



Extraction Kit

for BÜHLMANN fCAL[®] tests

For *In Vitro* Diagnostic Use Only

Rx Only

B-CAL-EX3

B-CAL-EX12

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ENGLISH

INTENDED USE

The extraction buffer (B-CAL-EX) is a reagent designed for the extraction of calprotectin in human stool specimens using the manual weighing method for laboratory analysis with BÜHLMANN fCAL® tests.

REAGENTS SUPPLIED

COMPOSITION AND PREPARATION OF REAGENTS

Code	Reagents	Quantity	Preparation
B-CAL-EX3	Extraction Kit extraction buffer	3 bottles x 125 mL	Ready to use
B-CAL-EX12	Extraction Kit extraction buffer	12 bottles x 125 mL	Ready to use

Table 1

MATERIALS REQUIRED BUT NOT PROVIDED

- 15 mL polypropylene tubes with screw caps (e.g. Sarstedt: #62.554.502) required for standard extraction procedure
- 10 µL single use inoculation loops, blue (e.g. Sarstedt: #86.1562.050)
- Precision balance 10-200 mg
- Vortex mixer
- Micro centrifuge
- 2 mL micro tube (e.g. Sarstedt: #72.691)
- 10, 100, and 1000 µL precision pipettes with disposable tips.

WARNINGS AND PRECAUTIONS

- This kit is for *in vitro* diagnostic use only.
- Read the instructions carefully prior to carrying out the extraction. Extraction buffer performance will be adversely affected, if stool samples are incorrectly diluted, modified or if extraction buffer is stored under conditions other than those as detailed in this instruction for use.
- Do not use extraction buffer beyond expiry date as shown on the kit labels.
- Used extraction buffer has to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
- Avoid contact of extraction buffer and specimens with mucous membranes.
- Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
- Wear disposable latex gloves when handling specimens. Microbial contamination of extraction buffer or specimens may give false results.

Technical precautions

- Allow extraction buffer to equilibrate for at least 30 minutes to 18-28 °C prior to use. Mix (vortex) the extraction buffer well before use.

Extraction procedure

- To achieve quantitative results, it is important to completely homogenize the added stool sample in the extraction buffer. There may be small amount of insoluble (undigested) particles remaining after mixing. The particles should not affect the results.
- Turbidity of the extract may still be observed after the 5 minute centrifugation step. The turbidity can be reduced by further centrifugation, but such turbidity has not been found to affect the quantitative results.

STORAGE AND STABILITY OF REAGENTS

Unopened reagents: Store at 2-8 °C. Do not use extraction buffer past expiration date printed on the labels.

Opened reagents: Store for up to 6 months at 2-8 °C.

SPECIMEN COLLECTION AND STORAGE

Collection of less than 1 g (1 mL) of stool sample is required. The extraction procedure requires 50-100 mg of stool sample.

Collect stool samples into plain tubes and store them refrigerated at 2-8 °C until ready for transport to the laboratory.

Important: The sample must be collected in empty collection devices; no chemical or biological additives should be added to the sample.

Specimen transport

Stool specimens should be received for processing by the laboratory within 3 days of collection. Stool specimens may be shipped at room temperature or on cold packs.

Specimen storage

Stool specimens should be refrigerated at 2-8 °C and extracted within 3 days of receipt at the laboratory. Do not store samples at elevated temperatures.

Extract storage

Fecal calprotectin extracts are stable refrigerated for up to 7 days at 2-8 °C. For longer storage, freeze the extracts at -20 °C. Frozen extracts are stable for a period of at least 2 months.

STOOL SAMPLE EXTRACTION PROCEDURE

- Step 1: Label and weigh the empty polypropylene tube, including the inoculation loop. Note the weight (tare).
- Step 2: Take out 50 to 100 mg of the stool sample by means of the inoculation loop and place it into the pre-weighted tube and weigh it again (gross weight). Avoid taking up dietary fibers present in the sample during the sampling process.
- Step 3: Calculate the net amount of sample, by subtracting tare from the gross weight, break the inoculation loop away, and leave the lower part of the loop in the tube. Add extraction buffer (49 times the weight [in μLs] of the sample) into the tube and cap the tube.
- Step 4: Extract the samples by
- Vigorously vortex the extraction tube containing buffer and stool sample on a vortex mixer (at highest speed) for 30 secs.
 - Incubate the extraction tube for 25 +/- 5 minutes on an orbital plate shaker at ca. 400 rpm. The inoculation loop inside the tube serves to enhance agitation.
 - Again, vigorously vortex the extraction tube for 30 seconds.

