

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.







Shipping damage

Please notify your distributor, if this product was received damaged

REACH

None of the materials and reagents in the kit require a 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
	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-U

This product is for research use only
It is not intended for use in diagnostic procedures

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EN: The complete Instruction for Use can
be downloaded on

www.buhlmannlabs.ch

Intended Use

The BÜHLMANN fCAL[®] turbo is a test for the quantitative determination of calprotectin in human stool specimens.

This product is for research use only. It is not intended for use in diagnostic procedures.

Calibrator Indication for use

The BÜHLMANN fCAL® turbo Calibrator is intended for calibration curve establishment for the BÜHLMANN fCAL® turbo turbidimetric assay to allow determination of calprotectin concentration in fecal sample extracts.

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 standardised 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-U	Ready to use

Table 1

Reagent Storage and Stability

Shelf life of unopened reagents at 2-8 °C: see expiry date on package label.

Shelf life of opened reagents at 2-8 °C: see expiry date on package label.

Warnings and Precautions

- This test is for *in vitro* use only, and must be handled by qualified personnel, in accordance with good laboratory practices (GLP).
- Do not mix reagents of different reagent lots or switch caps between reagents.
- Avoid evaporation of the calibrator.
- The calibrator contains potentially infectious substances of human origin and should be handled with due caution. Disposal of any discarded materials should be in accordance with local requirements.

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-U
BÜHLMANN fCAL® turbo Control Kit Controls low and high	3 x 2 vials 1 mL/vial	B-KCAL-CONSET-U

Table 2

Assay Procedure

Application Notes/ Assay Installation

Assay procedures for the BÜHLMANN fCAL® turbo are established on several clinical chemistry analysers. 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 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 lot. Otherwise, calibration should be performed every 4 to 8 weeks 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 QC controls, Low and High, (Code: B-KCAL-CONSET-U), each day before running fecal sample extracts. Refer to the Instruction for Use for BÜHLMANN fCAL® turbo Control Kit for further information.