## REFERENCES


1. Blirup-Jensen et al.: Clin Chem Lab Med 2001; 39, 1110 – 22.
2. Blirup-Jensen et al.: Clin Chem Lab Med 2008; 46, 1470 – 9.


## 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. 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**: 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 :/ **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/**

CE 0123



BÜHLMANN

# BÜHLMANN fCAL® turbo

Calprotectin turbidimetric assay
for professional use

# Calibrator Kit

B-KCAL-CASET
Version A4

For *In Vitro* Diagnostic Use




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## INTENDED USE

The BÜHLMANN fCAL® turbo Calibrator Kit is intended for use with the BÜHLMANN fCAL® turbo Reagent Kit for the determination of fecal calprotectin levels in extracted stool samples. Each calibrator establishes a point of reference for the working curve that is used to calculate test results from patient samples.

For laboratory use only.

## CALIBRATOR VALUE

Calibrator values are assigned according to a value transfer protocol (Ref. 1-2) and are indicated in the enclosed QC-data sheet. The calibrator material comprises blood-derived human calprotectin and is standardized against internal reference material.

## REAGENTS SUPPLIED

| Reagents | Quantity | Code | Preparation |
|---|---|---|---|
| **Calibrators**<br>Calibrators 1-6 containing an assigned concentration of human calprotectin | 1 x 6 vials<br>1 mL/vial | B-KCAL-CASET | Ready to use |

Table 1

## REAGENT STORAGE AND STABILITY

| |
|---|
| **Unopened calibrators** |
| Store at 2-8 °C. Do not use kit past expiration date printed on the labels. |
| **Opened calibrators** |
| Store for up to 3 months at 2-8 °C, capped. |
| **Calibration curve stability** |
| Refer to the instrument specific application note. |

Table 2

## MATERIALS REQUIRED BUT NOT PROVIDED

| Reagents | Quantity | Code |
|---|---|---|
| **BÜHLMANN fCAL® turbo Reagent Kit**<br>Reaction Buffer (R1)<br>Immunoparticles (R2) | <br>1 vial/35 mL<br>1 vial/7 mL | B-KCAL-RSET |
| **BÜHLMANN fCAL® turbo Control Kit**<br>Controls low and high | 3 x 2 vials<br>1 mL/vial | B-KCAL-CONSET |

Table 3

## WARNINGS AND PRECAUTIONS

- This test is for *in vitro* diagnostic use only.
- This kit contains components classified in accordance with the Regulation (EC) No. 1272/2008: 2-methyl-4-isothiazolin-3-one hydrochloride (conc. ≥ 0.0015%), thus the reagents may cause allergic skin reactions (H317).



- Before measuring please equilibrate reagents, controls, calibrators and samples as described in the application note.
- Do not mix calibrators of different lots or switch caps between reagents.
- Avoid evaporation of the calibrator.
- The calibrator contains components of human origin. Although tested and found negative for HBV, HCV and HIV, the calibrators should be handled as if capable of transmitting infections and should be handled in accordance with Good Laboratory Practices (GLP) using appropriate precautions. Disposal of any discarded materials should be in accordance with local requirements.

## ASSAY PROCEDURE

### Application notes / assay Installation

The assay procedure for the BÜHLMANN fCAL® turbo has been established on several clinical chemistry analyzers. Validated application notes describing installation and analysis on specific instruments are available from BÜHLMANN upon request.

### Establishment of the calibration curve

The BÜHLMANN fCAL® turbo Calibrator kit is used to establish a six point calibration curve according to the instrument manual. Calibrator values are lot-specific. A new calibration must be performed for each new calibrator and reagent lot. Otherwise, calibration should be performed every one to two months according to the instrument specific application notes. Refer to the enclosed QC-data sheet for assigned calibrator values. Contact BÜHLMANN support if calibration cannot be performed without error.

### QC controls

The calibration curve must be validated with controls, low and high, each day before running patient fecal sample extracts. Refer to the instruction for use for BÜHLMANN fCAL® turbo Control kit for further information.

## CHANGELOG

| Date/Version | Change |
|---|---|
| 2022-02-28/ A4 | Update to chapter “warnings and precautions”, revision of chapter “symbols”, inclusion of notified body number to CE-mark – conformity assessment procedure according to IVDR 2017/746 |