BÜHLMANN fCAL® turbo

Calprotectin turbidimetric assay
for professional use

Calibrator Kit

B-KCAL-CASET

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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.

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

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), each day before running patient fecal sample extracts. Refer to the Instruction for Use for BÜHLMANN fCAL® turbo Control Kit for further information.

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