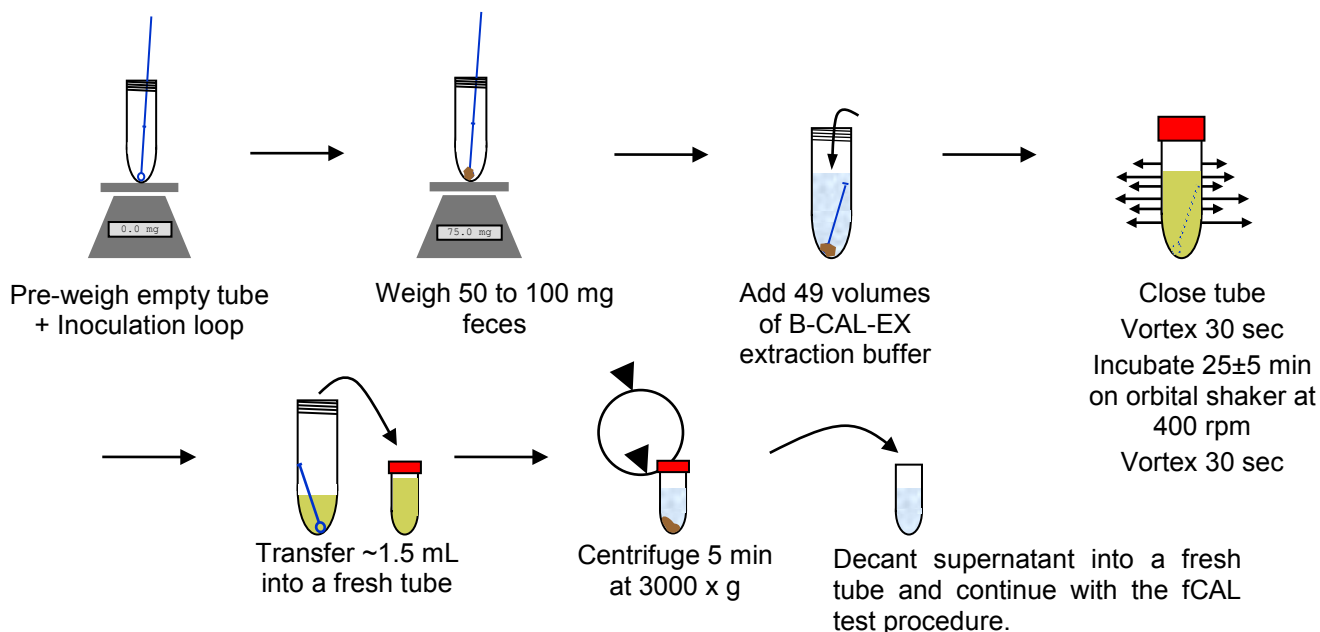
- Step 5: Transfer 1.5 mL of the homogenate into a 2 mL micro tube.
- Step 6: Centrifuge the extract in the tube for 5 minutes at 3000 x g.
- Step 7: Decant the supernatant into a fresh labeled tube and continue with the BÜHLMANN fCAL® test procedure, or store the extracts at 2-8 °C for ≤ 7 days or at ≤ -20 °C for ≤ 2 months.

Important: The extraction buffer (B-CAL-EX) should only be used in combination with BÜHLMANN fecal calprotectin tests.

APPENDIX I





SHORT TEST PROTOCOL




EXTRACTION PROCEDURE



APPENDIX II

SYMBOLS USED

Symbol	Explanation
	Use By
	Catalogue number
	Batch code
	<i>In Vitro</i> Diagnostic Medical Device

Symbol	Explanation
	Consult Instructions for Use
	Manufacturer
	Temperature limitation

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