively in PBCM samples.

13.2.2.1. Pathogens

Table 21. QIAstat-Dx BCID GPF Plus AMR Panel prospective clinical performance summary for PBCM samples

		PPA			NPA		
Pathogen	**Sample**	**TP/ (TP+FN)**	**%**	**95% CI (%)**	**TN/ (TN+FP)**	**%**	**95% CI (%)**
Bacillus cereus group*	Prospective Fresh	5 / 6	83.3	43.6–97.0	901 / 901	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	5 / 6	83.3	43.6–97.0	970 / 970	100.0	99.6–100.0
Corynebacterium†	Prospective Fresh	12 / 14	85.7	60.1–96.0	880 / 893	98.5	97.5–99.1
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	12 / 14	85.7	60.1–96.0	949 / 962	98.6	97.7–99.2
Enterococcus faecalis‡	Prospective Fresh	48 / 48	100.0	92.6–100.0	859 / 859	100.0	99.6–100.0
	Prospective Frozen	6 / 7	85.7	48.7–97.4	62 / 62	100.0	94.2–100.0

Table 21. QIAstat-Dx BCID GPF 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 (%)**
	Total	54 / 55	98.2	90.4–99.7	921 / 921	100.0	99.6–100.0
Enterococcus faecium§	Prospective Fresh	29 / 29	100.0	88.3–100.0	871 / 878	99.2	98.4–99.6
	Prospective Frozen	1 / 1	100.0	20.7–100.0	64 / 68	94.1	85.8–97.7
	Total	30 / 30	100.0	88.6–100.0	935 / 946	98.8	97.9–99.3
Listeria monocytogenes¶	Prospective Fresh	3 / 3	100.0	43.9–100.0	903 / 904	99.9	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	3 / 3	100.0	43.9–100.0	972 / 973	99.9	99.4–100.0
Micrococcus spp.**	Prospective Fresh	17 / 23	73.9	53.5–87.5	884 / 884	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	17 / 23	73.9	53.5–87.5	953 / 953	100.0	99.6–100.0
Staphylococcus aureus††	Prospective Fresh	206 / 208	99.0	96.6–99.7	696 / 699	99.6	98.7–99.9
	Prospective Frozen	13 / 13	100.0	77.2–100.0	55 / 56	98.2	90.6–99.7
	Total	219 / 221	99.1	96.8–99.8	751 / 755	99.5	98.6–99.8
Staphylococcus epidermidis‡‡	Prospective Fresh	228 / 232	98.3	95.7–99.3	662 / 675	98.1	96.7–98.9
	Prospective Frozen	26 / 28	92.9	77.4–98.0	41 / 41	100.0	91.4–100.0

Table 21. QIAstat-Dx BCID GPF 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 (%)**
	Total	254 / 260	97.7	95.1–98.9	703 / 716	98.2	96.9–98.9
Staphylococcus lugdunensis§§	Prospective Fresh	7 / 7	100.0	64.6–100.0	898 / 900	99.8	99.2–99.9
	Prospective Frozen	0 / 0	N/A	N/A	68 / 69	98.6	92.2–99.7
	Total	7 / 7	100.0	64.6–100.0	966 / 969	99.7	99.1–99.9
S. capitis / S. hominis¶¶	Prospective Fresh	110 / 113	97.3	92.5–99.1	770 / 794	97.0	95.5–98.0
	Prospective Frozen	3 / 3	100.0	43.9–100.0	60 / 66	90.9	81.6–95.8
	Total	113 / 116	97.4	92.7–99.1	830 / 860	96.5	95.1–97.5
*Streptococcus agalactiae****	Prospective Fresh	26 / 28	92.9	77.4–98.0	879 / 879	100.0	99.6–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	68 / 68	100.0	94.7–100.0
	Total	27 / 29	93.1	78.0–98.1	947 / 947	100.0	99.6–100.0
Streptococcus anginosus group†††	Prospective Fresh	11 / 11	100.0	74.1–100.0	895 / 896	99.9	99.4–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	68 / 68	100.0	94.7–100.0
	Total	12 / 12	100.0	75.8–100.0	963 / 964	99.9	99.4–100.0
Streptococcus pneumoniae‡‡‡	Prospective Fresh	27 / 27	100.0	87.5–100.0	877 / 880	99.7	99.0–99.9
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0

Table 21. QIAstat-Dx BCID GPF 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 (%)**
	Total	27 / 27	100.0	87.5–100.0	946 / 949	99.7	99.1–99.9
Streptococcus pyogenes	Prospective Fresh	22 / 22	100.0	85.1–100.0	885 / 885	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	22 / 22	100.0	85.1–100.0	954 / 954	100.0	99.6–100.0
Cryptococcus neoformans/gattii	Prospective Fresh	2 / 2	100.0	34.2–100.0	905 / 905	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	2 / 2	100.0	34.2–100.0	974 / 974	100.0	99.6–100.0
Fusarium	Prospective Fresh	0 / 0	N/A	N/A	907 / 907	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	0 / 0	N/A	N/A	976 / 976	100.0	99.6–100.0
Candida auris	Prospective Fresh	1 / 1	100.0	20.7–100.0	906 / 906	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7–100.0
	Total	1 / 1	100.0	20.7–100.0	975 / 975	100.0	99.6–100.0
Pan Gram-Negative§§§	Prospective Fresh	13 / 16	81.3	57.0–93.4	891 / 891	100.0	99.6–100.0
	Prospective Frozen	13 / 13	100.0	77.2–100.0	56 / 56	100.0	93.6–100.0

Table 21. QIAstat-Dx BCID GPF 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 (%)**
	Total	26 / 29	89.7	73.6–96.4	947 / 947	100.0	99.6–100.0
Candida group 1¶¶¶	Prospective Fresh	16 / 16	100.0	80.6–100.0	889 / 891	99.8	99.2–99.9
	Prospective Frozen	1 / 1	100.0	20.7–100.0	68 / 68	100.0	94.7–100.0
	Total	17 / 17	100.0	81.6–100.0	957 / 959	99.8	99.2–99.9
Candida group 2****	Prospective Fresh	18 / 19	94.7	75.4–99.1	888 / 888	100.0	99.6–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	68 / 68	100.0	94.7–100.0
	Total	19 / 20	95.0	76.4–99.1	956 / 956	100.0	99.6–100.0

* *Bacillus cereus* group was not detected in the single FN specimen using an additional molecular method.

† 11/13 *Corynebacterium* FP specimens were identified as cross-reactivities between the QIAstat-Dx BCID GPF Plus AMR Panel *Corynebacterium* target and other species: 4 *Cutibacterium* acnes, 3 *Rothia mucilaginosa,* 2 *Micrococcus* spp., 1 *Rothia dentocariosa,* and 1 *Cutibacterium granulosum*. *Corynebacterium* was not detected in the 13 FP specimens using an additional molecular method. *Corynebacterium* was not detected in 1/2 FN specimen using an additional molecular method.

‡ No additional testing was performed for the *Enterococcus faecalis* FN specimen.

§ Of the 11 *Enterococcus faecium* FP specimens, 7 specimens were tested using an additional method and *E. faecium* was not detected in the tested specimens.

¶ *Listeria monocytogenes* was detected in the single FP specimen using an additional molecular method.

** For the 6 *Micrococcus* spp FN samples, *Micrococcus* spp was not detected in 2/6 specimens and detected in 4/6 specimens using an additional molecular method. In 1/2 FN not detected with an additional molecular method, upon regrowth of the specimen and additional VITEK2 testing, the sample was identified as *Kocuria varians*.

