Guidelines for Laboratory Verification of Performance of QIAstat-Dx® Respiratory Panel Mini

QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, Germany

Introduction

This document provides a sample protocol for the verification of QIAstat-Dx Respiratory Panel Mini (cat. no. 691218). The protocol provides positive and negative tests for the pathogens detected by QIAstat-Dx Respiratory Panel Mini.

Each laboratory is responsible for defining their verification procedure and ensuring they meet regulatory, state and federal guidelines.

Table 1. Overview of sample verification method

Sample code	
Organism controls per sample control mix	2–3
Number of sample control mixes	2
Replicates per sample control mix	4
QIAstat-Dx cartridges required	8
Expected number of positive results	20
Expected number of negative results	20
Approximate days of testing	4
Number of operators	2

Materials and methods

The procedure described below and in Table 1 generates multiple positive and negative results for each of the sample control mixes tested. The sample protocol was developed using ZeptoMetrix® NATtrol® Respiratory Verification Panel 2 available from ZeptoMetrix Corporation (Buffalo, NY; cat. no. NATRVP2-QIA).

If testing is being performed using a QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 with additional Analytical Modules or the QIAstat-Dx Rise, 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.

Table 2. Materials needed for the sample verification method

Material	Catalog number	Quantity
QIAstat-Dx Respiratory Panel Mini Kit (6 tests)	691218	2
QIAstat-Dx Operational Module*	9002813	1
QIAstat-Dx Analytical Module(s)	9002814	1–4
NATtrol Respiratory Verification Panel 2	ZeptoMetrix NATRVP2-QIA	1
Universal transport media (UTM)†	*	At least 5 mL
Sample tubes, 5 mL	VWR 89497-740 (or similar)	2
Transfer pipettes	VWR 13-711-43 (or similar)	12

* Or QIAstat-Dx Rise Base (cat. no. 9003163)

† Refer to the QIAstat-Dx Respiratory Panel Mini instructions for use for universal transport media tested with QIAstat-Dx Respiratory Panel Mini.

Performance verification materials

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

Sample verification method

This sample verification method describes how to prepare sample control mixes by mixing together 2 or 3 different organism controls using ZeptoMetrix NATtrol Respiratory Verification Panel 2. Proposed mixing of organism controls is provided in Table 3. The method tests a total of 8 sample control mixes (2 sample control mixes tested in 4 replicates each). For each assay run, the method provides either 2 or 3 positive results for the 5 pathogens that are detected and differentiated by QIAstat-Dx Respiratory Panel Mini. In addition, either 2 or 3 negative results are provided for the 5 pathogens.

Any changes to this protocol should take into account additional lab personnel and 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 –20°C for up to 3 days. Avoid multiple freeze–thaw cycles to prevent compromising sample integrity.

Protocol

Day 1

1. Prepare Sample Control Mix 1 (refer to Table 3).
   a. Transfer 0.2 mL of each of the organism controls in the mix to a new 5 mL tube.
   b. Transfer the appropriate volume of universal transport medium to the 5 mL tube.
   c. Ensure the pooled sample is effectively mixed by vortexing prior to testing.
2. Test two replicates from Sample Control Mix 1. The duplicate samples should be tested in a single day by different operators (see Table 4).
3. Store the samples at –20°C for up to 3 days 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) by repeating step 2 above.

Day 3

Prepare Sample Control Mix 2 as described in step 1. Test Sample Control Mix 2 according to step 2.

Day 4

To evaluate day-to-day variation, test the remaining volume of the sample control mixes prepared on Day 3 (Sample Control Mix 2) by repeating step 2. Table 4 details a workflow for two operators.

Table 3. Proposed organism control mixing and expected positive/negative results

Mix	Organism	Organism control volume (mL)	UTM volume [mL]	Final volume of mix (mL)	Expected results	Number of expected negative results
Sample Control Mix 1	Influenza A H1N1	0.2	1.6	2.0	positive	3
	SARS-CoV-2	0.2			positive	
Sample Control Mix 2	Influenza B	0.2	1.4	2.0	positive	2
	Rhinovirus 1A	0.2			positive	
	RSVA	0.2			positive	

Table 4. 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 2	Sample Control Mix 2
Operator 2	Sample Control Mix 1	Sample Control Mix 1	Sample Control Mix 2	Sample Control Mix 2

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