Application Note

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Guidelines for Laboratory Verification of Performance of the QIAstat-Dx® Respiratory SARS-CoV-2 Panel (IVDR)

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Introduction

This document provides a sample protocol for the verification of QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) (cat. no. 691215). The protocol provides positive and negative tests for the pathogens detected by QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR).

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

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 the NATtrol™ Respiratory Verification Panel 2 available from ZeptoMetrix Corporation (Buffalo, NY; cat. no. NATRVP2-QIA).

Table 1. Overview of sample verification method

Sample protocol	
Organism controls per sample control mix	5
Number of sample control mixes	4
Replicates per sample control mix	4
QIAstat-Dx cartridges required	16
Expected number of positive results	92
Expected number of negative results	244
Approximate days of testing	4
Number of operators	2

If testing is being performed using a QIAstat-Dx Analyzer with additional Analytical Modules or a 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.

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 Respiratory SARS-CoV-2 Panel (IVDR) kit (6 tests)	691215	3
QIAstat-Dx Operational Module or QIAstat-Dx Operational Module PRO	9002813 or 9002826	1
QIAstat-Dx Analytical Module(s)	9002814	1–4
NATtrol Respiratory Verification Panel 2	NATRVP2-QIA	At least 5 mL
Universal Transport Media (UTM)*		
Sample tubes, 5 mL	VWR 89497-740 (or similar)	4
Transfer pipettes	VWR 13-711-43 (or similar)	24

* Refer to the QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for use for Universal Transport Media tested with the QIAstat-Dx Respiratory SARS-CoV-2 (IVDR) Panel.

Sample verification method

This sample verification method describes how to prepare sample control mixes by mixing together 5 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 16 sample control mixes (4 sample control mixes tested in 4 replicates each).

For each assay run, the method provides either 5 or 6 positive results and, correspondingly, 15 or 16 negative results for 21* pathogens detected and differentiated by QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR).

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. Sample control mixes can be stored at –20°C for up to 3 days. Avoid multiple freeze–thaw cycles to prevent compromising sample integrity.

* For verifying *Legionella pneumophila* and Bocavirus, which are not included in ZeptoMetrix NATtrol Respiratory Verification Panel 2, please use additional individual controls from ZeptoMetrix or another vendor of your choice.

Table 3. Proposed organism-control mixing and expected results (positive or negative)

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	1.0	2.0	positive	15
	Corona HKU1	0.2			positive	
	PIV 2	0.2			positive	
	C. pneumoniae	0.2			positive	
	SARS-CoV-2	0.2			positive	
Sample Control Mix 2	Influenza B	0.2	1.0	2.0	positive	16
	Corona 229E	0.2			positive	
	PIV 4	0.2			positive	
	hMPV	0.2			positive	
	B. pertussis	0.2			positive	
Sample Control Mix 3	Influenza A H1N1/2009	0.2	1.0	2.0	positive	15
	Corona C43	0.2			positive	
	PIV 3	0.2			positive	
	Rhinovirus 1A	0.2			positive	
	RSVA	0.2			positive	
Sample Control Mix 4	Influenza A H3N2	0.2	1.0	2.0	positive	15
	Corona NL63	0.2			positive	
	PIV 1	0.2			positive	
	Adenovirus	0.2			positive	
	M. pneumoniae	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 and Sample Control Mix 2 (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. Repeat step 2 for Sample Control Mix 2 to be tested on the same day.
4. 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 and Sample Control Mix 2) by repeating steps 2 and 3 above.

Day 3

Prepare Sample Control Mix 3 and Sample Control Mix 4 as described in step 1. Test Sample Control Mix 3 and Sample Control Mix 4 according to steps 2 and 3.

Day 4

To evaluate day-to-day variation, test the remaining volume of the sample control mixes prepared on Day 3 (Sample Control Mix 3 and Sample Control Mix 4) by repeating steps 2 and 3 above. Table 4 details a workflow for two 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 2	Sample Control Mix 1 Sample Control Mix 2	Sample Control Mix 3 Sample Control Mix 4	Sample Control Mix 3 Sample Control Mix 4
Operator 2	Sample Control Mix 1 Sample Control Mix 2	Sample Control Mix 1 Sample Control Mix 2	Sample Control Mix 3 Sample Control Mix 4	Sample Control Mix 3 Sample Control Mix 4