†† *Staphylococcus aureus* was detected in 1/4 FP specimens and not detected in 3/4 FP specimens using an additional molecular method, whereas *S. aureus* was detected in 1/2 FN specimens and not detected in 1/2 FN specimens using an additional molecular method.

Table 21. QIAstat-Dx BCID GPF 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 (%)**

‡‡ *Staphylococcus epidermidis* was detected in 8 of the 13 FP specimens using an additional molecular method and not detected in the remaining 5 specimens. Of the 6 FN specimens, *S. epidermidis* was detected in one specimen, and not detected in 5 specimens using an additional molecular method.

§§ Of the 3 *Staphylococcus lugdunensis* FP specimens, 2 were tested using an additional molecular method. *Staphylococcus lugdunensis* was detected in 1/2 FP specimen and not detected in 1/2 FP specimen.

¶¶ *Staphylococcus capitis/Staphylococcus hominis* were detected in 26/30 FP specimens using an additional molecular method, whereas it was not detected in one sample, and not tested for the 3 remaining FP specimens. Of the 3 FN specimens, *Staphylococcus capitis/Staphylococcus hominis* were detected in all specimens using an additional molecular method.

*** *Streptococcus agalactiae* was not detected in the 2 FN specimens using an additional molecular method.

††† *Streptococcus anginosus* group FP specimen was not detected using an additional molecular method.

‡‡‡ Of the 3 *Streptococcus pneumoniae* FP specimens none were not detected using an additional molecular method.

§§§ No additional testing was performed for the Pan Gram-Negative FN specimens.

¶¶¶ *Candida* group 1 was not detected in the 2 FP specimens using an additional molecular method.

**** *Candida* group 2 was not detected in the single FN specimen using an additional molecular method.

13.2.2.2. AMR

Table 22. QIAstat-Dx BCID GPF Plus AMR Panel prospective clinical performance summary for PBCM samples

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
cfr	Prospective Fresh	0 / 0	N/A	N/A	586 / 586	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	40 / 40	100.0	91.2–100.0
	Total	0 / 0	N/A	N/A	626 / 626	100.0	99.4–100.0
ermA	Prospective Fresh	39 / 43	90.7	78.4–96.3	563 / 568	99.1	98.0–99.6
	Prospective Frozen	5 / 5	100.0	56.6–100.0	39 / 40	97.5	87.1–99.6
	Total	44 / 48	91.7	80.4–96.7	602 / 608	99.0	97.9–99.5

Table 22. QIAstat-Dx BCID GPF 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 (%)**
ermC	Prospective Fresh	124 / 140	88.6	82.2–92.8	463 / 471	98.3	96.7–99.1
	Prospective Frozen	12 / 12	100.0	75.8–100.0	33 / 33	100.0	89.6–100.0
	Total	136 / 152	89.5	83.6–93.4	496 / 504	98.4	96.9–99.2
mecA	Prospective Fresh	262 / 286	91.6	87.8–94.3	235 / 249	94.4	90.8–96.6
	Prospective Frozen	22 / 23	95.7	79.0–99.2	16 / 16	100.0	80.6–100.0
	Total	284 / 309	91.9	88.3–94.5	251 / 265	94.7	91.3–96.8
mecC	Prospective Fresh	0 / 0	N/A	N/A	206 / 206	100.0	98.2–100.0
	Prospective Frozen	0 / 0	N/A	N/A	13 / 13	100.0	77.2–100.0
	Total	0 / 0	N/A	N/A	219 / 219	100.0	98.3–100.0
vanA	Prospective Fresh	12 / 12	100.0	75.8–100.0	267 / 271	98.5	96.3–99.4
	Prospective Frozen	1 / 1	100.0	20.7–100.0	18 / 18	100.0	82.4–100.0
	Total	13 / 13	100.0	77.2–100.0	285 / 289	98.6	96.5–99.5
vanB	Prospective Fresh	2 / 2	100.0	34.2–100.0	281 / 281	100.0	98.7–100.0
	Prospective Frozen	0 / 0	N/A	N/A	19 / 19	100.0	83.2–100.0
	Total	2 / 2	100.0	34.2–100.0	300 / 300	100.0	98.7–100.0
tetM	Prospective Fresh	83 / 91	91.2	83.6–95.5	589 / 599	98.3	97.0–99.1
	Prospective Frozen	9 / 9	100.0	70.1–100.0	36 / 38	94.7	82.7–98.5
	Total	92 / 100	92.0	85.0–95.9	625 / 637	98.1	96.7–98.9
tetK	Prospective Fresh	86 / 98	87.8	79.8–92.9	562 / 567	99.1	98.0–99.6
	Prospective Frozen	6 / 7	85.7	48.7–97.4	39 / 39	100.0	91.0–100.0
	Total	92 / 105	87.6	80.0–92.6	601 / 606	99.2	98.1–99.6
aac(6')-aph(2")	Prospective Fresh	73 / 94	77.7	68.2–84.9	537 / 543	98.9	97.6–99.5
	Prospective Frozen	5 / 6	83.3	43.6–97.0	39 / 40	97.5	87.1–99.6
	Total	78 / 100	78.0	68.9–85.0	576 / 583	98.8	97.5–99.4

13.2.2.3. Co-infections

The QIAstat-Dx BCID GPF Plus AMR Panel reported multiple organism detections (i.e., co-infections) for a total of 85/976 (9.0%) prospective specimens. Most multiple detections in prospective specimens (76/85; 89.4%) contained 2 organisms, while (9/85;10.6%) contained 3 organisms.

Table 23. Detection summary combinations determined by the QIAstat-Dx BCID GPF Plus AMR Panel in the prospective clinical study

Detection summary	
Detected pathogens on QIAstat-Dx BCID GPF Plus AMR Panel	**Number of specimens with multi-detections**
Total co-infection detections	85
Double detections	76
Triple detections	9

The most common multiple infections (>3 instances) are shown in Table 24.

Table 24. Most prevalent multiple detection combinations (>3 instances) as determined by the QIAstat-Dx BCID GPF Plus AMR Panel in the prospective clinical study

Detected pathogens on QIAstat-Dx	Number of specimens with multi-detections
Detection summary	
Candida group 1+ *Enterococcus faecium*	3
Enterococcus faecium + Pan Gram-Negative	4
Enterococcus faecium + *Staphylococcus epidermidis*	3
S. capitis / S. hominis + *Staphylococcus epidermidis*	46
Staphylococcus aureus + *Staphylococcus epidermidis*	6
S. capitis / S. hominis + *Staphylococcus epidermidis* + *Staphylococcus lugdunensis*	3

13.2.2.4. Testing of preselected archived (Retrospective) specimens

Several analytes in the QIAstat-Dx BCID GPF 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 GPF 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 290 evaluable archived specimen were collected and 281 were used in the analysis to support the QIAstat-Dx BCID GPF Plus AMR Panel performance evaluation. Table 25 provides a summary of demographic information for the archived specimens.

Table 25. Demographic summary of evaluable archived specimens for QIAstat-Dx BCID GPF Plus AMR Panel clinical evaluation

Sample type	Variable	Subgroup	N	%
Retrospective Archived	Age group	<1 year	3	1.1
		1–17 years	7	2.5
		18–44 years	41	14.6
		45–64 years	77	27.4
		65–89 years	144	51.2
		90+ years	9	3.2
	Sex	Female	134	47.7
		Male	147	52.3

The QIAstat-Dx BCID GPF 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 26 and Table 27 for pathogens and AMRs respectively.

