



CALEX[®] Cap

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For *In Vitro* Diagnostic Use

B-CALEX-C50

B-CALEX-C200

B-CALEX-C500

Release Date: 2022-04-20

Version A3



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Intended use

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

Device

Devices	Content	Code	Preparation	Storage / shelf life
CALEX® Cap device filled with 5 mL of extraction-buffer (B-CAL-EX)	50	B-CALEX-C50	Ready to use	2-28°C until the expiration date printed on the labels
	200	B-CALEX-C200		
	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)
- BÜHLMANN fCAL® ELISA (order code: EK-CAL / EK-CAL2 / EK-CAL2-WEX)
- Quantum Blue® fCAL extended (order code: LF-CALE25)
- Quantum Blue® fCAL high range (order code: LF-CHR25)

Precautions

- Read the instruction carefully before you use the CALEX® Cap device.
- The extraction buffer contains components classified in accordance with the Regulation (EC) No. 1272/2008: 2-methyl-4-isothiazolin-3-one hydrochloride (conc. $\geq 0.0015\%$), thus the extraction buffer may cause allergic skin reactions (H317).
- For use of CALEX® Cap on total laboratory automation (TLA) systems please contact the system manufacturer for further support.
- The devices must be equilibrated at room temperature (18-28°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 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.

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Components of the CALEX® Cap

Fig. A
CALEX® Cap
at delivery

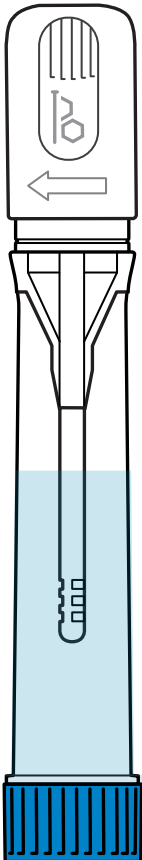


Fig. B
Sampling pin

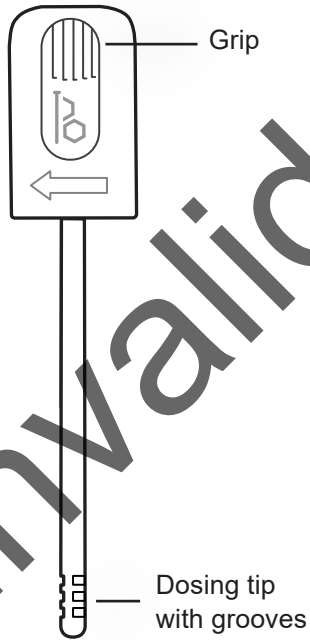
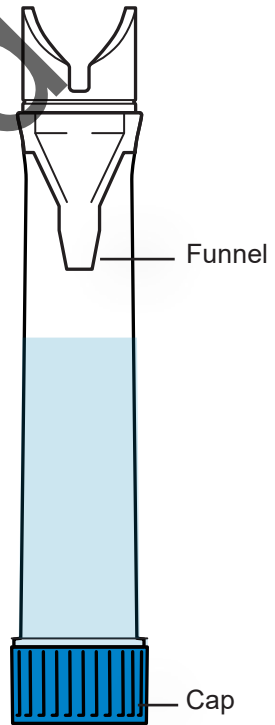


Fig. C
CALEX® Cap body



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 back into the final locking position (you feel and hear two clicks, picture C).

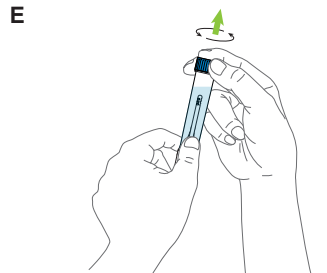
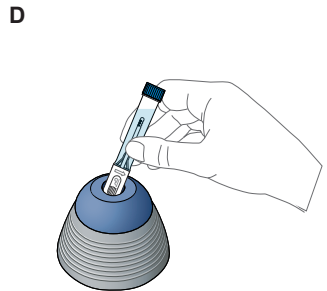
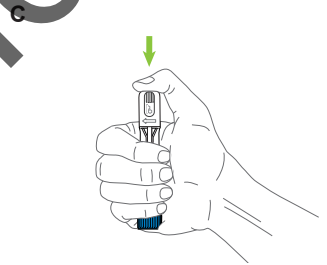
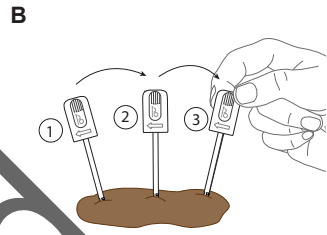
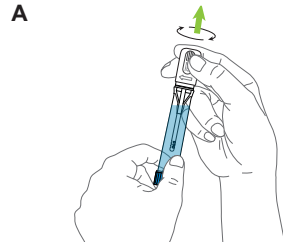
- 4 Vortex the CALEX® Cap device with the white head down vigorously on a vortex mixer for 30 sec (picture D) and allow it to stand for 10 min on the blue cap. If the stool does not completely come off the grooves, repeat the procedure until the grooves are completely free of stool. That is easily monitored 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.

- 5 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.

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

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



CHANGELOG

Date	Version	Change
2022-04-20	A3	Update to chapter <i>Precautions</i> Change to the storage/ shelf life 2-28°C 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.

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SYMBOLS

BÜHLMANN use symbols and signs listed and described in ISO 15223-1. 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 electrónica 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:** elektroonline 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:/ **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:

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Patented: EP2833795(B1); US9752967(B2); AU2016203121(C1); CA2997598(C); JP6307132(B2);
KR10-1875862(B1)



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