



Extraction Kit

for BÜHLMANN fCAL[®] tests

For *In Vitro* Diagnostic Use

Rx Only

B-CAL-EX3
B-CAL-EX12

Release Date: 2023-07-28

Version A3



ENGLISH

INTENDED USE

The extraction buffer is a reagent designed for the extraction of calprotectin in human stool specimens using the BÜHLMANN Smart-Prep¹⁾ or manual extraction method for laboratory analysis with BÜHLMANN fCAL[®] tests.

¹⁾ for US customers: for research use only, not for use in diagnostic procedure

REAGENTS SUPPLIED

Reagents	Quantity		Code	Reconstitution
	B-CAL-EX3	B-CAL-EX12		
Extraction Buffer	3 bottles x 125 mL	12 bottles x 125 mL	B-CAL-EX	Ready to use

Table 1

MATERIALS REQUIRED BUT NOT PROVIDED

- Optional: Smart-Prep (Code: B-CAL-RD)
- 10 µL disposable inoculation loops
- 15 mL polypropylene tubes with screw caps required for standard extraction procedure
- Multitube vortex mixer
- Precision balance (10-200 mg)
- Micro centrifuge (≥3000 g)
- Plate shaker

REAGENT STORAGE AND STABILITY

Sealed / unopened reagents
Store at 2-8 °C. Do not use the reagents beyond the expiration date printed on the labels.
Opened reagent
Store for up to 6 months at 2-8 °C.

Table 2

WARNINGS AND PRECAUTIONS

- This extraction kit is for *in vitro* diagnostic use only.
- The extraction buffer and specimens should be handled by qualified personnel, in accordance with good laboratory practice (GLP).
- Read the instructions carefully prior to the use of the buffer. Buffer performance will be adversely affected, if the reagent is incorrectly stored as detailed in this instruction for use.
- This kit contains components classified in accordance with the Regulation (EC) No. 1272/2008: 2-methyl-4-isothiazolin-3-one hydrochloride ≥ 0,0015%), thus the reagents may cause allergic skin reactions (H317).
- Components must not be used after the expiry date printed on the labels.
- Let the reagent adjust to room temperature and mix well (vortex) before use.

- Used extraction buffer has to be treated as hazardous waste according to the national biohazard safety guideline or regulation.

Extraction

- To receive quantitative results it is important to homogenize the stool sample completely with 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.

SPECIMEN COLLECTION AND STORAGE

Please refer to the instruction for use of the corresponding BÜHLMANN fCAL[®] tests.

STOOL SAMPLE EXTRACTION

With the BÜHLMANN Smart-Prep¹⁾

Refer to the corresponding Smart-Prep instruction for use.

¹⁾ for US customers: for research use only, not for use in diagnostic procedure

With the manual extraction method ²⁾

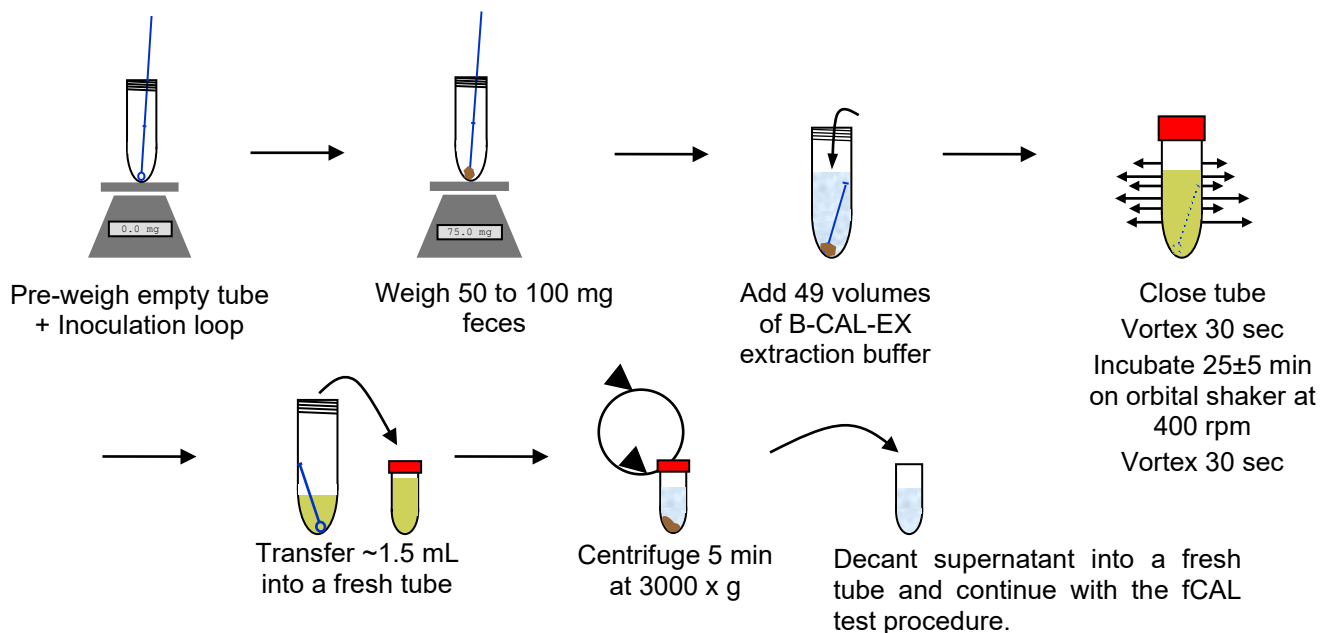
1. Label and weigh the empty polypropylene tube including the inoculation loop. Note the weight (tare).
2. Take 50 to 100 mg of the stool sample by means of the inoculation loop and place it into the pre-weighted tube and weigh it again (gross weight). Avoid taking up dietary fibers present in the sample during the sampling process.
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.
4. Add extraction buffer according to the formula
 $x \text{ mg stool} \times 49 = y \text{ } \mu\text{L extraction buffer}$ (e.g. 50 mg stool + 2450 µL buffer) to the tube and close the tube.
5. Extract the samples in the following way:
 - Vigorously vortex the extraction tube containing buffer and stool sample on a (multitube) vortexer (at highest speed) for 30 seconds.
 - Next, incubate the extraction tube for 25 +/-5 minutes on a 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.
6. Transfer 1.5 mL of the homogenate into a 2 mL Eppendorf tube and centrifuge in a microcentrifuge for 5 minutes at 3000 x g.
7. Decant the supernatant into a fresh labelled tube and continue with the assay procedure of the corresponding BÜHLMANN fCAL[®] tests.

