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*

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

Control Kit

B-KCAL-CONSET

Version A1

Manufacturer
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For *In Vitro* Diagnostic Use Only

Rx Only

CLIA Complexity: High

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 samples.

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 standardised 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 instrument calibration	1 x 6 vials 1 mL/vial	B-KCAL-CASET

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 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 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.

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 QC control 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 Diagnostics Corp.