



CALEX[®] Cap

For *In Vitro* Diagnostic Use

Rx only

B-CALEX-C50

B-CALEX-C200

B-CALEX-C500

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Version A5



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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.¹

¹ For US customers: only for use with BÜHLMANN fCAL® turbo and BÜHLMANN fPELA® turbo

Device

Devices	Content	Code	Preparation	Storage / shelf life
CALEX® Cap 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
- BÜHLMANN fPELA® turbo
- BÜHLMANN fCAL® ELISA (for US customers: not available in combination with CALEX® Cap)
- Quantum Blue® fCAL extended (not available in the US)
- Quantum Blue® fCAL high range (not available in the US)

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.
- 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.

Components of the CALEX® Cap

Fig. A
CALEX® Cap
at delivery

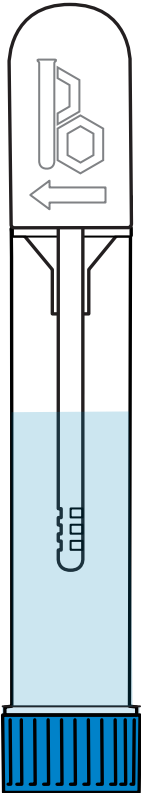


Fig. B
Sampling pin

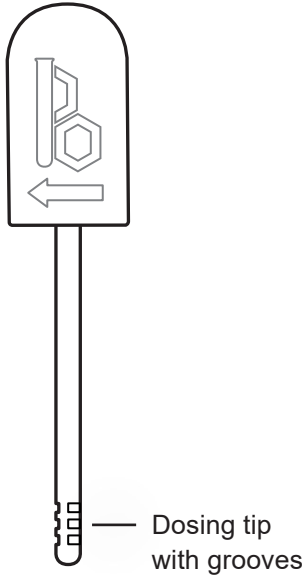
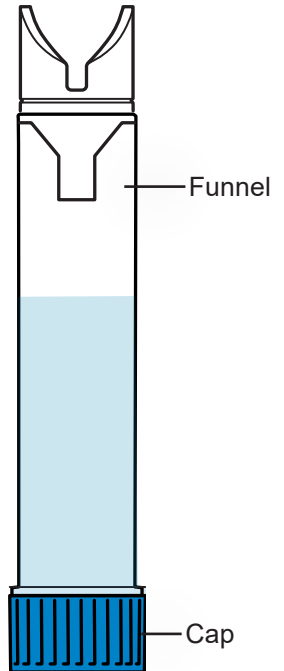


Fig. C
CALEX® Cap body



Sample Preparation

- 1 Hold the CALEX® Cap 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 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.

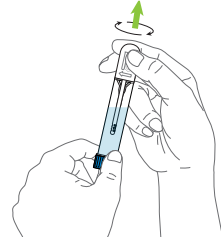
Note: The stool sample is now diluted 1:500.

- 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.

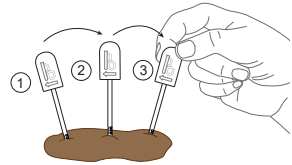
- 6 Tightly recap the CALEX® Cap after manual usage.

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

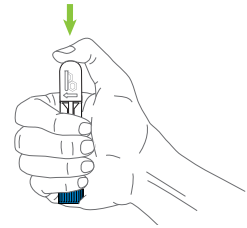
A



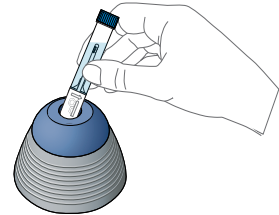
B



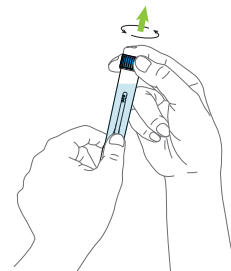
C



D



E



CHANGELOG

Date	Version	Change
2023-08-09	A5	Revision of chapter <i>Symbols</i> Global Instruction for use starting at version number VA5. Version A4 has been skipped during instruction for use harmonization.

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 use symbols and signs listed and described in ISO 15223-1. For definition of symbols see the symbol glossary at: www.buhmannlabs.ch/support/downloads/
In addition the following symbols and signs are used:



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

www.buhmannlabs.ch/support/downloads/

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KR10-1875862(B1)



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