September 2026

QIAstat-Dx® BCID GN Plus AMR Panel Summary of Safety and Performance

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Version 1

IVD

For In Vitro Diagnostic Use

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

CE 0197

REF 691814

QIAGEN, GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY

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Sample to Insight

Summary of Safety and Performance

This Summary of Safety and Performance (SSP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and performance of the device.

The SSP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users.

The following information is intended for professional users.

Document revision: 001
Date issued: September 2026
Manufacturer's reference number for the SSP: HB-3782-SPR

1. Device identification and general information	
1.1 Device trade name(s)	QIAstat-Dx® BCID GN Plus AMR Panel
1.2 Manufacturer's name and address	QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY
1.3 Manufacturer's single registration number (SRN)	DE-MF-000004949
1.4 Basic UDI-DI	4053228RBCIDGNQST00000148
1.5 European Medical Device Nomenclature (EMDN) description / text	W0105070201 Gram+ – Gram- – Fungi – Multiplex NA Reagents
1.6 Risk Class of the device	Class C
1.7 Year when the first certificate was issued under Regulation (EU) 2017/746 covering the device	2026

1.8 Authorised representative if applicable; name and the SRN	Not applicable
1.9 Notified body and the single identification number (SIN)	TÜV Rheinland LGA Products GmbH, Tillystrase 2 90431 Nürnberg, GERMANY 0197
2. Intended purpose and other indications	
2.1 Intended purpose	The QIAstat-Dx BCID GN Plus AMR Panel is an automated qualitative multiplexed real-time PCR-based in vitro diagnostic test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial targets and selected genetic determinants associated with antimicrobial resistance. The following gram-negative bacteria are identified and differentiated using the QIAstat-Dx BCID GN Plus AMR Panel: • *Acinetobacter calcoaceticus-baumannii* complex • *Bacteroides fragilis* • *Enterobacter* spp. • *Escherichia coli* • *Haemophilus influenzae* • *Klebsiella* spp. • *Neisseria meningitidis* (Encapsulated) • *Proteus* spp. • *Pseudomonas aeruginosa*

	• *Salmonella* spp. • *Serratia* spp. • *Stenotrophomonas maltophilia* • Pan *Enterobacterales* The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of the following genetic determinants of resistance: • *aac(6')-Ib* • *ampC* (CMY/LAT/DHA/FOX) • *armA* • CTX-M • GES • IMP • KPC • NDM • OXA-23 • OXA-24/40 • OXA-48-like • OXA-58 • PER • SHV • SPM • TEM • VEB • VIM The QIAstat-Dx BCID GN Plus AMR Panel is intended for use in patients suspected of having gram-negative bacterial infections identified as such via Gram stain in the following sample types:

	• **Positive blood culture samples** The test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain. The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens of bloodstream infection and select determinants of antimicrobial-resistance. Results should be used in conjunction with additional laboratory testing, e.g. sub-culturing of positive blood cultures for identification of organisms not detected by QIAstat-Dx BCID GN Plus AMR Panel and susceptibility testing and clinical presentation must be taken into consideration for patient management decisions. Negative results do not preclude the presence of pathogens that are not detected by this test. Positive QIAstat-Dx BCID GN Plus AMR results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GN Plus AMR Panel. Negative AMR results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure.

	• **Pure colonies** The test is performed on pure colonies of gram-negative bacteria. The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens isolated in culture plates and to aid clinicians in determining appropriate therapeutic strategies for known or suspected non-susceptible bacterial infections. Negative results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure. The QIAstat-Dx BCID GN Plus AMR Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional and is not intended for self-testing.
2.2 Indication(s) and target population(s)	The QIAstat-Dx BCID GN Plus AMR Panel is a qualitative multiplexed real-time PCR-based in vitro diagnostic test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial nucleic acids and selected genetic determinants of antimicrobial resistance: • In blood culture samples identified as positive by a continuous monitoring blood culture system that

	demonstrate the presence of gram-negative organisms as determined by Gram stain • On pure colonies of gram-negative bacteria The QIAstat-Dx BCID GN Plus AMR Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional and is not intended for self-testing. The QIAstat-Dx BCID GN Plus AMR Panel is intended for use in patients with gram-negative bacterial infections identified as such via gram stain.
2.3 Indication whether it is a device for near-patient testing and/or a companion diagnostic	The device is not for near patient testing. The device is not a companion diagnostic.
2.4 Limitations and/or contra-indications	• The QIAstat-Dx BCID GN Plus AMR Panel is not intended for testing samples other than 1) blood culture samples identified as positive by a continuously monitoring blood culture system; 2) pure colonies suspended in saline. • The QIAstat-Dx BCID GN Plus AMR Panel is indicated for use with positive blood culture samples identified via Gram stain to contain gram-negative bacteria. • All pathogen identification results from the QIAstat-Dx BCID GN Plus AMR Panel should be interpreted in conjunction with the Gram stain findings from the positive blood culture. Gram stain characteristics, including