Pathogens

Table 26. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for pathogens

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Bacillus cereus group*	10 / 12	83.3	55.2–95.3	269 / 269	100.0	98.6–100.0
Corynebacterium†	33 / 36	91.7	78.2–97.1	242 / 245	98.8	96.5–99.6

Table 26. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for pathogens (continued)

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Enterococcus faecalis	0 / 0	N/A	N/A	281 / 281	100.0	98.7–100.0
Enterococcus faecium	0 / 0	N/A	N/A	281 / 281	100.0	98.7–100.0
Listeria monocytogenes	14 / 14	100.0	78.5–100.0	267 / 267	100.0	98.6–100.0
Micrococcus spp.‡	34 / 36	94.4	81.9–98.5	245 / 245	100.0	98.5–100.0
Staphylococcus aureus	0 / 0	N/A	N/A	281 / 281	100.0	98.7–100.0
Staphylococcus epidermidis§	1 / 2	50.0	9.5–90.5	277 / 279	99.3	97.4–99.8
Staphylococcus lugdunensis	7 / 7	100.0	64.6–100.0	274 / 274	100.0	98.6–100.0
S. capitis / S. hominis¶	22 / 22	100.0	85.1–100.0	257 / 259	99.2	97.2–99.8
Streptococcus agalactiae	35 / 35	100.0	90.1–100.0	246 / 246	100.0	98.5–100.0
Streptococcus anginosus group	29 / 29	100.0	88.3–100.0	252 / 252	100.0	98.5–100.0
Streptococcus pneumoniae	37 / 37	100.0	90.6–100.0	244 / 244	100.0	98.5–100.0
Streptococcus pyogenes	39 / 39	100.0	91.0–100.0	242 / 242	100.0	98.4–100.0
Cryptococcus neoformans/gattii	1 / 1	100.0	20.7–100.0	280 / 280	100.0	98.6–100.0
Fusarium	1 / 1	100.0	20.7–100.0	280 / 280	100.0	98.6–100.0
Candida auris	1 / 1	100.0	20.7–100.0	280 / 280	100.0	98.6–100.0
Pan Gram-Negative**	6 / 6	100.0	61.0–100.0	273 / 275	99.3	97.4–99.8
Candida group 1	2 / 2	100.0	34.2–100.0	279 / 279	100.0	98.6–100.0

Table 26. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for pathogens (continued)

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Candida group 2	9 / 9	100.0	70.1–100.0	272 / 272	100.0	98.6–100.0

* Of the 2 *Bacillus* group FN specimens, 1/2 FN specimens was tested using an additional molecular method and *Bacillus cereus* group was detected in the tested specimen.

† 3/3 *Corynebacterium*FP specimens were not associated with cross-reactivities between the QIAstat-Dx BCID GPF Plus AMR Panel *Corynebacterium* target and other species. *Corynebacterium* was not detected in the 3 FP specimens using an additional molecular method. *Corynebacterium* was not detected in the FN specimens using an additional molecular method.

‡ *Micrococcus* spp was detected in the 2 FN specimens using an additional molecular method.

§ *Staphylococcus epidermidis* was detected in 1 of the 2 FP specimens using an additional molecular method and not detected in the other specimen. The single *Staphylococcus epidermidis* FN specimen was detected using an additional molecular method.

¶ *Staphylococcus capitis/Staphylococcus hominis* were detected in the 2 FP specimens using an additional molecular method.

** No additional testing was performed for the Pan Gram-Negative retrospective FP specimens.

AMRs

Table 27. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for AMRs

	PPA			NPA		
AMR	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
cfr	0 / 0	N/A	N/A	61 / 61	100.0	94.1–100.0
ermA	0 / 0	N/A	N/A	32 / 32	100.0	89.3–100.0
ermC	2 / 3	66.7	20.8–93.9	29 / 29	100.0	88.3–100.0
mecA	6 / 6	100.0	61.0–100.0	25 / 25	100.0	86.7–100.0
tetM	34 / 34	100.0	89.8–100.0	126 / 127	99.2	95.7–99.9
tetK	4 / 4	100.0	51.0–100.0	98 / 98	100.0	96.2–100.0
aac(6')-aph(2")	1 / 1	100.0	20.7–100.0	64 / 64	100.0	94.3–100.0

13.2.2.5. Validity of results

The proportion of failed runs in clinical specimens (prospective and retrospective samples) on initial attempt was 1.5 % (19/1259) and following repeats was 0.2 % (2/1259), yielding an

overall success rate of 98.5 % (1240/1259) before retesting, and 99.8% (1257/1259) after retesting.

13.2.2.6. Testing of contrived specimens

Contrived specimen testing was required for all 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. The results are summarized in Table 28 and Table 29 for pathogens and AMRs respectively.

13.2.2.7. Pathogens

Table 28. Test results summary for contrived specimens

	PPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**
Bacillus cereus group	50 / 50	100.0	92.9–100.0
Enterococcus faecalis	59 / 59	100.0	93.9–100.0
Enterococcus faecium	40 / 40	100.0	91.2–100.0
Listeria monocytogenes	50 / 50	100.0	92.9–100.0
Staphylococcus aureus	69 / 69	100.0	94.7–100.0
Staphylococcus epidermidis	49 / 49	100.0	92.7–100.0
Staphylococcus lugdunensis	50 / 50	100.0	92.9–100.0
Cryptococcus neoformans/gattii	50 / 50	100.0	92.9–100.0
Fusarium	49 / 50	98.0	89.5–99.6
Candida auris	49 / 50	98.0	89.5–99.6
Candida group 1	50 / 50	100.0	92.9–100.0
Candida group 2	50 / 50	100.0	92.9–100.0

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

13.2.2.8. AMRs

Table 29. Test results summary for contrived specimens

	PPA		
AMR	**TP/(TP+FN)**	**%**	**95% CI (%)**
cfr	46 / 49	93.9	83.5–97.9
ermC	56 / 59	94.9	86.1–98.3
mecA	68 / 69	98.6	92.2–99.7
mecC	49 / 49	100.0	92.7–100.0
vanA	60 / 60	100.0	94.0–100.0
vanB	50 / 50	100.0	92.9–100.0
tetM	76 / 80	95.0	87.8–98.0
tetK	19 / 20	95.0	76.4–99.1
aac(6')-aph(2")	116 / 129	89.9	83.5–94.0

The proportion of positive results was ≥95% for all prepared contrived samples for AMRs in all tested analytes (except *cfr*, 93.9%; *erm(C)*, 94.9 % and *aac(6')-aph(2")*, 89.9%).

13.2.2.9. Expected values for all targets

The number and percentage of positive cases, as determined by the QIAstat-Dx BCID GPF Plus AMR Panel, calculated by testing site and by age group are present in Table 30. Overall, 976 prospective specimens were included in the prevalence assessment and the QIAstat-Dx BCID GPF Plus AMR Panel detected at least one organism in a total of 854 prospective specimens (87.5% positivity rate).

