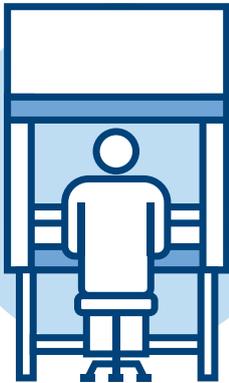


Laboratory guidelines for handling stool samples

Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the Biosafety in Microbiological and Biomedical Laboratories from the Centers for Disease Control and Prevention (1).



Per CDC guidelines, primary barriers such as biosafety cabinets should be used when procedures might cause splashing of droplets – including pipetting, shaking and opening containers of infectious materials (2).

Special attention to timely and appropriate decontamination of work surfaces is advised (2).



Gloves must be worn when working with hazardous materials.

Change gloves often and when contaminated or integrity is compromised (2).



Laboratory directors are responsible for establishing standard procedures in the laboratory of infectious clinical specimens (2).



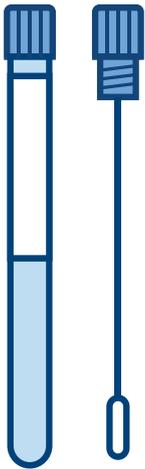
References:

1. QIAsta-Dx Gastrointestinal Instructions for Use. QIAGEN. 2019
2. Biosafety in Microbiology and Biomedical Laboratories, 5th Edition. CDC. December 2009

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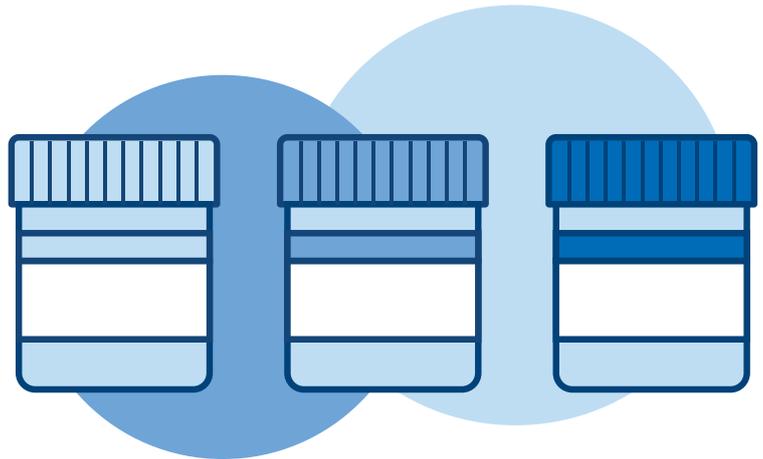
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Sample collection recommendations for the QIAstat-Dx Gastrointestinal Panel



The optimal concentration of 25–100 mg of unpreserved stool per ml of Cary-Blair transport medium should be used.

The maximum concentration that can be used is 250mg of unpreserved stool per ml of Cary-Blair transport medium.



Collect and resuspend the stool sample according to the Cary-Blair transport medium following manufacturer's recommended procedures.

Sample Storage

Recommended storage conditions for stool resuspended in Cary-Blair transport medium specimens are listed below:

- Room temperature up to 4 hours at 15–25°C
- Refrigerated up to 3 days at 2–8°C
- Frozen up to 24 days at –15 to –25°C



Recommended stool resuspension procedure for FecalSwab[®] from Copan #4C024S per Instructions for Use (3)

- 1** Collect a small amount of stool. Fully insert tip of the flocked swab into stool sample and rotate it. Bloody, slimy or watery area of stools should be selected and sampled.

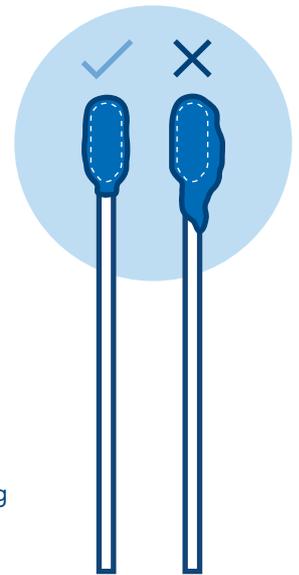


- 2** Examine swab to make sure there is fecal material visible on the tip. The swab tip only needs to be coated with sample material.

The swab should not be used as a paddle or spoon.

Do not collect and transfer excessive amount of fecal sample into the transport medium tube.

Excess of stool can lead to invalid results or cartridge failure when using QIAstat-Dx Gastrointestinal Panel.



- 3** Transfer swab into tube. Break off the swab's shaft on the marked breakpoint.



- 4** Check that the maximum filling line indicated on the label is not exceeded (3).



- 5** Shake the tube until the sample acquires a homogeneous appearance.



