



QIAstat-Dx GI 2 Control Panel

INTENDED USE:

QIAstat-Dx GI 2 Control Panel is intended for use as reference material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of bacterial, viral, and parasitic pathogens: Adenovirus F40/F41, Astrovirus, *Campylobacter*, *Clostridium difficile* toxin A/B, *Cyclospora cayetanensis*, *Cryptosporidium*, *E.coli* 0157, *Entamoeba histolytica*, Enteroaggregative *E.coli* (EAEC), Enteropathogenic *E.coli* (EPEC), Enterotoxigenic *E.coli* (ETEC) *lt/st*, *Giardia lamblia*, Norovirus GI/GII, *Plesiomonas shigelloides*, Rotavirus A, *Salmonella*, Sapovirus, *Shigella*/Enteroinvasive *E.coli* (EIEC), Shiga-like toxin *E.coli* (STEC) *stx1 + stx2*, *Vibrio cholerae*, *Vibrio parahaemolyticus*, *Vibrio vulnificus* and *Yersinia enterocolitica* on the QIAstat-Dx® Gastrointestinal Panel 2 performed on QIAstat-Dx® systems.

PRODUCT SUMMARY and PRINCIPLE:

QIAstat-Dx GI 2 Control Panel is composed of 3 controls, QIAstat-Dx GI 2 Positive A, QIAstat-Dx GI 2 Positive B, and QIAstat-Dx GI 2 Negative. QIAstat-Dx GI 2 Positive A and QIAstat-Dx GI 2 Positive B contain surrogate control material composed of synthetic nucleic acid corresponding to genome segments of pathogens listed in Table 1. QIAstat-Dx GI 2 Negative contains no nucleic acid.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Routine use of quality controls assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

The QIAstat-Dx GI 2 Control Panel is comprised of 12 tubes, 4 tubes of QIAstat-Dx GI 2 Positive A, 4 tubes of QIAstat-Dx GI 2 Positive B, and 4 tubes of QIAstat-Dx GI 2 Negative, 200µL each. QIAstat-Dx GI 2 Positive A and QIAstat-Dx GI 2 Positive B contain synthetic DNA and RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. QIAstat-Dx GI 2 Negative contains buffers and preservatives. Table 1 lists the pathogens that are monitored by the QIAstat-Dx GI 2 Control Panel.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* analytical testing and is provided for Research Use only, not for use in diagnostic procedures.
- This product does not contain the entire genome of the pathogens listed in Table 1.
- This product is not intended to replace manufacturer controls provided with the device.
- Appearance: Positive A & B controls are slightly cloudy and Negative control is clear.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- QIAstat-Dx GI 2 Control Panel cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

QIAstat-Dx GI 2 Control Panel should be stored frozen (-25°C to -15°C). Unopened QIAstat-Dx GI 2 Control Panel material is stable through the expiration date printed on the kit label when consistently stored frozen. QIAstat-Dx GI 2 Positive A, QIAstat-Dx GI 2 Positive B, and QIAstat-Dx GI 2 Negative are for single use only. Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

QIAstat-Dx GI 2 Control Panel
 Part Number: M475
 Kit Contains: 12 tubes x 200µL
 4 each Positive A, Positive B, and Negative

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come completely to room temperature (18°C – 25°C).
2. Use the control as provided. DO NOT DILUTE.
3. Prepare a QIAstat-Dx GI Panel 2 Cartridge according to the QIAstat-Dx GI Panel 2 Instructions for Use.
4. Open the sample lid of the main port on the front of the QIAstat-Dx GI Panel 2 Cartridge according to the QIAstat-Dx GI Panel 2 Instructions for Use.
5. Immediately before use, **mix the control thoroughly by inverting 3-5 times or pulse vortex for 3-5 seconds**, and tap the tube several times on the bench to remove any control caught in the cap before opening the tube.
6. Use the supplied transfer pipette to draw up the liquid control to the second fill line on the pipette (200µL).
7. Carefully transfer 200µL of sample volume into the main port on the QIAstat-Dx GI Panel 2 cartridge. Firmly close the sample lid of the main port until it clicks.
8. Visually confirm that the sample has been loaded by checking the sample inspection window in the cartridge.
9. The controls are single use only. Discard control tube after use according to your local and federal regulations.
10. Continue to process the control according to manufacturer’s instructions.

EXPECTED VALUES:

The expected results when the controls are analyzed are listed in Table 1.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for QIAstat-Dx GI 2 Control Panel in demonstrating adequate system performance.

Table 1: Expected Results for QIAstat-Dx GI 2 Control Panel

Result Details	Positive A	Positive B	Negative
Viruses			
Adenovirus F40/F41	Not Detected	+ Detected	Not Detected
Astrovirus	+ Detected	Not Detected	Not Detected
Norovirus GI/GII	+ Detected	Not Detected	Not Detected
Rotavirus A	+ Detected	Not Detected	Not Detected
Sapovirus	+ Detected	Not Detected	Not Detected
Bacteria			
<i>Campylobacter</i>	+ Detected	Not Detected	Not Detected
<i>Clostridium difficile</i> toxin A/B	+ Detected	Not Detected	Not Detected
<i>E. coli</i> 0157	+ Detected	N/A	N/A
Enteroaggregative <i>E.coli</i> (EAEC)	Not Detected	+ Detected	Not Detected
Enteropathogenic <i>E.coli</i> (EPEC)	N/A	+ Detected	Not Detected
Enterotoxigenic <i>E.coli</i> (ETEC) <i>lt/st</i>	+ Detected	Not Detected	Not Detected
<i>Plesiomonas shigelloides</i>	Not Detected	+ Detected	Not Detected
<i>Salmonella</i>	+ Detected	Not Detected	Not Detected
Shiga-like toxin <i>E.coli</i> (STEC) <i>stx1 + stx2</i>	+ Detected	Not Detected	Not Detected
<i>Shigella</i> /Enteroinvasive <i>E.coli</i> (EIEC)	Not Detected	+ Detected	Not Detected
<i>Vibrio cholerae</i>	Not Detected	+ Detected	Not Detected
<i>Vibrio parahaemolyticus</i>	Not Detected	+ Detected	Not Detected
<i>Vibrio vulnificus</i>	+ Detected	Not Detected	Not Detected
<i>Yersinia enterocolitica</i>	Not Detected	+ Detected	Not Detected
Parasites			
<i>Cryptosporidium</i>	+ Detected	Not Detected	Not Detected
<i>Cyclospora cayetanensis</i>	Not Detected	+ Detected	Not Detected
<i>Entamoeba histolytica</i>	+ Detected	Not Detected	Not Detected
<i>Giardia lamblia</i>	Not Detected	+ Detected	Not Detected