Important: The extraction buffer should only be used in combination with BÜHLMANN fCAL[®] tests.

²⁾ According to the instruction for use of the BÜHLMANN fCAL[®] ELISA and Quantum Blue[®] fCAL tests.

SHORT TEST PROTOCOL

EXTRACTION PROCEDURE



CHANGELOG

Date	Version	Change
2023-07-28	VA3	Global instruction for use starting at version number A3. The US version A2 has been skipped during instruction for use harmonization. Update to chapter <i>warnings and precautions</i> Revision of chapter <i>symbols</i>

INCIDENT REPORTING IN EU MEMBER STATES

If any serious incident in relation to this device has occurred, please report without delay to the manufacturer and competent authority of your Member State.

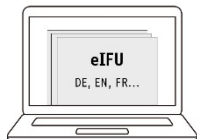
SHIPPING DAMAGE

Please notify your distributor, if this product was received damaged.

SYMBOLS

BÜHLMANN uses symbols and signs listed and described in ISO 15223-1. For definition of symbols see the symbol glossary at: <http://www.buhlmannlabs.ch/support/downloads/>

In addition the following symbols and signs are used:



EN: electronic instruction for use available in different languages at:/ **DE:** elektronische Gebrauchsanweisung in verschiedenen Sprachen verfügbar unter:/ **FR:** un mode d'emploi électronique disponible en différentes langues à l'adresse:/ **IT:** istruzioni elettroniche per l'uso disponibili in diverse lingue su:/ **ES:** instrucciones de uso electrónicas disponibles en diferentes idiomas en:/ **PT:** instrução eletrónica para utilização disponível em diferentes línguas em:/ **BG:** електронни инструкции за употреба на различни езици на адрес:/ **DA:** elektronisk brugsanvisning på forskellige sprog på:/ **ET:** elektrooniline kasutusjuhend, mis on saadaval erinevates keeltes aadressil:/ **EL:** ηλεκτρονικές οδηγίες χρήσης διαθέσιμες σε διάφορες γλώσσες στη διεύθυνση:/ **LV:** dažādās valodās pieejama elektroniska lietošanas instrukcija:/ **LT:** elektroninės naudojimo instrukcijos įvairiomis kalbomis:/ **NO:** elektronisk instruksjon for bruk tilgjengelig på forskjellige språk på:/ **PL:** elektroniczna instrukcja obsługi dostępna w różnych językach na stronie:/ **RO:** instrucțiuni electronice de utilizare disponibile în diferite limbi la adresa:/ **SV:** elektronisk bruksanvisning på olika språk på följande adress:/ **SK:** elektronický návod na použitie dostupný v rôznych jazykoch na:/ **SL:** elektronska navodila za uporabo, ki so na voljo v različnih jezikih na:/ **CS:** elektronický návod k použití dostupný v různých jazycích na adrese:/ **HU:** különböző nyelveken elérhető elektronikus használati utasítás a következő címen/
SR: elektronsko uputstvo za upotrebu dostupno na različitim jezicima na:

www.buhlmannlabs.ch/support/downloads/

US Distribution

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