Guidelines for Laboratory Verification of Performance of QIAstat-Dx® BCID GPF Plus AMR Panel

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Introduction

This document provides a sample protocol for the verification of QIAstat-Dx BCID GPF Plus AMR Panel (cat. no. 691822). The protocol provides positive and negative tests for the pathogens detected by QIAstat-Dx BCID GPF Plus AMR Panel.

Each laboratory is responsible for defining their verification procedure and ensuring that they meet applicable local, regional and national guidelines.

Table 1. Overview of sample verification method

Sample code	
Organism controls per sample control mix	5–6
Number of sample control mixes	5
Replicates per sample control mix	4
QIAstat-Dx Cartridges required	20
Expected number of positive results per mix	5–9
Expected number of negative results per mix (pathogens only)	15–16
Approximate days of testing	4
Number of operators	2

Materials and methods

The procedure described in Table 1 and below generates multiple positive and negative results for each of the sample control mixes tested. The sample protocol was developed using organism strains available from American Type Culture Collection (ATCC®), National Collection of Type Cultures (NCTC®) and Culture Collection University Of Gothenburg (CCUG).

If testing is being performed using a QIAstat-Dx Analyzer with additional Analytical Modules, the laboratory director may choose not to perform the verification protocol on each Analytical Module. If the complete verification protocol is not performed on each Analytical Module, we advise distributing test replicates evenly among the different Analytical Modules of the system.

Performance verification materials

The materials listed in Table 2 are required to perform verification with the sample protocol.

Table 2. Materials needed for the sample verification method

Material	Catalog number	Quantity
QIAstat-Dx BCID GPF Plus AMR Panel (6 tests)	691822	5
QIAstat-Dx Operational Module*	9002813	1
QIAstat-Dx Analytical Module(s)	9002814	1–4
Whole Human Blood (in Acid Citrate Dextrose)	Cambridge Bioscience®, BLD1DC4ACD42-X (or similar)	
BD® BACTEC® Standard Aerobic Medium†	Becton Dickinson and Company®, 442260	1
Remel™ McFarland Turbidity Equvalence Standard 1.0	Thermo Fisher Scientific®, R20411 (or similar)	1
Remel McFarland Turbidity Equivalence Standard 5.0	Thermo Fisher Scientific, R20415 (or similar)	1
Phosphate Buffered Saline, pH 7.4	VWR E504-500ML (or similar)	
Conical Bottom Centrifuge Tubes, 15 mL	Falcon®, 352096 (or similar)	5
Transfer Pipettes	VWR 13-711-43 (or similar)	24

* Or QIAstat-Dx Operational Module PRO (cat. no. 9002826).

† Note: Other compatible blood culture types can be used. See *QIAstat-Dx BCID GPF Plus AMR Instructions for Use (Section 13.1.3. Bottle equivalency)* for a list of compatible bottle types.

Sample verification method

The method described evaluates the performance of the QIAstat-Dx BCID GPF Plus AMR panel by testing mixtures of the microorganism suspensions described in Table 3 in a simulated blood culture matrix.

Proposed mixing of organism controls is provided in Table 4. The method tests a total of 20 sample control mixes (5 sample control mixes tested in 4 replicates each). For each assay run, the method provides 5–9 positive results (including pathogens and AMR targets) and 15–16 negative results for pathogens (including Pan assays and excluding AMRs) detected by the QIAstat-Dx BCID GPF Plus AMR Panel.

Alteration of this protocol should take into account additional lab personnel and the number of instruments, based on individual laboratory needs.

Mix the organism controls to create control samples at the beginning of the sample verification method. The sample control mixes can be stored at room temperature (15–25 °C) for up to 24 hours.

Protocol

Day 1

1. Microbiologically negative human whole blood should be loaded into the commercial blood culture bottles as indicated by the manufacturer and maintained under standard blood culture incubation conditions for at least 5 days. Bottles that remain negative for growth throughout the incubation period should be used as the Negative Blood Culture Matrix in the scheme shown in Table 4.
2. Obtain a pure culture of each organism listed in Table 3 on appropriate agar plates.
3. In a clear test tube, prepare a suspension of each organism equivalent to a 1.0 McFarland Turbidity Standard (or 5.0 McFarland Turbidity Standard for *Escherichia coli* [ATCC BAA-196], *Candida auris* [NCPF 8971], *Candida tropicalis* [ATCC 750] and *Candida krusei* [ATCC 32196]) in phosphate-buffered saline (PBS) at pH 7.4, per relevant guidelines or laboratory protocols (total volume required is approximately 0.5–1 mL).