	cellular morphology (e.g. Gram-negative rods (bacilli), coccobacilli or diplococci), should be carefully analyzed. • The QIAstat-Dx BCID GN Plus AMR Panel is intended to be used in conjunction with standard of care culture for organism recovery, identification, and/or antimicrobial susceptibility testing where applicable. • The QIAstat-Dx BCID GN Plus AMR Panel provides qualitative results and does not provide quantitative values for detected organisms. • The performance of this test has not been established for monitoring response to treatment for any of the panel organisms. • Results from the QIAstat-Dx BCID GN Plus AMR Panel must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory, and epidemiological findings. • The QIAstat-Dx BCID GN Plus AMR Panel is cleared for use with QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0. • This assay cannot be run on positive blood culture bottles containing charcoal resins. • Positive samples from bioMérieux and Becton Dickinson blood culture bottles require dilution prior to loading into the cartridge. • The performance of this test has primarily been evaluated with the BD BACTEC (Lytic Anaerobic, Plus Aerobic, Plus Anaerobic, and PedPlus), bioMérieux BACT/ALERT (FA Plus, FN Plus, and PF Plus) and Thermo Scientific VersaTREK (REDOX 1 EZ Draw and REDOX 2 EZ Draw) blood culture bottles. Other media have been assessed

	analytically for interference with the detection of organisms at positive blood culture levels (see "Bottle Equivalency" section in Instructions For Use). • A false negative result may originate from several factors and/or combinations, including improper specimen collection, improper culture techniques, handling or storage, technical error, sample mix-up, variation in the nucleic acid sequences targeted by the assay, infection by organisms not included in the assay, target organism levels that are below the limit of detection of the assay, or use of certain medications, therapies, or agents by the patient. • Organism and amplicon contamination may produce erroneous results for this test. Particular attention should be given to the Laboratory Precautions noted under the "Precautions" section in Instructions For Use. • 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 Instructions for Use can lead to erroneous results. • A detected result does not rule out co-infection with organisms not included (off-panel) in the QIAstat-Dx BCID GN Plus AMR Panel. • A detected result does not imply that the microorganism detected is the definitive cause of the disease. • Negative results for targeted microorganisms does not preclude the presence of pathogens that are not detected by this test.

	• A negative result with the QIAstat-Dx BCID GN Plus AMR Panel does not exclude the infectious nature of the syndrome and should not be used as the sole basis for diagnosis, treatment, or patient management decisions. • QIAstat-Dx BCID GN Plus AMR Panel detects bacterial nucleic acids and does not differentiate between viable and non-viable organisms. Bacterial nucleic acids may persist in vivo, even if the organism is not viable or infectious, leading to false positive results. • Bacteria detected by the QIAstat-Dx BCID GN Plus AMR Panel may not be culturable if the patient has been on antimicrobial therapy prior to or at the time of blood culture collection. • In specimens containing multiple organisms and/or multiple detectable antimicrobial resistance targets, the assay may not identify all detectable targets present in the specimen, depending upon the concentration of each target and the growth characteristics of organisms within the sample. • Competitive inhibition has been observed for certain pathogens and AMRs in mixed cultures (see Instructions For Use for combinations tested in Competitive Inhibition). • Isolation on solid media is needed to differentiate mixed growth with other microorganisms and to identify possible blood cultures yielding a negative result. • The QIAstat-Dx BCID GN Plus AMR Panel contains targets designed to detect different species within a genus or organism group but not differentiate certain species. • Mixed cultures with species belonging to the same genus or organism group cannot be differentiated in a specimen

