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Application Note

Guidelines for Laboratory Verification of Performance of the QIAstat-Dx® SARS-CoV-2/Flu A/B/RSV Panel

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Introduction

This document provides a sample protocol for the verification of the QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel (cat. no. 691226). The protocol provides positive and negative tests for the pathogens detected by the QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel.

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

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 the NATtrol™ Respiratory Verification Panel available from ZeptoMetrix® Corporation (Buffalo, NY; cat. no. NATRVP2-QIA).

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.

Table 1. Overview of sample verification method

Sample protocol	
Organism controls per sample control mix	2
Number of sample control mixes	2
Replicates per sample control mix	4
QIAstat-Dx Cartridges required	8
Expected number of positive results	16
Expected number of negative results	16
Approximate days of testing	4
Number of operators	2

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 SARS-CoV-2/Flu A/B/RSV Panel Kit (6 tests)	691226	2
QIAstat-Dx Operational Module	9002813	1
QIAstat-Dx Analytical Module(s)	9002814	1–4
NATtrol Respiratory Verification Panel	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

* Refer to the *QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel Handbook* for Universal Transport Media tested with the QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel.

Sample verification method

This sample verification method describes how to prepare sample control mixes by mixing together 2 different organism controls using the 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 2 positive results and, correspondingly, 2 negative results for the 4 pathogens, in total, which are detected and differentiated by the QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel.

Alteration of 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.

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	2
	SARS-CoV-2	0.2			Positive	
Sample Control Mix 2	Influenza B	0.2	1.6	2.0	Positive	2
	RSVA	0.2			Positive	

Note: It is important to prepare only the number of sample control mixes that will be tested within 3 days of preparation. The number of samples prepared may be increased or decreased based on the laboratory's work schedule and number of QIAstat-Dx instruments.

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 above. Table 4 details a workflow for 2 operators.

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

Revision History

Date	Changes
R1 October 2021	Initial release.

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