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

Control Kit

B-KCAL-CONSET
Version A4

For *In Vitro* Diagnostic Use

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INTENDED USE

The BÜHLMANN fCAL® turbo Control Kit is intended for use with the BÜHLMANN fCAL® turbo Reagent Kit, for quality control, in the determination of fecal calprotectin levels in extracted stool sample.

For laboratory use only.

CONTROL VALUE

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

REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
Controls Low / High Controls containing an assigned concentration of human calprotectin	3 x 2 vials 1 mL/vial	B-KCAL-CONSET	Ready to use

Table 1

REAGENT STORAGE AND STABILITY

Unopened controls
Store at 2-8 °C. Do not use kit past expiration date printed on the labels.
Opened controls
Store for up to 3 months at 2-8 °C, capped.

Table 2

MATERIALS REQUIRED BUT NOT PROVIDED

Reagents	Quantity	Code
BÜHLMANN fCAL® turbo Reagent Kit Reaction Buffer (R1) Immunoparticles (R2)	 1 vial/35 mL 1 vial/7 mL	B-KCAL-RSET
BÜHLMANN fCAL® turbo Calibrator Kit Calibrators 1-6 for establishment of six point calibration curve	 1 x 6 vials 1 mL/vial	B-KCAL-CASET

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 controls of different lots or switch caps between reagents.
- Avoid evaporation of the controls.
- The controls contain components of human origin. Although tested and found negative for HBV, HCV and HIV, the controls 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.

QC controls

The BÜHLMANN fCAL® turbo Control kit must be assayed each day before running patient fecal sample extracts. This is to validate the calibration curve established with the BÜHLMANN fCAL® turbo Calibrator kit. The controls have assigned, lot-specific value ranges indicated on the QC-data sheet enclosed. The control measurements must be within the indicated value ranges to obtain valid results for patient fecal sample extracts.

If the control values are not valid, repeat measurement with fresh controls. If control values remain invalid, recalibrate the instrument. If valid control values cannot be reproduced, after performing the steps described above, contact BUHLMANN support.

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