Table 30. Expected value (EV) (as determined by the QIAstat-Dx BCID GPF Plus AMR Panel) summary overall for prospective samples and by age for all targets

Target	Overall (n=976)	<1 year (n=15)	1–17 years (n=17)	18–44 years (n=148)	45–64 years (n=280)	65–89 years (n=473)	90+ years (n=43)
Bacillus cereus group	5 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.7%)	2 (0.4%)	1 (2.3%)
Corynebacterium	25 (2.6%)	0 (0.0%)	0 (0.0%)	3 (2.0%)	9 (3.2%)	11 (2.3%)	2 (4.7%)

Table 30. Expected value (EV) (as determined by the QIAstat-Dx BCID GPF Plus AMR Panel) summary overall for prospective samples and by age for all targets (continued)

Target	Overall (n=976)	<1 year (n=15)	1–17 years (n=17)	18–44 years (n=148)	45–64 years (n=280)	65–89 years (n=473)	90+ years (n=43)
Enterococcus faecalis	54 (5.5%)	1 (6.7%)	0 (0.0%)	4 (2.7%)	19 (6.8%)	29 (6.1%)	1 (2.3%)
Enterococcus faecium	41 (4.2%)	0 (0.0%)	0 (0.0%)	11 (7.4%)	10 (3.6%)	18 (3.8%)	2 (4.7%)
Listeria monocytogenes	4 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	2 (0.4%)	1 (2.3%)
Micrococcus spp.	17 (1.7%)	1 (6.7%)	0 (0.0%)	4 (2.7%)	2 (0.7%)	9 (1.9%)	1 (2.3%)
Staphylococcus aureus	223 (22.8%)	4 (26.7%)	5 (29.4%)	39 (26.4%)	66 (23.6%)	100 (21.1%)	9 (20.9%)
Staphylococcus epidermidis	267 (27.4%)	4 (26.7%)	4 (23.5%)	41 (27.7%)	81 (28.9%)	124 (26.2%)	13 (30.2%)
Staphylococcus lugdunensis	10 (1.0%)	0 (0.0%)	0 (0.0%)	2 (1.4%)	2 (0.7%)	6 (1.3%)	0 (0.0%)
S. capitis / S. hominis	143 (14.7%)	1 (6.7%)	1 (5.9%)	20 (13.5%)	36 (12.9%)	79 (16.7%)	6 (14.0%)
Streptococcus agalactiae	27 (2.8%)	2 (13.3%)	0 (0.0%)	3 (2.0%)	8 (2.9%)	13 (2.7%)	1 (2.3%)
Streptococcus anginosus group	13 (1.3%)	0 (0.0%)	1 (5.9%)	1 (0.7%)	5 (1.8%)	6 (1.3%)	0 (0.0%)
Streptococcus pneumoniae	30 (3.1%)	0 (0.0%)	1 (5.9%)	3 (2.0%)	9 (3.2%)	11 (2.3%)	6 (14.0%)
Streptococcus pyogenes	22 (2.3%)	0 (0.0%)	0 (0.0%)	7 (4.7%)	7 (2.5%)	8 (1.7%)	0 (0.0%)
Cryptococcus neoformans/gattii	2 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (2.3%)
Fusarium	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Candida auris	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
Pan Gram-Negative	26 (2.7%)	0 (0.0%)	2 (11.8%)	5 (3.4%)	7 (2.5%)	11 (2.3%)	1 (2.3%)
Candida group 1	19 (1.9%)	1 (6.7%)	0 (0.0%)	3 (2.0%)	10 (3.6%)	5 (1.1%)	0 (0.0%)

Table 30. Expected value (EV) (as determined by the QIAstat-Dx BCID GPF Plus AMR Panel) summary overall for prospective samples and by age for all targets (continued)

Target	Overall (n=976)	<1 year (n=15)	1–17 years (n=17)	18–44 years (n=148)	45–64 years (n=280)	65–89 years (n=473)	90+ years (n=43)
Candida group 2	19 (1.9%)	0 (0.0%)	2 (11.8%)	1 (0.7%)	8 (2.9%)	8 (1.7%)	0 (0.0%)
cfr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ermA	50 (5.1%)	1 (6.7%)	1 (5.9%)	3 (2.0%)	10 (3.6%)	29 (6.1%)	6 (14.0%)
ermC	145 (14.9%)	1 (6.7%)	1 (5.9%)	21 (14.2%)	45 (16.1%)	72 (15.2%)	5 (11.6%)
mecA	300 (30.7%)	4 (26.7%)	5 (29.4%)	38 (25.7%)	86 (30.7%)	157 (33.2%)	10 (23.3%)
mecC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
vanA	17 (1.7%)	0 (0.0%)	0 (0.0%)	7 (4.7%)	3 (1.1%)	7 (1.5%)	0 (0.0%)
vanB	2 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	0 (0.0%)
tetM	106 (10.9%)	1 (6.7%)	1 (5.9%)	20 (13.5%)	29 (10.4%)	53 (11.2%)	2 (4.7%)
tetK	97 (9.9%)	0 (0.0%)	0 (0.0%)	14 (9.5%)	26 (9.3%)	50 (10.6%)	7 (16.3%)
aac(6')-aph(2")	87 (8.9%)	0 (0.0%)	0 (0.0%)	10 (6.8%)	18 (6.4%)	55 (11.6%)	4 (9.3%)
Overall	**854 (87.5%)**	**14 (93.3%)**	**12 (70.6%)**	**135 (91.2%)**	**256 (91.4%)**	**399 (84.4%)**	**38 (88.4%)**

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

The QIAstat-Dx BCID GPF Plus AMR Panel prospective data for Positive Percent Agreement and Negative Percent Agreement against the comparator methods are presented by analyte in Table 31 and Table 32 for pathogens and AMRs respectively in PC samples.

13.2.3.1. Pathogens

Table 31. QIAstat-Dx BCID GPF Plus AMR Panel prospective clinical performance summary for PC samples

		PPA			NPA		
Pathogen	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI**
Bacillus cereus group*	Prospective Fresh	5 / 6	83.3	43.6–97.0	940 / 940	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	5 / 6	83.3	43.6–97.0	997 / 997	100.0	99.6–100.0
Corynebacterium†	Prospective Fresh	13 / 14	92.9	68.5–98.7	917 / 932	98.4	97.4–99.0
	Prospective Frozen	0 / 0	N/A	N/A	56 / 57	98.2	90.7–99.7
	Total	13 / 14	92.9	68.5–98.7	973 / 989	98.4	97.4–99.0
Enterococcus faecalis‡	Prospective Fresh	49 / 52	94.2	84.4–98.0	893 / 894	99.9	99.4–100.0
	Prospective Frozen	8 / 8	100.0	67.6–100.0	49 / 49	100.0	92.7–100.0
	Total	57 / 60	95.0	86.3–98.3	942 / 943	99.9	99.4–100.0

Table 31. QIAstat-Dx BCID GPF 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**
Enterococcus faecium§	Prospective Fresh	28 / 28	100.0	87.9–100.0	918 / 918	100.0	99.6–100.0
	Prospective Frozen	0 / 1	0.0	0.0–79.3	56 / 56	100.0	93.6–100.0
	Total	28 / 29	96.6	82.8–99.4	974 / 974	100.0	99.6–100.0
Listeria monocytogenes	Prospective Fresh	3 / 3	100.0	43.9–100.0	943 / 943	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	3 / 3	100.0	43.9–100.0	1000 / 1000	100.0	99.6–100.0
Micrococcus spp. ¶	Prospective Fresh	16 / 23	69.6	49.1–84.4	922 / 923	99.9	99.4–100.0
	Prospective Frozen	0 / 1	0.0	0.0–79.3	55 / 56	98.2	90.6–99.7
	Total	16 / 24	66.7	46.7–82.0	977 / 979	99.8	99.3–99.9
*Staphylococcus aureus***	Prospective Fresh	219 / 222	98.6	96.1–99.5	723 / 724	99.9	99.2–100.0
	Prospective Frozen	8 / 8	100.0	67.6–100.0	49 / 49	100.0	92.7–100.0
	Total	227 / 230	98.7	96.2–99.6	772 / 773	99.9	99.3–100.0

