September 2022

Application Note

# Guidelines for Laboratory Verification of Performance of the QIAstat-Dx® Gastrointestinal Panel 2

QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, Germany

## Introduction

This document provides a sample protocol for the verification of the QIAstat-Dx Gastrointestinal Panel 2 (cat. no. 691412). The protocol provides positive and negative tests for the pathogens detected by the QIAstat-Dx Gastrointestinal Panel 2.

Each laboratory is responsible for defining their verification procedure and ensuring that they meet state and federal 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™ Gastrointestinal Verification Panel available from ZeptoMetrix Corporation (Buffalo, NY; cat. no. NATGIP-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 advised 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 | 5–6 |
| 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 | 276 |
| 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 Gastrointestinal Panel 2 Kit (6 tests) | 691412 | 3 |
| QIAstat-Dx Operational Module | 9002813 | 1 |
| QIAstat-Dx Analytical Module(s) | 9002814 | 1–4 |
| NATtrol Gastrointestinal Verification Panel* | ZeptoMetrix NATGIP-QIA | 2 |
| Sample tubes, 5 ml | VWR 89497-740 (or similar) | 4 |
| Transfer pipettes | VWR 13-711-43 (or similar) | 24 |
| Cary-blair transport media† Copan FecalSwab™ Collection, Transport and Preservation System of Enteric Bacteria | Cat#470CE | 4 |

* The NATtrol Gastrointestinal Verification Panel does not include the Cary-Blair transport media that serves as sample diluent in the sample verification method.

† The Copan FecalSwab Collection media (Cat#470CE) is the media used for the validation testing. Other similar Cary-blair might also want to be considered.

## Sample verification method

This sample verification method describes how to prepare sample control mixes by mixing together either 5 or 6 different organism controls using a combination of pathogens from ZeptoMetrix NATtrol GI (Gastrointestinal) Panel. 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 5-6 positive results and, correspondingly, 17-18 negative results for the 23 targets in total, which are detected and differentiated by the QIAstat-Dx Gastrointestinal Panel 2.

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. Avoid multiple freeze–thaw cycles to avoid compromising sample integrity.

**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 mixing and expected results (positive or negative)**

| Mix | Organism | Organism control volume (ml) | Cary-blair media* volume (ml) | Final volume of mix (ml) | Expected results | Number of expected negative results |
|---|---|---|---|---|---|---|
| Sample Control Mix 1 | *Giardia lamblia* | 0.05 | 0.61 | 1.5 | Positive | 17 |
| | *Cyclospora cayetanensis* | 0.15 | | | Positive | |
| | Enteroaggregative *Escherichia coli* (EAEC) | 0.02 | | | Positive | |
| | *Campylobacter jejuni* | 0.15 | | | Positive | |
| | Adenovirus Type 41 | 0.47 | | | Positive | |
| | *Shigella sonnei* | 0.05 | | | Positive | |
| Sample Control Mix 2 | Astrovirus Type 8 | 0.47 | 0.56 | 1.5 | Positive | 17 |
| | *Entamoeba histolytica* | 0.15 | | | Positive | |
| | *Clostridium difficile* | 0.15 | | | Positive | |
| | Enterotoxigenic *Escherichia coli* (ETEC) | 0.15 | | | Positive | |
| | Shiga-like toxin-producing *Escherichia coli* (STEC) O157† | 0.02 | | | Positive | |
| Sample Control Mix 3 | Enteropathogenic Escherichia coli (EPEC) | 0.05 | 0.90 | 1.5 | Positive | 17 |
| | *Vibrio parahaemolyticus* | 0.15 | | | Positive | |
| | *Yersinia enterocolitica* | 0.05 | | | Positive | |
| | *Plesiomonas shigelloides* | 0.05 | | | Positive | |
| | Sapovirus | 0.15 | | | Positive | |
| | Rotavirus | 0.15 | | | Positive | |
| Sample Control Mix 4 | Norovirus GII | 0.47 | 0.43 | 1.5 | Positive | 18 |
| | *Cryptosporidium parvum* | 0.15 | | | Positive | |
| | *Vibrio vulnificus* | 0.15 | | | Positive | |
| | *Salmonella enterica typhimurium* | 0.15 | | | Positive | |
| | *Vibrio cholerae* | 0.15 | | | Positive | |

* The NATtrol Gastrointestinal Verification Panel does not include the Cary-blair transport media that serves as sample diluent in the sample verification method.
† Shiga-like toxin-producing *E. coli* (STEC) serotype O157:H7 is detected in the QIAstat-Dx Gastrointestinal Panel 2 by a combination of two different signals, one corresponding to the Shiga-like toxin-producing *E. coli* (STEC) *stx1+stx2* assay and the other to *E. coli* O157 assay.

## Protocol

### Day 1

1. Prepare Sample Control Mix 1 and Sample Control Mix 2 (refer to Table 3).
   1a. Transfer specified volume of each of the organism controls in the mix to a new 5 ml tube.
   1b. Transfer the appropriate volume of transport media (not provided in the kit) to the 5 ml tube.
   1c. 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 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 1 | Sample Control Mix 3 | Sample Control Mix 3 |
| | Sample Control Mix 2 | Sample Control Mix 2 | Sample Control Mix 4 | Sample Control Mix 4 |
| 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 | Sample Control Mix 4 | Sample Control Mix 4 |

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.