	(e.g. *Klebsiella pneumoniae* and *Klebsiella oxytoca*, or *Proteus mirabilis*, and *Proteus hauseri*). Refer to the section "Group- and genus assay result interpretation" in the Instructions For Use for details. • The genus level and group assays included as a part of the QIAstat-Dx BCID GN Plus AMR Panel (*Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Salmonella* spp., *Serratia* spp., and Pan *Enterobacterales*), are designed to detect a broad range of species but will not necessarily detect all species within a genus or group or may have reduced sensitivity for some species. For species detected by these assays, including those not detected or detected with reduced sensitivity, please refer to the "Inclusivity (analytical reactivity)" section in the Instructions For Use. • Inclusivity testing demonstrated that the QIAstat-Dx BCID GN Plus AMR Panel may have reduced sensitivity for some pathogen strains and may not be detected at concentration normally observed at the time of bottle positivity, but can be detected at higher concentrations. Refer to the "Inclusivity (analytical reactivity)" section in the Instructions For Use. • There is a risk of false not-detected results due to the presence of strains with sequence variability in the target regions of the oligonucleotides design. Refer to the "Inclusivity (analytical reactivity)" section in the Instructions For Use. • Only encapsulated strains of *Neisseria meningitidis* will be detected by the QIAstat-Dx BCID GN Plus AMR Panel.

	• There is a risk of false positive results due to cross-reactivity with target organisms as well as cross-contamination by their nucleic acids, or the amplified product, or from non-specific signals in the assay. • Cross-reactivity with bloodstream infection organisms not evaluated in the "Analytical Specificity" section in the Instructions For Use may occur and may generate erroneous results. • In silico analyses used to predict detection and cross-reactivity of organisms and antimicrobial resistance genes were based on sequence comparisons between the CARD (McMaster University) and GenBank (NCBI) databases and the QIAstat-Dx BCID GN Plus AMR Panel primers. These analyses were conducted in September 2025; sequences added after this date were not evaluated, and additional limitations may arise as new sequence data or novel variants emerge. • Cross-reactivity was identified for certain assays based on in silico and/or in vitro analyses and a comprehensive list is shown in the "Exclusivity (Analytical Specificity)" section of the Instructions For Use. As a result, these assays may produce false detected results in the presence of cross-reacting organisms. • Results generated by the QIAstat-Dx BCID GN Plus AMR Panel do not replace antimicrobial susceptibility testing (AST). Subculturing and standard susceptibility testing of isolates are required to determine final antimicrobial susceptibility. • Antimicrobial resistance (AMR) can occur via multiple mechanisms. A Not Detected result for AMR targets on the

	QIAstat-Dx BCID GN Plus AMR Panel does not indicate antimicrobial susceptibility as other off-panel AMR determinants conferring resistance to certain antibiotics can be present in the organism. • A detected AMR result does not preclude phenotypic resistance nor the presence of other off-panel AMR determinants and therefore may not correlate with final phenotypic results. A detected AMR also cannot predict the level of resistance to a certain antibiotic as other cellular and molecular mechanisms can influence the expression and/or inhibition of AMR genes. Subculturing and standard susceptibility testing of isolates are required to determine final antimicrobial susceptibility. • Molecular AMR gene detection should be interpreted together with organism identification, Gram stain findings, culture results, phenotypic susceptibility testing, local epidemiology, antimicrobial stewardship guidance, and the patient's clinical context. • A detected AMR result cannot be definitely associated to the microorganism(s) detected by the QIAstat-Dx BCID GN Plus AMR Panel. • For the AMR targets listed in the "Exclusivity (Analytical Specificity)" section in the Instructions For Use, cross-reactivity was identified by in silico analysis and was not evaluated in vitro; therefore, these AMR assays could potentially generate false detected signals for the reported target(s). • Some resistance markers (e.g., TEM, SHV) include variants with different activity against multiple antibiotic classes. The primer sets used in the QIAstat-Dx BCID GN

	Plus AMR Panel therefore detect but do not differentiate a broad range of TEM and SHV genes, including penicillinases, cephalosporinases, and extended spectrum beta-lactamase (ESBL) variants. • Inclusivity testing demonstrated that the QIAstat-Dx BCID GN Plus AMR Panel may have reduced sensitivity or not be inclusive for some AMR variants and thus, they may not be detected at a 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 "Inclusivity (analytical reactivity)" of Instructions For Use for further details.
3. Device description	
3.1 Description of the device, including the conditions to use the device	**General description of the device, including its intended purpose and intended users** The QIAstat-Dx BCID GN Plus AMR Panel Cartridge is a single-use, fully automated molecular testing device designed to detect Gram-negative bacteria 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 QIAstat-Dx BCID GN Plus AMR Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional and is not intended for self-testing. **Description of the principle of the assay method or principles of operation of the instrument** After the QIAstat-Dx BCID GN Plus AMR Panel Cartridge containing the sample is introduced into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0, the following assay steps occur automatically: • Resuspension of Internal Control • Cell lysis using mechanical and/or chemical means • Membrane-based nucleic acid purification • Mixing of the purified nucleic acid with lyophilized master mix reagents • Transfer of defined aliquots of eluate/master mix to different reaction chambers • Performance of multiplex real-time PCR testing within each reaction chamber.
3.2 In case the device is a kit, description of the components (including regulatory status of	The kit contents are:

components, for example, IVDs, medical devices and any Basic UDI-DIs)	6 individually packaged cartridges containing all reagents needed for sample preparation and multiplex real-time RT-PCR, plus Internal Control. 6 individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx BCID GN Plus AMR Panel Cartridge. The kit contents are not sold separately. The QIAstat-Dx BCID GN Plus AMR Panel meets the definition of an in vitro diagnostic device (IVDR Article 2(2)) since it is intended for the detection and identification of pathogens in patients with gram-negative bacterial infections identified as such via gram stain and therefore provides information on the physiological state. Risk Class C (Annex VIII Rule 3 (c))
3.3 A reference to previous generation(s) or variants if such exists, and a description of the differences	Not applicable (no previous generation or generations of the device produced by the manufacturer).
3.4 Description of accessories intended to be used in combination with the device	Not applicable.

3.5 Description of any other devices and products which are intended to be used in combination with the device	QIAstat-Dx BCID GN Plus AMR Panel is designed for use with the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0. Please note that the Assay Definition File (ADF) for QIAstat-Dx BCID GN Plus AMR Panel is available at **www.qiagen.com**.
4. Reference to any harmonised standards and CS applied	
4.1 Harmonised standards and Common Specifications (CS) applied	Harmonised Standards: • EN ISO 13485:2016+AC:2018+A11:2021 – Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) • EN ISO 14971:2019+A11:2021 – Medical devices – Application of risk management to medical devices • EN ISO 15223-1:2021 – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements • EN ISO 20916:2024 – In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019) There are no common specifications established by the European Commission applicable to QIAstat-Dx BCID GN Plus AMR Panel.
5. Risks and warnings	
5.1 Residual risks and undesirable effects	Risks have been mitigated as far as possible and deemed as acceptable. There are no undesirable effects.

5.2 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 the regulatory authority in which the user and/or the patient is established. • The QIAstat-Dx BCID GN Plus AMR Panel is for in vitro diagnostic use. • The QIAstat-Dx BCID GN Plus AMR Panel is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0. **Safety information** • When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF at **www.qiagen.com/safety** where you can find, view, and print the SDS for each QIAGEN kit and kit component. • Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the Biosafety in Microbiological and Biomedical Laboratories from the Centers for Disease Control and Prevention and the National Institutes of Health (**https://www.cdc.gov/labs/BMBL.html**).

	• Specimens and samples are potentially infectious. Discard sample and assay waste according to your local safety procedures. • Always wear appropriate personal protective equipment and follow your laboratory's safety procedures for handling biological samples. Handle all samples, cartridges, and transfer pipettes as if they are capable of transmitting infectious agents. • Always observe safety precautions as outlined in relevant guidelines, such as the *Clinical and Laboratory Standards Institute®* (*CLSI*) *Protection of Laboratory Workers from Occupationally Acquired Infections*; Approved Guideline (M29), or other appropriate documents provided by local authorities. • The QIAstat-Dx BCID GN Plus AMR Panel Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0. Do not use a QIAstat-Dx BCID GN Plus AMR Panel Cartridge that is past its expiration date, appears damaged, or leaks fluid. • Dispose of samples, used or damaged cartridges, and transfer pipettes in accordance with all national, state, and local health and safety regulations and laws. • In the event of cartridge leakage, follow the *QIAstat-Dx Analyzer 1.0 User Manual* or *QIAstat-Dx Analyzer 2.0*

User Manual, decontaminate the external surfaces accordingly, and contact Technical Service at the appropriate regional number or email for internal decontamination assistance.