Table 31. QIAstat-Dx BCID GPF 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**
Staphylococcus epidermidis††	Prospective Fresh	233 / 245	95.1	91.6–97.2	697 / 701	99.4	98.5–99.8
	Prospective Frozen	22 / 27	81.5	63.3–91.8	30 / 30	100.0	88.6–100.0
	Total	255 / 272	93.8	90.2–96.1	727 / 731	99.5	98.6–99.8
Staphylococcus lugdunensis‡‡	Prospective Fresh	6 / 7	85.7	48.7–97.4	938 / 939	99.9	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	6 / 7	85.7	48.7–97.4	995 / 996	99.9	99.4–100.0
S. capitis / S. hominis§§	Prospective Fresh	109 / 116	94.0	88.1–97.0	814 / 830	98.1	96.9–98.8
	Prospective Frozen	3 / 4	75.0	30.1–95.4	49 / 53	92.5	82.1–97.0
	Total	112 / 120	93.3	87.4–96.6	863 / 883	97.7	96.5–98.5
Streptococcus agalactiae¶¶	Prospective Fresh	26 / 28	92.9	77.4–98.0	918 / 918	100.0	99.6–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	56 / 56	100.0	93.6–100.0
	Total	27 / 29	93.1	78.0–98.1	974 / 974	100.0	99.6–100.0

Table 31. QIAstat-Dx BCID GPF 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**
Streptococcus anginosus group	Prospective Fresh	12 / 12	100.0	75.8–100.0	934 / 934	100.0	99.6–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	56 / 56	100.0	93.6–100.0
	Total	13 / 13	100.0	77.2–100.0	990 / 990	100.0	99.6–100.0
*Streptococcus pneumoniae***	Prospective Fresh	31 / 31	100.0	89.0–100.0	914 / 915	99.9	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	31 / 31	100.0	89.0–100.0	971 / 972	99.9	99.4–100.0
Streptococcus pyogenes†††	Prospective Fresh	25 / 25	100.0	86.7–100.0	920 / 921	99.9	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	25 / 25	100.0	86.7–100.0	977 / 978	99.9	99.4–100.0
Cryptococcus neoformans/gattii	Prospective Fresh	2 / 2	100.0	34.2–100.0	944 / 944	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	2 / 2	100.0	34.2–100.0	1001 / 1001	100.0	99.6–100.0

Table 31. QIAstat-Dx BCID GPF 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**
Candida auris	Prospective Fresh	1 / 1	100.0	20.7–100.0	945 / 945	100.0	99.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	57 / 57	100.0	93.7–100.0
	Total	1 / 1	100.0	20.7–100.0	1002 / 1002	100.0	99.6–100.0
Candida group 1‡‡‡	Prospective Fresh	16 / 17	94.1	73.0–99.0	929 / 929	100.0	99.6–100.0
	Prospective Frozen	2 / 2	100.0	34.2–100.0	55 / 55	100.0	93.5–100.0
	Total	18 / 19	94.7	75.4–99.1	984 / 984	100.0	99.6–100.0
Candida group 2§§§	Prospective Fresh	19 / 20	95.0	76.4–99.1	926 / 926	100.0	99.6–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	56 / 56	100.0	93.6–100.0
	Total	20 / 21	95.2	77.3–99.2	982 / 982	100.0	99.6–100.0

Table 31. QIAstat-Dx BCID GPF 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**

* *Bacillus cereus* group was not detected in the single FN specimen using an additional molecular method.

† 12/16 *Corynebacterium* FP specimens were identified as cross-reactivities between the QIAstat-Dx BCID GPF Plus AMR Panel *Corynebacterium* target and other species: 4 *Cutibacterium* acnes, 3 *Rothia mucilaginosa,* 2 *Micrococcus* spp., 1 *Rothia dentocariosa,* and 1 *Cutibacterium granulosum*. *Corynebacterium* was not detected in the 13/16 FP specimens that were tested using an additional molecular method. *Corynebacterium* was detected in the single FN specimen using an additional molecular method.

‡ No additional testing was performed for the *Enterococcus faecalis* FP and FN specimen.

§ *Enterococcus faecium* single FN specimen was detected using an additional molecular method.

¶ For the 8 *Micrococcus* spp FN specimens, *Micrococcus* spp was not detected in 2/8 specimens and detected in 4/8 specimens using an additional molecular method, it was not tested in the remaining 2 specimens. In 1/2 FN not detected with an additional molecular method, upon regrowth of the specimen and additional VITEK2 testing, the sample was identified as *Kocuria varians*. No additional testing was performed for the 2 *Micrococcus* spp. FP specimens.

** Of the 3 *Staphylococcus aureus* FN specimens, 2 were tested using an additional molecular method. *Staphylococcus aureus* was detected in 1/2 FN specimens and not detected in 1/2 FN specimens. No additional testing was performed for the *S. aureus* FP specimen.

†† *Staphylococcus epidermidis* was detected in 3/4 FP specimens using an additional molecular method and not tested in the other specimen. Of the seventeen (17) FN specimens, S. epidermidis was detected in 1 specimen, not detected in 3 specimens using an additional molecular method and not tested in the remaining 13 specimens.

‡‡ No additional testing was performed for the *Staphylococcus lugdunensis* FP and FN specimens.

§§ Of the 20 *Staphylococcus capitis / Staphylococcus hominis* FP specimens, 15 were tested and detected using an additional molecular method. Of the 8 FN specimens, 3 were tested and detected using an additional molecular method.

¶¶ *Streptococcus agalactiae* was not detected in the 2 FN specimens using an additional molecular method.

*** No additional testing was performed for the *Streptococcus pneumoniae* FP specimen.

††† No additional testing was performed for the *Streptococcus pyogenes* FP specimen.

‡‡‡ No additional testing was performed for the *Candida* group 1 FN specimen.

§§§ *Candida* group 2 was not detected in the single FN specimen using an additional molecular method.

