QC CONTROLS

The calibration curve must be validated with QC 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.

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.

CHANGELOG

Date/Version	Change
2022-08-09/ A1	Update to chapter *Warnings and precautions* Revision of chapter *Symbols* Deletion of chapter *Hazardous material*

REFERENCES

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

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.

BUHLMANN Diagnostics Corp (U.S.):
Technical Service Mon-Fri 8:00AM-5:00PM EST
(844)300-9799

BÜHLMANN

BÜHLMANN fCAL® turbo

Calprotectin turbidimetric assay
for professional use

Calibrator Kit

B-KCAL-CASET

Version A1

For *In Vitro* Diagnostic Use Only

Manufacturer

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Rx Only

CLIA Complexity: High

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.

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	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 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 2

WARNINGS AND PRECAUTIONS

- This test is for *in vitro* use only.
- This kit contains 2-methyl-4-isothiazolin-3-one hydrochloride (conc. ≥ 0.0015%), thus the reagents may cause allergic skin reactions (H317).
- Avoid contact of reagents with the skin, eyes or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, irritation can occur.
- 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 the Roche cobas® c501/502 platforms and will be expanded to other platforms over time. Application notes describing installation and analysis on all validated clinical chemistry analyzers are available from BUHLMANN Diagnostics Corp.

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.