



Instruction for use

CALEX[®] Cap

**For Research Use Only.
Not for use in diagnostic procedures.**

B-CALEX-C50-U

B-CALEX-C200-U

B-CALEX-C500-U

Revision: 18-01-2018

Intended use

The BÜHLMANN CALEX® Cap is a single use tube filled with extraction buffer. It is intended for sampling of human stool specimens and extraction of calprotectin for either manual or automated laboratory analysis with BÜHLMANN fCAL® assays.

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Device

Devices	Content	Code	Preparation	Storage / shelf life
CALEX® Cap device filled with 5 mL of extraction buffer	50	B-CALEX-C50-U	Ready to use	2-8 °C until the expiration date printed on the labels
	200	B-CALEX-C200-U		
	500	B-CALEX-C500-U		

The CALEX® Cap can be used in combination with:

- BÜHLMANN fCAL® turbo (order code: KK-CAL-U)
- BÜHLMANN fCAL® ELISA (order code: EK-CAL-U / EK-CAL2-U / EK-CAL2-WEX-U)
- Quantum Blue® fCAL (order code: LF-CAL25-U)
- Quantum Blue® fCAL extended (order code: LF-CALE25-U)
- Quantum Blue® fCAL high range (order code: LF-CHR25-U)

Precautions

- Read the instruction carefully before you use the CALEX® Cap device.
- For implementation of CALEX® Cap on total laboratory automation (TLA) solutions please refer to the corresponding manufacturer.
- The extraction buffer does not contain components of human origin.
- The devices must be equilibrated at room temperature (18-28 °C) before starting the extraction.
- The devices must not be used after the expiration date printed on the labels.
- The devices can be shipped at ambient temperature.
- The devices must not be reused for stool sample extraction.

How to proceed with difficult stool samples

- Liquid stool samples can be pipetted directly into the CALEX® Cap device. Unscrew the blue cap and pipet 10 µL of stool sample into the device. Recap the CALEX® Cap device and proceed with step 4 on page 5.
- Stool that does not stick to the grooves can be sampled as follows: Position the stool sample on the wall of your stool collection tube or place it on a spatula/spoon. The dosing tip (refer to Fig. B, page 4) has to be pressed along the wall of the tube or against the surface of the spatula/spoon. Rotate dosing tip until the grooves are completely filled with stool. Continue with step 3 on page 5.

Components of the CALEX® Cap

Fig. A
CALEX® Cap at delivery

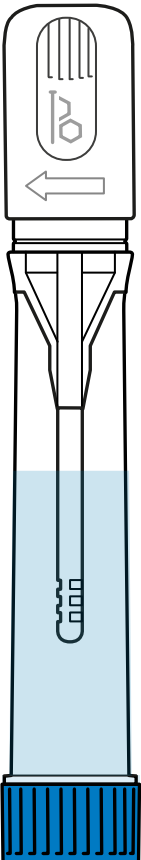


Fig. B
Sampling pin

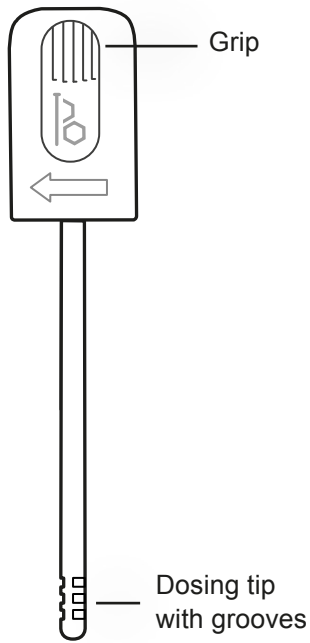
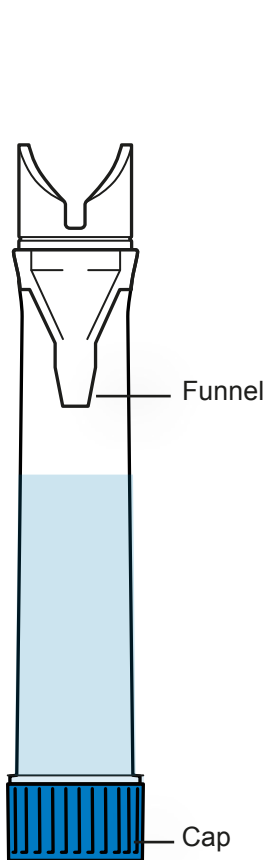


Fig. C
CALEX® Cap body



- 1 Hold the CALEX® Cap device upright and remove the white sampling pin by simultaneously turning and pulling it upwards (picture A).

Caution: Do not unscrew the blue cap!

- 2 Dip the dosing tip with the grooves into the stool and twist before removing. Repeat the procedure at 3-5 different positions of the stool sample in order to fill the grooves completely (picture B).

Note: Excess stool is stripped off in the funnel during re-introduction of the sampling pin into the CALEX® Cap body.

- 3 Re-introduce the sampling pin into the CALEX® Cap body and push it into the final locking position (you feel and hear two clicks, picture C).
- 4 Vortex the CALEX® Cap device with the white head down vigorously on a vortex mixer for 30 sec (picture D) and allow it to stand for 10 min on the blue cap. If the stool does not completely come off the grooves, repeat the procedure until the grooves are completely free of stool. That is easily monitored by checking that the grooves are empty (refer to page 4, fig. B) before proceeding with step 5.

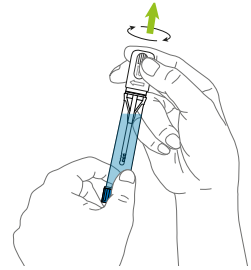
Note: The stool sample is now diluted 1:500.

Centrifuge the CALEX® Cap according to the instruction for use of the corresponding BÜHLMANN fCAL® assays.

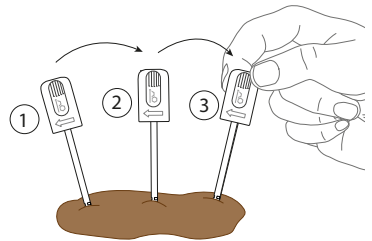
- 5 Either place the CALEX® Cap into a preanalytical system according to the corresponding instructions or manually unscrew the blue cap (picture E) to access the sample for further analysis.
- 6 Tightly recap the CALEX® Cap device after manual usage.

Note: Robotic systems will generally close tubes automatically with an appropriate sealing.

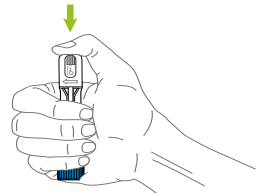
A



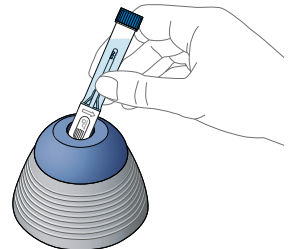
B



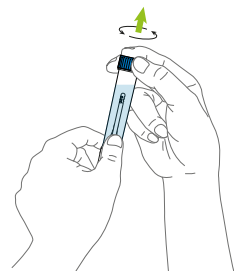
C



D



E



NOTES

SYMBOLS



Use by

Consult instructions for use



Temperature limitation



Batch code

Content sufficient for <n> tests



CALEX® is a registered trademark of BÜHLMANN in many countries.

Patented: US 9,752,967 B1



BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax orders +41 61 487 12 99
info@buhlmannlabs.ch
www.buhlmannlabs.ch