13.2.3.2. AMRs

Table 32. QIAstat-Dx BCID GPF Plus AMR Panel prospective clinical performance summary for PC samples

		PPA			NPA		
AMR	**Sample**	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
cfr	Prospective Fresh	0 / 0	N/A	N/A	578 / 578	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	32 / 32	100.0	89.3–100.0
	Total	0 / 0	N/A	N/A	610 / 610	100.0	99.4–100.0
ermA	Prospective Fresh	37 / 43	86.0	72.7–93.4	555 / 559	99.3	98.2–99.7
	Prospective Frozen	4 / 4	100.0	51.0–100.0	34 / 35	97.1	85.5–99.5
	Total	41 / 47	87.2	74.8–94.0	589 / 594	99.2	98.0–99.6
ermC	Prospective Fresh	112 / 135	83	75.7–88.4	462 / 467	98.9	97.5–99.5
	Prospective Frozen	8 / 10	80.0	49.0–94.3	29 / 29	100.0	88.3–100.0
	Total	120 / 145	82.8	75.8–88.0	491 / 496	99.0	97.7–99.6
mecA	Prospective Fresh	244 / 278	87.8	83.4–91.1	234 / 249	94.0	90.3–96.3
	Prospective Frozen	15 / 17	88.2	65.7–96.7	15 / 15	100.0	79.6–100.0
	Total	259 / 295	87.8	83.6–91.1	249 / 264	94.3	90.8–96.5

Table 32. QIAstat-Dx BCID GPF 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 (%)**
mecC	Prospective Fresh	0 / 0	N/A	N/A	206 / 206	100.0	98.2–100.0
	Prospective Frozen	0 / 0	N/A	N/A	8 / 8	100.0	67.6–100.0
	Total	0 / 0	N/A	N/A	214 / 214	100.0	98.2–100.0
vanA	Prospective Fresh	11 / 11	100.0	74.1–100.0	265 / 269	98.5	96.2–99.4
	Prospective Frozen	0.0% - 79.3%	0 / 1	0.0	14 / 14	100.0	78.5–100.0
	Total	11 / 12	91.7	64.6–98.5	279 / 283	98.6	96.4–99.4
vanB	Prospective Fresh	2 / 2	100.0	34.2–100.0	278 / 278	100.0	98.6–100.0
	Prospective Frozen	0 / 0	N/A	N/A	15 / 15	100.0	79.6–100.0
	Total	2 / 2	100.0	34.2–100.0	293 / 293	100.0	98.7–100.0
tetM	Prospective Fresh	78 / 89	87.6	79.2–93.0	578 / 588	98.3	96.9–99.1
	Prospective Frozen	8 / 9	88.9	56.5–98.0	30 / 32	93.8	79.9–98.3
	Total	86 / 98	87.8	79.8–92.9	608 / 620	98.1	96.6–98.9
tetK	Prospective Fresh	76 / 95	80.0	70.9–86.8	554 / 557	99.5	98.4–99.8
	Prospective Frozen	4 / 7	57.1	25.0–84.2	32 / 33	97.0	84.7–99.5
	Total	80 / 102	78.4	69.5–85.3	586 / 590	99.3	98.3–99.7
aac(6')-aph(2")	Prospective Fresh	65 / 87	74.7	64.7–82.7	535 / 538	99.4	98.4–99.8
	Prospective Frozen	5 / 6	83.3	43.6–97.0	33 / 34	97.1	85.1–99.5
	Total	70 / 93	75.3	65.6–82.9	568 / 572	99.3	98.2–99.7

13.2.3.3. Co-infections

The QIAstat-Dx BCID GPF Plus AMR Panel reported multiple organism detections (i.e., co-infections) for a total of 44/1003 (4.4%) prospective PC specimens. All multiple detections in prospective specimens (44/44; 100%) contained 2 organisms.

Table 33. Detection summary combinations determined by the QIAstat-Dx BCID GPF Plus AMR Panel in the prospective clinical study

Detection summary	
Detected pathogens on QIAstat-Dx BCID GPF Plus AMR Panel	**No. of specimens with multi-detections**
Total co-infection detections	44
Double detections	44

The most common multiple infections (>3 instances) are shown in Table 34.

Table 34. Most prevalent multiple detection combinations (>3 instances) as determined by the QIAstat-Dx BCID GPF Plus AMR Panel in the prospective clinical study

Detected pathogens on QIAstat-Dx	No. of specimens with multi-detections
Detection summary	
S. capitis / S. hominis + Staphylococcus epidermidis	28
Staphylococcus aureus + Streptococcus pyogenes	3

13.2.3.4. Testing of preselected archived (Retrospective) specimens

Several analytes in the QIAstat-Dx BCID GPF 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 1 of the QIAstat-Dx BCID GPF 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 280 evaluable archived specimen were collected and 279 were used in the analysis to support the QIAstat-Dx BCID GPF Plus AMR Panel performance evaluation. Table 35 provides a summary of demographic information for the archived specimens.

Table 35. Demographic summary of evaluable archived specimens for QIAstat-Dx BCID GPF Plus AMR Panelclinical evaluation

Sample Type	Variable	Subgroup	N	%
Retrospective Archived	Age group	< 1 year	3	1.1
		1–17 years	7	2.5
		18–44 years	40	14.3
		45–64 years	78	28.0
		65–89 years	142	50.9
		90+ years	9	3.2
	Sex	Female	133	47.7
		Male	146	52.3

The QIAstat-Dx BCID GPF 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 36 and Table 37 for pathogens and AMRs respectively.

Pathogens

Table 36. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for pathogens

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
*Bacillus cereus** group	10 / 12	83.3	55.2–95.3	267 / 267	100.0	98.6–100.0
Corynebacterium†	32 / 35	91.4	77.6–97.0	243 / 244	99.6	97.7–99.9
Enterococcus faecalis	0 / 0	N/A	N/A	279 / 279	100.0	98.6–100.0
Enterococcus faecium	0 / 0	N/A	N/A	279 / 279	100.0	98.6–100.0
Listeria monocytogenes	14 / 14	100.0	78.5–100.0	265 / 265	100.0	98.6–100.0
Micrococcus spp. ‡	34 / 36	94.4	81.9–98.5	243 / 243	100.0	98.4–100.0
Staphylococcus aureus	0 / 0	N/A	N/A	279 / 279	100.0	98.6–100.0
Staphylococcus epidermidis§	2 / 2	100.0	34.2–100.0	276 / 277	99.6	98.0–99.9
Staphylococcus lugdunensis	7 / 7	100.0	64.6–100.0	272 / 272	100.0	98.6–100.0
S. capitis / S. hominis	22 / 22	100.0	85.1–100.0	257 / 257	100.0	98.5–100.0

Table 36. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for pathogens (continued)

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
Streptococcus agalactiae	34 / 34	100.0	89.8–100.0	245 / 245	100.0	98.5–100.0
Streptococcus anginosus group	30 / 30	100.0	88.6–100.0	249 / 249	100.0	98.5–100.0
Streptococcus pneumoniae¶	35 / 36	97.2	85.8–99.5	242 / 243	99.6	97.7–99.9
Streptococcus pyogenes	39 / 39	100.0	91.0–100.0	240 / 240	100.0	98.4–100.0
Cryptococcus neoformans/gattii	1 / 1	100.0	20.7–100.0	278 / 278	100.0	98.6–100.0
Candida auris	1 / 1	100.0	20.7–100.0	278 / 278	100.0	98.6–100.0
Candida group 1**	2 / 2	100.0	34.2–100.0	276 / 277	99.6	98.0–99.9
Candida group 2	9 / 9	100.0	70.1–100.0	270 / 270	100.0	98.6–100.0

* Of the 2 *Bacillus* group FN specimens, 1/2 FN specimens was tested using an additional molecular method and *Bacillus cereus* group was detected in the tested specimen.

† The single (1) *Corynebacterium* FP specimen was not associated with cross-reactivities between the QIAstat-Dx BCID GPF Plus AMR Panel *Corynebacterium* target and other species, *Corynebacterium* was not detected in the single (1) FP specimen using an additional molecular method. Of the 3 *Corynebacterium* FN specimens, 2 were tested using an additional molecular method and were not detected.

‡ *Micrococcus* spp was detected in the 2 FN specimens using an additional molecular method.

§ The single *Staphylococcus epidermidis* FP specimen was detected using an additional molecular method.

¶ No additional testing was performed for *Streptococcus pneumoniae* FP and FN specimens.