Day 1 (continued)

4. Prepare sample control mixes 1–3 according to the scheme shown in Table 4. For each sample control mix, follow the next steps:
   a. Transfer the appropriate volume of the negative blood culture matrix to a 15 mL conical tube.
   b. Use a micropipette to transfer the corresponding volume of the organism suspensions as indicated in Table 3.
   c. Ensure the sample mix is thoroughly mixed prior to removing 100 µL for testing in the QIAstat-Dx BCID GPF Plus AMR panel, as indicated in the Instructions for Use.
5. Test two replicates (100 µL of sample per each replicate) from Sample Control Mix 1, Sample Control Mix 2 and Sample Control Mix 3. The duplicate samples should be tested in a single day by different operators (see Table 4).
6. Store the samples at room temperature for up to 24 hours for the evaluation of day-to-day variation.

Day 2

To evaluate day-to-day variation, test the remaining volume of the sample control mixes prepared on Day 1 (Sample Control Mix 1, Sample Control Mix 2 and Sample Control Mix 3).

Day 3

Prepare Sample Control Mix 4 and Sample Control Mix 5 as described in Day 1, step 4. Test Sample Control Mix 4 and Sample Control Mix 5 according to steps 5 and 6.

Day 4

To evaluate day-to-day variation, test the remaining volume of the sample control mixes prepared on Day 3 (Sample Control Mix 4 and Sample Control Mix 5). Table 5 details a workflow for two operators.

Table 3. Workflow for the sample verification method

Organism	Expected targets	Supplier, catalog number
Bacillus cereus	*Bacillus cereus* group	ATCC 21769
Corynebacterium jeikeium	*Corynebacterium*	ATCC BAA-949
Escherichia coli	Pan Gram Negative	ATCC BAA-196
Enterococcus faecalis	*Enterococcus faecalis, vanB, aac(6')-aph(2'')*	ATCC BAA-2365
Enterococcus faecium	*Enterococcus faecium, vanA, cfr, aac(6')-aph(2'')*	NCTC 14767
Enterococcus faecium	*Enterococcus faecium, vanA, aac(6')-aph(2''), tetM*	ATCC BAA-2316
Listeria monocytogenes	*Listeria monocytogenes*	ATCC 19111
Micrococcus luteus	*Micrococcus* spp.	NCTC 07743
Staphylococcus aureus	*Staphylococcus aureus, mecC, mecA*	ATCC BAA-2312
Staphylococcus aureus	*Staphylococcus aureus, ermC, mecA, tetK*	ATCC BAA-1556
Staphylococcus aureus	*Staphylococcus aureus, ermA*	ATCC BAA-977
Staphylococcus capitis	*Staphylococcus capitis/hominis*	CCUG 42761
Staphylococcus epidermidis	*Staphylococcus epidermidis, tetK*	NCTC 13360
Staphylococcus lugdunensis	*Staphylococcus lugdunensis*	ATCC 49576
Streptococcus agalactiae	*Streptococcus agalactiae*	ATCC 12401
Streptococcus anginosus	*Streptococcus anginosus* group	ATCC 27335
Streptococcus pneumoniae	*Streptococcus pneumoniae*	ATCC BAA-334
Streptococcus pyogenes	*Streptococcus pyogenes*	ATCC 12384
Candida auris	*Candida auris*	NCPF 8971
Candida krusei	*Candida* Group 2	ATCC 32196
Candida tropicalis	*Candida* Group 1	ATCC 750
Cryptococcus neoformans	*Cryptococcus gattii/neoformans*	ATCC 208821
Fusarium verticillioides	*Fusarium*	NCPF 7484

Note: Other suitable microorganism sources may be used for the verification of the QIAstat-Dx BCID GPF Plus AMR Panel. The use of alternative sources might require adjustment of the sample volumes or the mixing scheme described in Table 3. In addition, alternative strains may not produce the same antimicrobial resistance genes as those indicated in the Table 3.

