



Instruction for use

CALEX[®] Cap

For *In Vitro* Diagnostic Use

Rx only

B-CALEX-C50

B-CALEX-C200

B-CALEX-C500

Release Date: 29-04-2020

Version A2



Intended use

The BÜHLMANN CALEX® Cap is a single use tube intended for the preparation of human stool samples to be used with the BÜHLMANN fCAL® turbo and BÜHLMANN fPELA® turbo.

Device

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

The CALEX® Cap can be used in combination with:

- BÜHLMANN fCAL® turbo (order code: KK-CAL)
- BÜHLMANN fPELA® turbo (order code: KK-PELA)

Performance data for each assay with the CALEX® Cap can be found in the instruction for use of the corresponding BÜHLMANN assay.

Precautions

- Read the instruction carefully before you use the CALEX® Cap device.
- For use of CALEX® Cap on total laboratory automation (TLA) systems please contact the system manufacturer for further support.
- The extraction buffer does not contain components of human origin.
- The devices must be equilibrated at room temperature (18-24 °C) before starting the sample preparation.
- 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 preparation.

How to proceed with difficult stool samples

- For handling of liquid stool samples please refer to the instruction for use of the corresponding BÜHLMANN assay.
- 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 3) 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

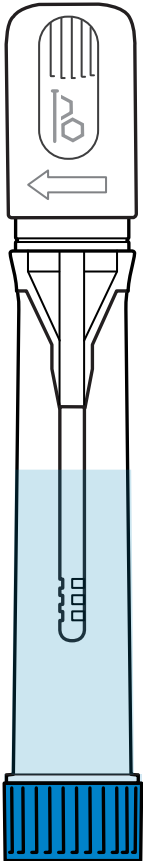


Fig. B
Sampling pin

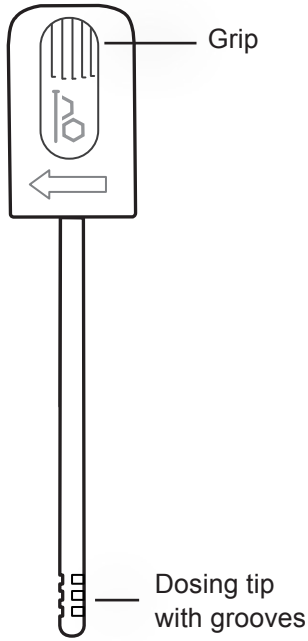
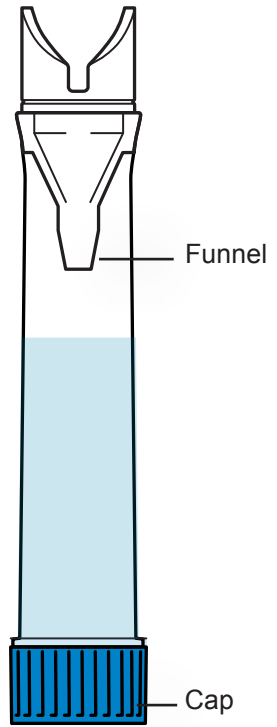


Fig. C
CALEX® Cap body



Sample Preparation

- 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).

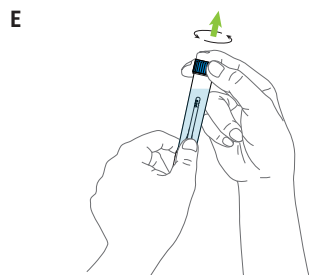
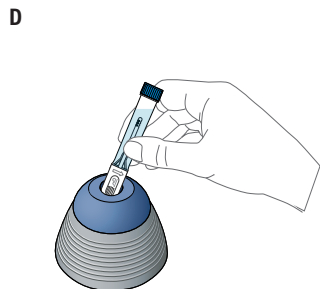
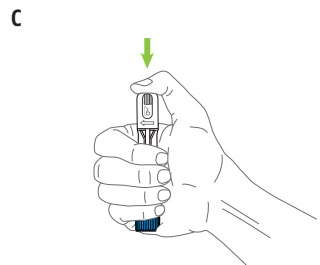
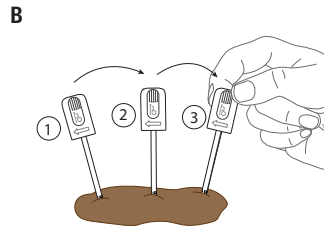
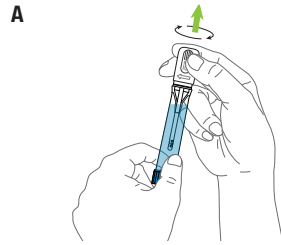
- 4 Vortex the CALEX® Cap device with the white head down vigorously on a vortex mixer for 30 sec (picture D) and allow it to stand for 10 min on the blue cap. If the stool does not completely come off the grooves, repeat the procedure until the grooves are completely free of stool. That is easily monitored by checking that the grooves are empty (refer to page 4, fig. B). Before proceeding with step 5, please refer to the instruction for use of the corresponding BÜHLMANN assay for specific processing time of samples and centrifugation.

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

- 6 To measure the sample, either place the CALEX® Cap into a preanalytical system according to the appropriate instructions or manually unscrew the blue cap (picture E) to access the sample for further analysis.

- 7 Tightly recap the CALEX® Cap device after manual usage.

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



NOTES

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SYMBOLS



Use by



Consult instructions for use



Temperature limitation



Batch code



Content sufficient for <n> tests



In Vitro Diagnostic Medical Device.

CALEX® is a registered trademark of BÜHLMANN Laboratories AG in many countries.
Patented: US 9,752,967 B1

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