** No additional testing was performed for the *Candida* group 1 FP.

AMRs

Table 37. QIAstat-Dx BCID GPF Plus AMR Panel archived clinical performance summary for AMRs

	PPA			NPA		
Pathogen	**TP/(TP+FN)**	**%**	**95% CI (%)**	**TN/(TN+FP)**	**%**	**95% CI (%)**
cfr	0 / 0	N/A	N/A	58 / 58	100.0	93.8–100.0
ermA	0 / 0	N/A	N/A	165 / 165	100.0	97.7–100.0
ermC	2 / 3	66.7	20.8–93.9	132 / 132	100.0	97.2–100.0
mecA	5 / 6	83.3	43.6–97.0	24 / 24	100.0	86.2–100.0
tetM	29 / 32	90.6	75.8–96.8	125 / 126	99.2	95.6–99.9
tetK	3 / 4	75.0	30.1–95.4	94 / 94	100.0	96.1–100.0
aac(6') aph(2")	1 / 1	100.0	20.7–100.0	62 / 62	100.0	94.2–100.0

13.2.3.5. Validity of results

The proportion of failed runs in clinical specimens (prospective and retrospective samples) on initial attempt was 0.8 % (11/1385) and following repeats was 0.1 % (2/1385), yielding an overall success rate of 99.2 % (1374/1385) before retesting, and 99.9% (1383/1385) after retesting.

13.2.3.6. Testing of contrived specimens

Contrived specimen testing was required for targets on the panel were 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. The results are summarized in Table 38.

Table 38. Test results summary for contrived PC specimens

Target	TP/(TP+FN)	%	95% CI (%)
Bacillus cereus group	50 / 50	100.0	92.9–100.0
Enterococcus faecalis	60 / 60	100.0	94.0–100.0
Enterococcus faecium	40 / 40	100.0	91.2–100.0
Listeria monocytogenes	50 / 50	100.0	92.9–100.0
Staphylococcus aureus	70 / 70	100.0	94.8–100.0
Staphylococcus epidermidis	50 / 50	100.0	92.9–100.0
Staphylococcus lugdunensis	50 / 50	100.0	92.9–100.0
Cryptococcus neoformans/gattii	50 / 50	100.0	92.9–100.0
Candida auris	48 / 50	96.0	86.5–98.9
Candida group 1	50 / 50	100.0	92.9–100.0
Candida group 2	50 / 50	100.0	92.9–100.0
cfr	48 / 50	96.0	86.5–98.9
ermC	58 / 60	96.7	88.6–99.1

Table 38. Test results summary for contrived PC specimens (continued)

Target	TP/(TP+FN)	%	95% CI (%)
mecA	69 / 70	98.6	92.3–99.7
mecC	50 / 50	100.0	92.9–100.0
vanA	60 / 60	100.0	94.0–100.0
vanB	50 / 50	100.0	92.9–100.0
tetM	79 / 80	98.8	93.3–99.8
tetK	20 / 20	100.0	83.9–100.0
aac(6') aph(2")	109 / 130	83.8	76.6–89.2

The proportion of positive results was ≥95% for all prepared contrived samples for pathogen and AMR in all tested analytes (except *aac(6')aph(2"),* 83.8%).

13.2.3.7. Expected values for all targets

The number and percentage of positive cases, as determined by the QIAstat-Dx BCID GPF Plus AMR Panel, calculated by testing site and by age group are present in Table 39 respectively. Overall, 1003 prospective specimens were included in the prevalence assessment and the QIAstat-Dx BCID GPF Plus AMR Panel detected at least one organism in a total of 873 prospective specimens (87.0% positivity rate).

Table 39. Expected value (EV) (as determined by the QIAstat-Dx BCID GPF Plus AMR Panel) summary overall for prospective samples and by age for all targets

Target	Overall (n=1003)	<1 year (n=18)	1–17 years (n=17)	18–44 years (n=149)	45–64 years (n=287)	65–89 years (n=485)	90+ years (n=47)
Bacillus cereus group	5 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.7%)	2 (0.4%)	1 (2.1%)
Corynebacterium	29 (2.9%)	0 (0.0%)	0 (0.0%)	3 (2.0%)	9 (3.1%)	15 (3.1%)	2 (4.3%)
Enterococcus faecalis	59 (5.9%)	1 (5.6%)	0 (0.0%)	5 (3.4%)	21 (7.3%)	31 (6.4%)	1 (2.1%)
Enterococcus faecium	28 (2.8%)	0 (0.0%)	0 (0.0%)	10 (6.7%)	5 (1.7%)	12 (2.5%)	1 (2.1%)
Listeria monocytogenes	3 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	2 (0.4%)	0 (0.0%)

Table 39. Expected value (EV) (as determined by the QIAstat-Dx BCID GPF Plus AMR Panel) summary overall for prospective samples and by age for all targets (continued)

Target	Overall (n=1003)	<1 year (n=18)	1–17 years (n=17)	18–44 years (n=149)	45–64 years (n=287)	65–89 years (n=485)	90+ years (n=47)
Micrococcus spp.	18 (1.8%)	1 (5.6%)	0 (0.0%)	4 (2.7%)	2 (0.7%)	10 (2.1%)	1 (2.1%)
Staphylococcus aureus	228 (22.7%)	4 (22.2%)	4 (23.5%)	40 (26.8%)	67 (23.3%)	104 (21.4%)	9 (19.1%)
Staphylococcus epidermidis	259 (25.8%)	5 (27.8%)	3 (17.6%)	38 (25.5%)	82 (28.6%)	118 (24.3%)	13 (27.7%)
Staphylococcus lugdunensis	7 (0.7%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.3%)	4 (0.8%)	0 (0.0%)
S. capitis / S. hominis	132 (13.2%)	2 (11.1%)	0 (0.0%)	17 (11.4%)	30 (10.5%)	75 (15.5%)	8 (17.0%)
Streptococcus agalactiae	27 (2.7%)	2 (11.1%)	0 (0.0%)	3 (2.0%)	8 (2.8%)	13 (2.7%)	1 (2.1%)
Streptococcus anginosus group	13 (1.3%)	0 (0.0%)	1 (5.9%)	1 (0.7%)	5 (1.7%)	6 (1.2%)	0 (0.0%)
Streptococcus pneumoniae	32 (3.2%)	1 (5.6%)	1 (5.9%)	6 (4.0%)	8 (2.8%)	12 (2.5%)	4 (8.5%)
Streptococcus pyogenes	26 (2.6%)	1 (5.6%)	0 (0.0%)	7 (4.7%)	9 (3.1%)	8 (1.6%)	1 (2.1%)
Cryptococcus neoformans/gattii	2 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (2.1%)
Candida auris	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
Candida group 1	18 (1.8%)	1 (5.6%)	0 (0.0%)	3 (2.0%)	9 (3.1%)	5 (1.0%)	0 (0.0%)
Candida group 2	20 (2.0%)	0 (0.0%)	2 (11.8%)	1 (0.7%)	8 (2.8%)	9 (1.9%)	0 (0.0%)
cfr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ermA	50 (5.0%)	1 (5.6%)	1 (5.9%)	2 (1.3%)	10 (3.5%)	31 (6.4%)	5 (10.6%)
ermC	132 (13.2%)	2 (11.1%)	1 (5.9%)	19 (12.8%)	45 (15.7%)	61 (12.6%)	4 (8.5%)
mecA	293 (29.2%)	5 (27.8%)	3 (17.6%)	35 (23.5%)	87 (30.3%)	152 (31.3%)	11 (23.4%)