Table 4. Proposed organism-control mixing and expected results (positive or negative)

Mix	Organism	Supplier catalog number	Organism control volume (mL)	Negative blood culture matrix (mL)	Approximate final mix volume (mL)	Expected results	Expected positive results	Expected negative results
Sample Control Mix 1	*Enterococcus faecium*	ATCC BAA-2316	0.1	5.5	6	*Enterococcus faecium, vanA, aac(6')-aph(2'), tetM*	9 (4 pathogens, 5 AMRs)	16 (pathogens only)
	Staphylococcus aureus	ATCC BAA-2312	0.1			*Staphylococcus aureus, mecA, mecC*		
	Fusarium verticillioides	NCPF 7484	0.2			*Fusarium*		
	Bacillus cereus	ATCC 21769	0.1			*Bacillus cereus* epmsn		
Sample Control Mix 2	*Staphylococcus aureus*	ATCC BAA-977	0.1	5	6	*Staphylococcus aureus, ermA*	3 (4 pathogens, 1 AMR)	16 (pathogens only)
	Escherichia coli	ATCC BAA-196	0.1			Pan Gram Negative		
	Streptococcus pneumoniae	ATCC BAA-334	0.1			*Streptococcus pneumoniae*		
	Candida auris	NCPF 8971	0.7			*Candida auris*		
Sample Control Mix 3	*Staphylococcus aureus*	ATCC BAA-1556	0.1	5.5	6	*Staphylococcus aureus, ermC, mecA, tetK*	8 (5 pathogens, 3 AMRs)	15 (pathogens only)
	Streptococcus anginosus	ATCC 27335	0.1			*Streptococcus anginosus* group		
	Cryptococcus neoformans	ATCC 208821	0.1			*Cryptococcus gattii/ neoformans*		
	Corynebacterium jeikeium	ATCC BAA-949	0.1			*Corynebacterium*		
	Streptococcus pyogenes	ATCC 12384	0.1			*Streptococcus pyogenes*		
Sample Control Mix 4	*Staphylococcus epidermidis*	NCTC 13360	0.1	5.5	6	*Staphylococcus epidermidis, tetK*	6 (5 pathogens, 1 AMR)	14 (pathogens only)
	Staphylococcus capitis	CCUG 42761	0.1			*Staphylococcus capitis/hominis*		
	Micrococcus luteus	NCTC 7743	0.1			*Micrococcus* spp.		
	Candida tropicalis	ATCC 750	0.2			*Candida* Group 1		
	Listeria monocytogenes	ATCC 19111	0.1			*Listeria monocytogenes*		
Sample Control Mix 5	*Enterococcus faecalis*	ATCC BAA-2365	0.1	5.5	6	*Enterococcus faecalis, vanB, aac(6')-aph(2')*	8 (5 pathogens, 4 AMRs)	15 (pathogens only)
	Staphylococcus lugdunensis	ATCC 49576	0.1			*Staphylococcus lugdunensis*		
	Enterococcus faecium	ATCC BAA-2365	0.1			*Enterococcus faecium, cfr, vanA, aac(6')-aph(2)*		
	Candida krusei	ATCC 32196	0.2			*Candida* Group 2		
	Streptococcus agalactiae	ATCC 12401	0.1			*Streptococcus agalactiae*		

Note: The estimated total time for completion for this verification example is 4 days. It is important to prepare only the number of sample control mixes that will be tested within 2 days of preparation. The number of samples prepared may be increased or decreased based on the laboratory's work schedule and the number of QIAstat-Dx instruments.

Note: Sample control mixes can be stored up to 24 hours at room temperature for subsequent testing.

Table 5. Workflow for the sample verification method

	Day 1	Day 2	Day 3	Day 4
Operator 1	Sample Control Mix 1	Sample Control Mix 1	Sample Control Mix 4	Sample Control Mix 4
	Sample Control Mix 2	Sample Control Mix 2	Sample Control Mix 5	Sample Control Mix 5
	Sample Control Mix 3	Sample Control Mix 3		
Operator 2	Sample Control Mix 1	Sample Control Mix 1	Sample Control Mix 4	Sample Control Mix 4
	Sample Control Mix 2	Sample Control Mix 2	Sample Control Mix 5	Sample Control Mix 5
	Sample Control Mix 3	Sample Control Mix 3		

This document provides a exemplary verification protocol intended as guidance. The protocol content was compiled based on data generated during development and/or verification studies; however, the complete protocol exactly as described in this document has not been empirically verified as a single, end-to-end study. Laboratories remain responsible for defining and executing their own verification procedure and for ensuring compliance with applicable guidelines and regulations.

The protocol references biological materials and information obtained from third-party sources (e.g., organism strains and culture collections). QIAGEN cannot guarantee the quality, characteristics, or continued availability of third-party materials, nor can QIAGEN control future changes, reclassifications, updated characterization, or other new information introduced by these suppliers. Use of alternative sources may require adjustments to volumes, mixing schemes, and may impact expected targets/results.

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