

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

Calibrator Kit

B-KCAL-CASET
Version A1

For *In Vitro* Diagnostic Use

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DE: Die vollständige Gebrauchs-anweisung 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.buhmannlabs.ch

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 Calibrators 1-6 containing an assigned concentration of human calprotectin	1 x 6 vials 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
Calibration curve is stable for up to 2 months, when reagents are stored on-board.

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 Control Kit Controls low and high	3 x 2 vials 1 mL/vial	B-KCAL-CONSET

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 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 standard 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, (Code: B-KCAL-CONSET), each day before running patient fecal sample extracts. Refer to the instruction for use for BÜHLMANN fCAL® turbo Control kit for further information.