Precautions

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

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

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

	• Change gloves and clean the work area between each sample. • Discard used cartridges in an appropriate biohazard container immediately after the run has been completed. • Avoid excessive handling or shaking of the cartridges before and after test runs. • Avoid damaging the cartridge. **Precautions related to public health reporting** National, State and local public health authorities have published guidelines for notification of reportable diseases in their jurisdictions to determine necessary measures for verification of results to identify and trace outbreaks and for epidemiological investigations. E.g. following the Official Journal of the European Union 6.7.2018 L 170/1, the list includes *Haemophilus influenzae*, *Neisseria meningitidis*, and *Salmonella* spp., of the pathogens included in the QIAstat-Dx BCID GN Plus AMR Panel. Several initiatives are also in place worldwide to track AMR (antimicrobial resistance), such as the EARS-Net in the EU. Laboratories are responsible for following their state or local regulations for submission of clinical material or isolates on positive specimens to their state public health laboratories.
5.3 Other relevant aspects of safety, including a	Not applicable.

summary of any field safety corrective action (FSCA including FSN), if applicable	
6. Summary of the performance evaluation and post-market performance follow-up (PMPF)	
6.1 Summary of scientific validity of the device	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. 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. 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. The QIAstat-Dx BCID GN Plus AMR Panel offers rapid multiplex detection of Gram-negative bacteria and key AMR genetic markers associated with gram-negative organisms - all within a single cartridge. When integrated with antimicrobial stewardship programs, rapid diagnostic tools for blood cultures can support timely and targeted antimicrobial therapy. This approach has the

	potential to reduce mortality, shorten hospital stays, and lower healthcare costs for patients with BSIs and sepsis.
6.2 Summary of performance data from the equivalent device, if applicable	Not applicable (no equivalent device for the panel).
6.3 Summary of performance data from conducted studies of the device prior to CE-marking	For information regarding analytical and clinical performance, please refer to the Instructions For Use.
6.4 Summary of performance data from other sources, if applicable	Not applicable.
6.5 An overall summary of the performance and safety	The overall performance and safety of the QIAstat-Dx BCID GN Plus AMR Panel is based on: **Scientific validity** Assessment of scientific validity based on a systematic literature review, assessment of available/retrieved/new data relevant to the QIAstat-Dx BCID GN Plus AMR Panel and its intended purpose, intended purpose of medical alternatives and consensus experts' opinions/positions from international guidelines demonstrated the

	scientific validity of the QIAstat-Dx BCID GN Plus AMR Panel for its Intended Use. **Analytical performance** The assessment of analytical performance studies showed that the analytical performance of the QIAstat-Dx BCID GN Plus AMR Panel is adequate for its Intended Use. **Clinical performance** Clinical performance was demonstrated in a clinical performance study assessing key indicators, including sensitivity, specificity, and agreement metrics (positive percent agreement (PPA), negative percent agreement (NPA)) with comparator methods. The study results confirmed that the clinical performance of the QIAstat-Dx BCID GN Plus AMR Panel is adequate for its Intended Use. The assessment of scientific validity, analytical performance, and clinical performance allows to constitute the clinical evidence for the QIAstat-Dx BCID GN Plus AMR Panel. The benefit-risk assessment based on systematic literature and database review, risk assessment activities (medical risk assessment, product and manufacturing process risk assessment), vigilance activities conducted, and the experience gained from routine diagnostic testing supported a favorable benefit-risk ratio for the QIAstat-Dx BCID GN Plus AMR Panel.
6.6 Ongoing or planned post-market	Systematic monitoring of the device's safety and performance is ensured through QIAGEN's post-market surveillance (PMS)

performance follow-up	framework. Post Market Performance Follow up (PMPF) activities form part of this framework and contribute to the ongoing collection, review, and assessment of post market data relevant to the confirmation of the device's safety, performance, and scientific validity throughout its lifecycle. Based on the collected evidence which demonstrates that this device meets the performance evaluation requirements the assay is considered safe and effective for its intended use, and no unacceptable residual risks remain. There are no ongoing or planned post-market performance follow-up studies.
7. Metrological traceability of assigned values	
7.1 Explanation of the unit of measurement, if applicable	Not applicable.
7.2 Identification of applied reference materials and/or reference measurement procedures of higher order used by the manufacturer for the calibration of the device	Not applicable.
8. Suggested profile and training for users	

8.1 Suggested profile and training for users	The QIAstat-Dx BCID GN Plus AMR Panel is a qualitative multiplexed nucleic acid real-time PCR-based in vitro diagnostic test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial targets and selected genetic determinants associated with antimicrobial resistance. The QIAstat-Dx BCID GN Plus AMR Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional and is not intended for self-testing.

Revision History

SSP Revision Number	Date issued	Change description	Revision validated by the Notified Body
01	September 2026	1st revision	□ Yes Validation Language: English ☑ No (only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)