BÜHLMANN fCAL® turbo

Calprotectin turbidimetric assay

for professional use

Control Kit

B-KCAL-CONSET

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BÜHLMANN LABORATORIES AG
Baselstrasse 55
4124 Schönenbuch, Switzerland
Tel.: +41 61 487 1212
Fax: +41 61 487 1234
info@buhlmannlabs.ch

ENGLISH

INTENDED USE

The BÜHLMANN fCAL® turbo is an *in vitro* diagnostic test for the quantitative determination of calprotectin in human stool specimens intended as an aid in the assessment of intestinal mucosal inflammation. The assay results can be used as an aid to diagnosis in distinguishing organic, inflammatory disease of the gastrointestinal tract (inflammatory bowel disease, IBD, e.g. Crohn's disease or ulcerative colitis, UC) from functional disease (irritable bowel syndrome, IBS), in patients with chronic abdominal pain, above the age of four, and as an aid to IBD disease monitoring.
For laboratory use only.

CONTROL KIT INDICATION FOR USE

The BÜHLMANN fCAL® turbo Control Kit is intended for validation of the quality of calibration established with the BÜHLMANN fCAL® turbo Calibrator for the BÜHLMANN fCAL® turbo calprotectin turbidimetric assay.

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

- 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 controls.
- The controls 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
BÜHLMANN fCAL® turbo Calibrator Kit Calibrators 1-6 for instrument calibration	1 x 6 vials 1 mL/vial	B-KCAL-CASET

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.

QC Controls

The BÜHLMANN fCAL® turbo Control, Low and High, 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. 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, perform the following procedures :

- Repeat QC control measurement with fresh controls.
- Recalibrate the instrument.

Contact BÜHLMANN support if valid control values cannot be reproduced.

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).

APPENDIX I

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.

APPENDIX II

SYMBOLS

Symbol	Explanation
	Expiration date
REF	Catalogue Number
LOT	Lot number
IVD	*In Vitro* Diagnostic Medical Device

Symbol	Explanation
	Consult Instructions for Use
	Manufacturer
	Temperature limitations

CE

IVD