Guidelines for Laboratory Verification of Performance of the QIAstat-Dx® Meningitis/Encephalitis (ME) Panel (cat. no. 691612)

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Introduction

This document provides a sample protocol for the verification of the QIAstat-Dx Meningitis/Encephalitis Panel (cat. no. 691612). The protocol provides positive and negative tests for the pathogens detected by the QIAstat-Dx Meningitis/Encephalitis (ME) Panel (cat. no. 691612).

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

Table 1. Overview of sample verification method

Sample protocol	
Organism controls per sample control mix	5–6
Number of sample control mixes	3
Replicates per sample control mix	4
QIAstat-Dx cartridges required	12
Expected number of positive results	64
Expected number of negative results	128
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 the NATtrol™ Meningitis/Encephalitis Verification Panel available from ZeptoMetrix Corporation (Buffalo, NY; cat. no. NATMEP-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 2. Materials needed for the sample verification method

Material	Catalog number	Quantity
QIAstat-Dx Meningitis/Encephalitis Panel kit (6 tests)	691612	2
QIAstat-Dx Operational Module or QIAstat-Dx Operational Module PRO	9002813 or 9002826	1
QIAstat-Dx Analytical Module(s)	9002814	1–4
NATtrol Meningitis/Encephalitis Verification Panel	ZeptoMetrix, NATMEP-QIA	1
Sample tubes, 2 mL	Sarstedt 72.694.005 (or similar)	4
Filter tips for microliter pipette	Sarstedt 70.3040.255 (or similar)	24

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 between 4 to 6 different organism controls using a combination of pathogens from ZeptoMetrix NATtrol ME (Meningitis/Encephalitis) Panel. Proposed mixing of organism controls is provided in Table 3. The method tests a total of 3 sample control mixes (3 sample control mixes tested in 4 replicates each).

For each assay run, the method provides either 5 or 6 positive results and, correspondingly, 10 or 11 negative results for the 16 pathogens detected and differentiated by the QIAstat-Dx Meningitis/Encephalitis (ME) 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 refrigerated conditions (2–8°C) for up to 3 days.

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 Analyzer instruments.

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

Mix	Organism	Organism control volume (mL)	Final volume of mix (mL)	Expected results	Number of expected negative results
Sample Control Mix 1	*S. pneumoniae*	0.25	1.5	positive	10
	N. meningitidis	0.25		positive	
	S. agalactiae	0.25		positive	
	L. monocytogenes	0.25		positive	
	H. influenzae	0.25		positive	
	Echovirus Type 11 (Enterovirus target)	0.25		positive	
Sample Control Mix 2	CMV	0.25	1.25	positive	11
	S. pyogenes	0.25		positive	
	HSV1	0.25		positive	
	HHV6	0.25		positive	
	VZV	0.25		positive	
Sample Control Mix 3	*M. pneumoniae*	0.25	1.25	positive	11
	C. gattii	0.25		positive	
	Parechovirus	0.25		positive	
	HSV-2	0.25		positive	
	E. coli	0.25		positive	

Protocol

Day 1

1. Prepare Sample Control Mix 1 and Sample Control Mix 2 (refer to Table 3).
   a. Transfer 0.25 mL of each of the organism controls in the mix to a new 2 mL tube using a microliter pipette.
   b. 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 2–8°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 as described in step 1. Test Sample Control Mix 3 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) 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 1	Sample Control Mix 3	Sample Control Mix 3
	Sample Control Mix 2	Sample Control Mix 2		
Operator 2	Sample Control Mix 1	Sample Control Mix 1	Sample Control Mix 3	Sample Control Mix 3
	Sample Control Mix 2	Sample Control Mix 2		