

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.

REACH

None of the materials and reagents in the kit require a Material Safety Data Sheet (MSDS) according to CLP-Regulation (EC) No 1272/2008 and directive EC 1907/2006 (REACH).

SYMBOLS KEY

	Expiration date
	Consult Instructions for Use
	Manufacturer
	Catalogue Number
	<i>In Vitro</i> Diagnostic Medical Device
	Lot number
	Temperature limitations

 **Manufacturer**
BÜHLMANN Laboratories AG
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BÜHLMANN fCAL® turbo

Calprotectin turbidimetric assay
for professional use

Control Kit

B-KCAL-CONSET
Version A2

For *In Vitro* Diagnostic Use

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DE: Die vollständige Gebrauchsanweisung kann heruntergeladen werden unter **FR:** La notice d'utilisation complète peut être téléchargée sur le site **IT:** Le istruzioni per l'uso complete possono essere scaricate dal sito **ES:** Las instrucciones de uso completas pueden descargarse en **PT:** A Instrução de uso completa pode ser baixada pelo site www.buhlmannlabs.ch

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.
- 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 BÜHLMANN support.