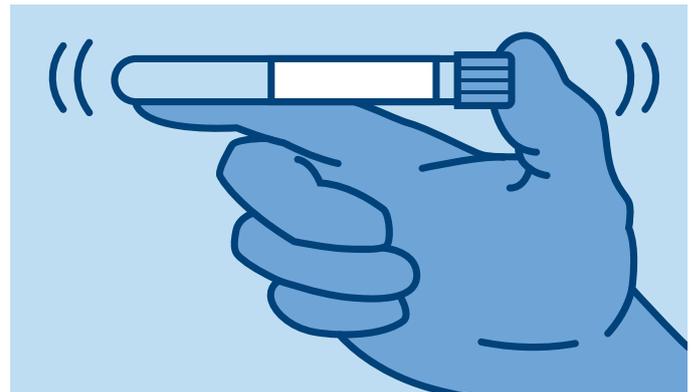
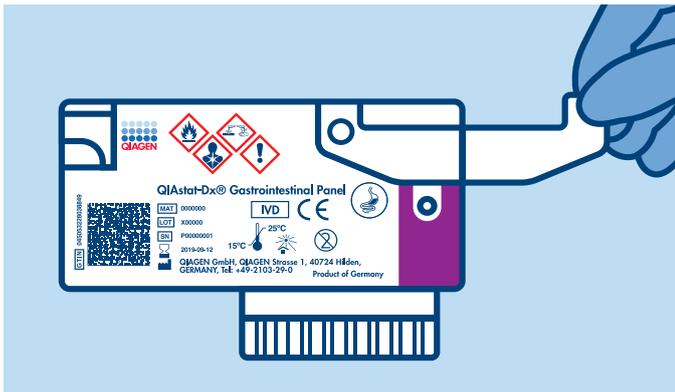
References:

3. FecalSwab Package Insert and How to Use guide. Copan. 2016

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Loading a sample into the QIAstat-Dx Gastrointestinal Panel cartridge



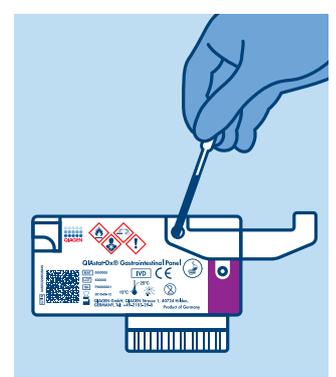
1 Open sample lid of main port on the front of QIAstat-Dx Gastrointestinal Panel Cartridge.

2 Thoroughly mix stool in Cary-Blair transport medium, for example, by vigorously agitating the tube 3 times.

3 Use supplied transfer pipette to draw up fluid to second fill line on the pipette (200 µl).
Important note: Do not draw air into pipette. If air is drawn into pipette, carefully expel the sample fluid in the pipette back into sample tube and draw up fluid again.



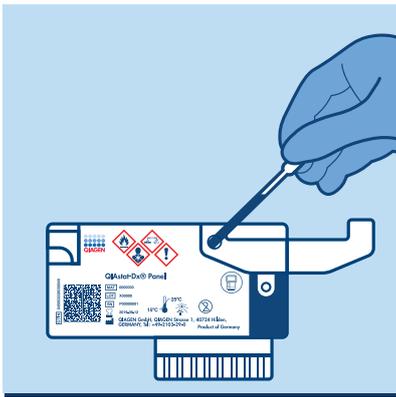
4 Carefully transfer 200 µl of sample into main port of the QIAstat-Dx Gastrointestinal Panel Cartridge. Firmly close the lid of the main port until it clicks.



5 Visually confirm sample has been loaded by checking sample inspection window.
Important note: Once sample is placed inside QIAstat-Dx Gastrointestinal Panel Cartridge, the cartridge must be loaded into QIAstat-Dx Analyzer 1.0 within 90 minutes.



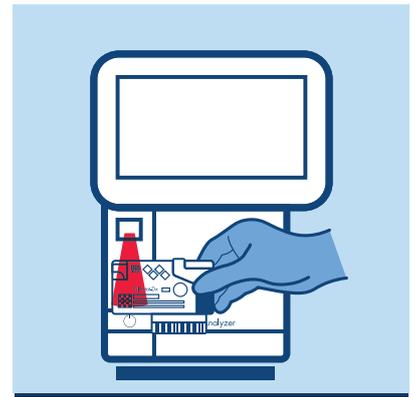
Running a QIAstat-Dx Gastrointestinal Panel cartridge



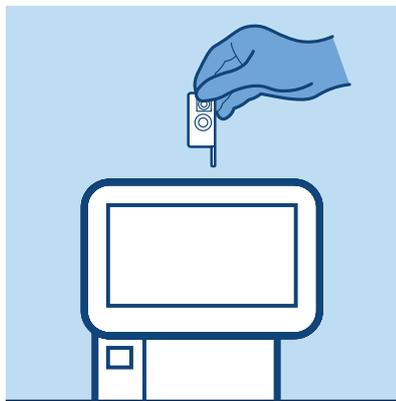
1 Transfer sample to main port of cartridge.



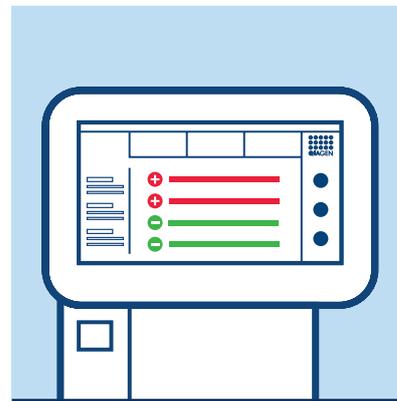
2 Press the Run Test button and scan sample ID barcode.



3 Scan barcode of cartridge to be used.



4 Position cartridge on sample port - cartridge automatically moves in and test starts.



5 View results after about an hour.

The QIAstat-Dx Analyzer and the QIAstat-Dx Gastrointestinal Panel are intended for in vitro diagnostic use.

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