



Unfilled Easy 2 Stool Extraction Device

For the preparation of human stool samples.

For In Vitro Diagnostic Use in the United States and Canada.

For Research Use Only in other territories.

Catalog Number: 80-EXDEV2-100

Size: 100 unfilled devices

Version: 1.0

INTENDED USE

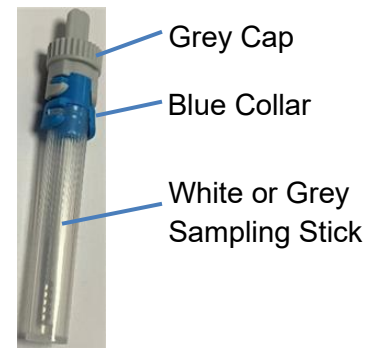
The unfilled Easy 2 Stool Extraction Device is intended for the preparation of human stool samples in conjunction with a designated buffer for analysis in compatible test kits. It is for *in vitro* diagnostic use in the United States and Canada. For Research Use Only in other territories.

PRINCIPLE OF THE DEVICE

The unfilled Easy 2 Stool Extraction Device is a universal tool for the preparation of stool extracts in conjunction with a designated buffer for analysis in compatible stool-based test kits. Devices are unfilled. The notched sampling stick accurately delivers 15 mg of stool to the device, eliminating the need for manual weighing. Final sample dilution will vary depending on the volume of buffer added to the device.

MATERIALS SUPPLIED

80-EXDEV2-100		
Component	Quantity	Preparation
Unfilled Easy 2 Stool Extraction Device	100 unfilled devices	Ready for addition of buffer



ADDITIONAL PRODUCTS

Contact ALPCO at info@alpc.com or 800-592-5726 for a list of compatible immunoassay kits or to inquire about validation of the unfilled Easy 2 Stool Extraction Device for use with other assays.

MATERIALS AND DEVICES REQUIRED BUT NOT PROVIDED

1. Stirring sticks or similar devices for homogenization of individual stool samples
2. Extraction buffer
3. Tube rack shaker
4. Centrifuge capable of 3,000 x g

PRECAUTIONS

1. The Easy 2 Device should not be used for the extraction of liquid/watery stool samples (type 7 on Bristol stool scale) or extremely hard stool samples (type 1 on Bristol stool scale). Refer to the instructions for use for specific immunoassay kits regarding the preparation of liquid stool samples.
2. The unfilled device is designed to accommodate stool-based assay kits that are not compatible with the pre-filled Easy 2 Extraction Device due to a required dilution < 1:100 and / or a specialized buffer formulation. Refer to the instructions for use for specific immunoassay kits for dilution and buffer instructions.

3. Stool samples are generally heterogeneous. Mechanical homogenization using an applicator, inoculation loop, or similar device prior to sampling is recommended. Use a new stirring stick for each stool sample¹.
4. All stool samples are potentially infectious. Handling and disposal of samples and used devices should be in accordance with all appropriate national and local regulations for the handling of potentially biohazardous materials.
5. Do not mix device components from different lots.
6. Carefully follow each step of the extraction procedure found in these instructions and in the kit manual. **Where different, always follow kit-specific sample preparation instructions.** Not following instructions in their entirety may lead to insufficient stool collection and / or extraction.
7. Stool extract stability is dependent upon the buffer used and the biomarker(s) of interest for subsequent testing. Refer to the instructions for use for specific immunoassay kits for stool extract handling and stability.
8. Easy 2 Devices are strictly for one-time use.


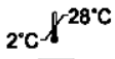


STORAGE CONDITIONS

Unfilled devices may be stored at room temperature or refrigerated (2-28°C).

REFERENCES

1. Pansart, C. *et al.* (2020). Preanalytical Heterogeneity in Fecal Calprotectin Measurement Needs to Be Considered for Tight Control. *Clinical Gastroenterology and Hepatology*. V18(2): p524-525.

SYMBOLS GLOSSARY

	<i>In vitro</i> diagnostic medical device
	Temperature limitation: store at room temperature or refrigerated
	Expiration or use by date
	Read electronic instructions for use

Instructions for Use (IFU) Revision 1.0
Revision Date: 14Jan26

EXTRACTION PROCEDURE

Step 1

Allow samples and extraction buffer to equilibrate to room temperature. Label device with sample number. Unscrew and remove the grey cap with sampling stick. Add the specified amount of kit-specific extraction buffer to the device.



Step 2

Insert the stick at three different sites to collect sample for extraction. Avoid picking up undigested solid material, as this can reduce the amount of usable sample.



Step 3

Ensure the notches at the bottom of the sampling stick are filled with sample.



Step 4

Wipe the tip of the stick on the inside edge of the extraction tube to remove any sample clinging to the end.



Step 5

Place sampling stick into filled tube only once. Excess stool will be removed and will collect at the top of the tube as the sampling stick is inserted. 15mg of sample will remain within the notches in the stick.



Step 6

Place tubes in a rack. Shake samples at 1,000 rpm for 30 minutes.



Step 7

Centrifuge samples for 3 minutes (3,000 x g).



Step 8

Unscrew and remove the entire grey cap / blue cap / stick assembly.



Step 9

The extracted sample is now ready for processing. Take care not to disrupt solids that have settled at the bottom of the tube. If applicable, aliquot and freeze remaining sample for future testing.

