Easy Stool Extraction Devices
For the storage and preparation of human stool samples for examination

For In Vitro Diagnostic use within the United States of America. This product is for “Research Use Only” outside of the United States of America.

Catalog Numbers: 30-EZEX-100
Size: 100 pre-filled devices
Version: January 28, 2019 – ALPCO 1.1
INTENDED USE

The ALPCO Easy Stool Extraction Device is intended for the storage and preparation of human stool samples for examination. For In Vitro diagnostic use within the United States of America. This product is for “Research Use Only” outside of the United States of America.

PRINCIPLE OF THE EASY STOOL EXTRACTION DEVICE

The Easy Stool Extraction Device is a universal stool extraction tool that can be used with 13 stool-based ELISAs. Standardized extraction is 15 mg of stool in 1.5 mL of universal extraction buffer (final dilution of 1:100). One single extraction can be used to determine the levels of 13 biomarkers in multiple gastroenterology research areas including:

- Calprotectin
- Pancreatic Elastase
- Alpha-1 Antitrypsin
- Secretory IgA
- Lysozyme
- Beta Defensin 2
- Bile Acids
- Anti-Gliadin Antibodies
- Anti-Transglutaminase Antibodies
- EDN/EPX
- Albumin
- Hemoglobin
- Hemoglobin/Haptoglobin Complex

MATERIALS SUPPLIED

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy Stool Extraction Device</td>
<td>100 pre-filled devices/pack</td>
<td>Ready to use</td>
</tr>
</tbody>
</table>

Yellow: Dipstick with click connector

Blue: Cone-shaped insert to strip off excessive stool
STORAGE AND PREPARATION OF REAGENTS

The extraction buffer in the pre-filled Easy Stool Extraction Device is stable at 2-8°C until the expiry date stated on the label. The sample tube is already pre-filled with working strength (1x) extraction buffer and it is not necessary to modify it any further.

SAMPLE HANDLING

1. The stool sample must be thawed. For particularly heterogenous samples, mechanical homogenization using an applicator, inoculation loop, or similar device is recommended.

2. Refer to IFU for specific analyte of interest for more details.

3. Dilution with 1.5 mL of universal extraction buffer:
   - Applied amount of stool: 15 mg
   - Buffer Volume: 1.5 mL
   - Total Dilution Factor: 1:100

   Note: For fluid samples, 15 mg = 15 µL

EXTRACTION OF THE STOOL SAMPLE USING THE PRE-FILLED EASY STOOL EXTRACTION DEVICE

Important: Allow the extraction buffer to reach room temperature.
Refer to instructions for use for specific ELISA for final dilution details.

1. Remove Dipstick
   Open the upper yellow part of the cap and remove the attached dipstick. The blue cone-shaped insert remains on the tube.

2. Obtain stool sample
   Insert the dipstick into the stool at 3 different sites to ensure proper representation of the stool sample. Make sure the notches at the lower part of the stick are covered and filled completely with stool. Excess stool is acceptable and will be removed as the stick is placed back into the device.
3. Place the dipstick back into the tube
Stick the dipstick with the attached stool only once back into the sample tube. Excess material will be stripped off by the cone-shaped insert and will result in a total of 15 mg of sample being deposited into the extraction buffer within the tube.

Steps 3. - 4.

4. Prepare stool sample suspension
Close the tube completely by turning until a click from the yellow shutter is heard. Then shake well until no stool sample remains in the notches and the stool is completely suspended in the extraction buffer. Placement on a shaker for up to 30 minutes may be necessary for some stool samples to be fully suspended in the extraction buffer. The suspension now contains 15 mg of stool (if the stool sample is fluid, pipet 15 µL into the tube). For details about dilutions and volumes, please refer to the SAMPLE HANDLING Section of the Easy Extraction Device IFU and the analyte specific ELISA IFU.

Attention: The stool dilution in the sample tube hardly changes color. Repeated insertion of sample into the tube will falsify the results.
5. Apply stool sample solution
   Open the complete cap of the tube including the **lower blue cone-shaped insert**. The stool-buffer solution is now ready for use according to the corresponding ELISA manual.

**TECHNICAL HINTS**

- Do not interchange different lot numbers of any kit component within the same assay
- Reagents should not be used beyond the expiration date stated on the kit label
- Do not mix plugs and caps from different reagents
- The assay used should always be performed according to the enclosed instructions for use.