Table 39. Expected value (EV) (as determined by the QIAstat-Dx BCID GPF Plus AMR Panel) summary overall for prospective samples and by age for all targets (continued)

Target	Overall (n=1003)	<1 year (n=18)	1–17 years (n=17)	18–44 years (n=149)	45–64 years (n=287)	65–89 years (n=485)	90+ years (n=47)
mecC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
vanA	15 (1.5%)	0 (0.0%)	0 (0.0%)	7 (4.7%)	2 (0.7%)	6 (1.2%)	0 (0.0%)
vanB	2 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	0 (0.0%)
tetM	106 (10.6%)	2 (11.1%)	1 (5.9%)	20 (13.4%)	30 (10.5%)	51 (10.5%)	2 (4.3%)
tetK	89 (8.9%)	1 (5.6%)	0 (0.0%)	13 (8.7%)	23 (8.0%)	47 (9.7%)	5 (10.6%)
aac(6')-aph(2")	81 (8.1%)	1 (5.6%)	0 (0.0%)	6 (4.0%)	18 (6.3%)	49 (10.1%)	7 (14.9%)
Overall	**873 (87.0%)**	**17 (94.4%)**	**12 (70.6%)**	**134 (89.9%)**	**258 (89.9%)**	**411 (84.7%)**	**41 (87.2%)**

13.2.4. Conclusion

The QIAstat-Dx BCID GPF 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 section can be downloaded from the Eudamed website.

14. References

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15. Troubleshooting Guide

In case of damaged cartridge, please refer to Safety information. For technical assistance and more information, please see our Technical Support Center at **support.qiagen.com** (for contact information, visit **www.qiagen.com**). For issues that may occur with the QIAstat-Dx Analyzer, please refer to the corresponding User Manuals which are also available at **www.qiagen.com**.

16. Symbols

The following symbols may 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 GPF Plus AMR Panel must be installed on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 prior to testing with QIAstat-Dx BCID GPF Plus AMR Panel Cartridges.

Note: Whenever a new version of the QIAstat-Dx BCID GPF Plus AMR Panel assay is released, the new QIAstat-Dx BCID GPF 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).

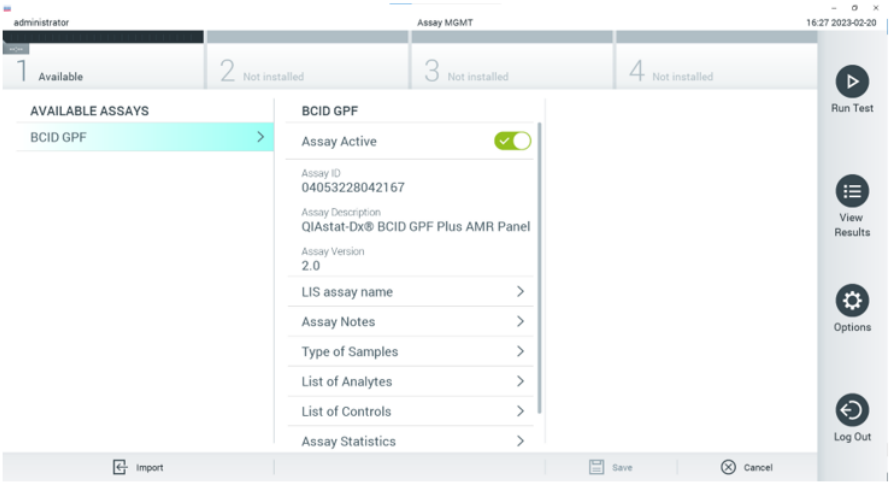

Figure 24. Assay Management screen.

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 GPF 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).

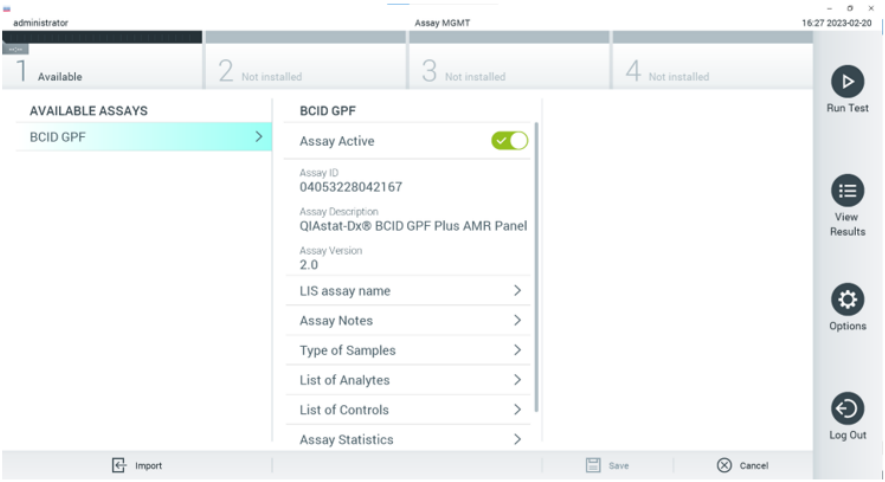

Figure 25. Activating the assay.

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**.

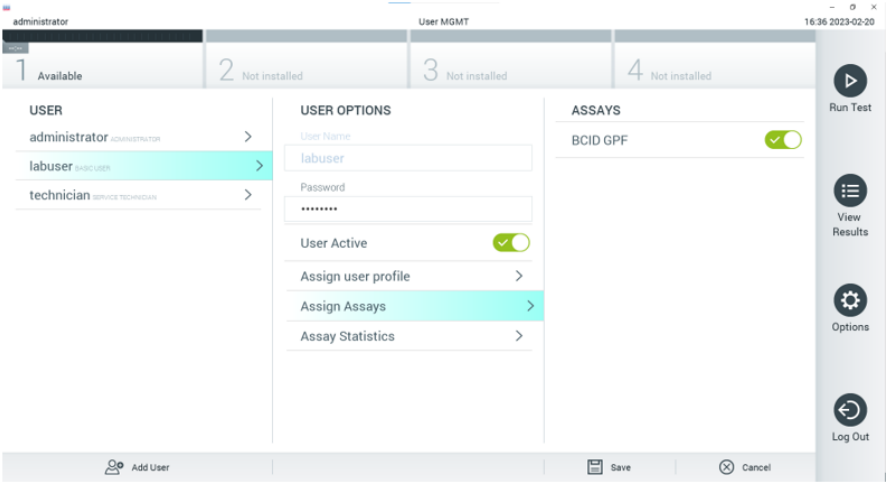

Figure 26. Assigning the active assay.

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

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

19. Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx BCID GPF Plus AMR Panel	For 6 tests: 6 individually packaged QIAstat-Dx BCID GPF Plus AMR Panel Cartridges and 6 individually packaged transfer pipettes	691812
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, December 2025	Initial release
Rev. 02, April 2026	Revised Table 21, Table 26, Table 31, and Table 36 to apply the following: • Footnotes updated to modify incorrect false negative and positive statement for some targets • Precision added specifying the organism with absence of detection • Discordant method corrected from PCR-BDS to Additional Molecular Method NPA corrected for *ermA* and *ermC* in Table 27 and Table 32 *ermC* PPA corrected in Table 32 Modified sections 13.3.5 and 13.3.11 to exclude referral to negative contrived samples Corrected TP number for *aac(6') aph(2')* in Table 29

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