BÜHLMANN fCAL® turbo

Immuno turbidimetric fecal CALPROTECTIN Assay

Automation

Speed

Simple stool preparation

Automated fecal Calprotectin results

- Streamlined Workflow & Random Access
- Full integration into your Routine Work

Fecal Sample Preparation with CALEX® Cap

- Hassle free pre-Analytics
- Fully compatible with Total Laboratory Automation

Use the established reference

- Proven & stable Standardization
- Established & Validated Cut-off in IBD Diagnosis & IBD Monitoring

BÜHLMANN fCAL® turbo is FDA 510(k) cleared (K190784). For *in vitro* Diagnostic Use.

CALEX® Cap: FDA 510(k) cleared (K191718 & 232057). For *in vitro* Diagnostic Use.

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Fecal Calprotectin in 10 minutes

BÜHLMANN fCAL® turbo, a groundbreaking turbidimetric immunoassay, offers rapid calprotectin quantification. Compatible with most clinical chemistry analyzers, this technology allows flexible random-access use, perfect for high-throughput routines. The fCAL turbo significantly reduces hands-on time, ensuring swift reporting of calprotectin results from human stool samples.

Centrifuged stool samples from BÜHLMANN's CALEX® Cap can be applied directly to your existing analyzer, requiring no special equipment. The results, spanning 30 to 10,000 µg/g, takes only ten minutes, with automatic re-testing for highly concentrated samp-les.

Available application notes	Siemens	Advia 1650/1800, Advia 2400, Advia XPT, Atellica CH 930
	Roche	Cobas c501/c502, Cobas c701/c702, Cobas Pro c503, Cobas Pure c303
	Abbott	Architect (c series), Alinity
	Beckman	AU series (AU400/640), AU480, AU680, AU5800, DxC 700 AU, DxC 600/800
	Mindray	BS-200E, BS-240/ 240 Pro, BS-380, BS-400
	Thermo Fisher	Konelab30i, Indiko/Indiko Plus
	Ortho	Vitros 5600
	The Binding Site	Optilite
	Horiba ABX	Pentra 400
	BioSystems	BA200

The analyzers mentioned in the above table are registered trademarks held by the corresponding manufactures.

PRODUCT DESCRIPTION	
Method	Particle-enhanced turbidimetric immunoassay (PETIA)
Sample Type	CALEX® Cap prepared stool sample
Kit Format	2 reagents (wedge bottles for direct loading on many platforms) Reagents last for ~200 tests (platform dependent)
Sample Preparation	CALEX® Cap stool sample can be used directly without additional dilution
Reagent on board	Stable for at least 60 days
Calibration	Stable for up to 60 days
Calibration range	0-2000 µg/g
Measuring range	30-10,000 µg/g
Sample volume	~10 µL centrifuged fecal Extract (1:500)
Time to First Result	10 min CALEX® stool preparation ~20 min

Stool Samples on Clin Chem Platforms

Centrifuged CALEX® prepared stool samples are devoid of undigested dietary fibers, reducing bacterial load by ~95%, comparable to routine urine samples from UTI patients.

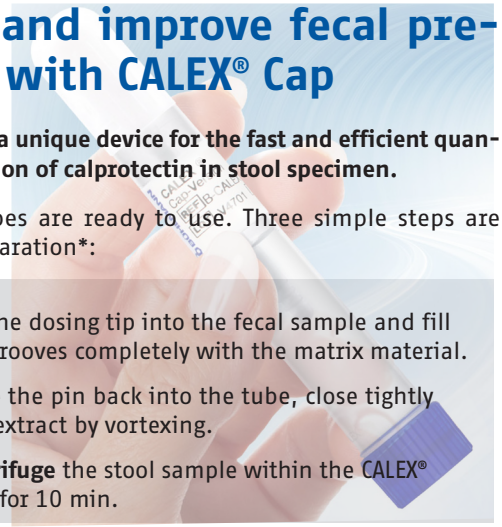
Minimal carry-over effects (<0.5%) on high-throughput analyzers have been confirmed, excluding serum contaminations.

Turbidimetric reagents lack critical compounds, making interactions with other assays highly unlikely and unobserved.

Simplify and improve fecal preparation with CALEX® Cap

The CALEX® Cap is a unique device for the fast and efficient quantitative preparation of calprotectin in stool specimen.

The prefilled tubes are ready to use. Three simple steps are required for preparation*:



STEP 1 **Dip** the dosing tip into the fecal sample and fill the grooves completely with the matrix material.

STEP 2 **Place** the pin back into the tube, close tightly and extract by vortexing.

STEP 3 **Centrifuge** the stool sample within the CALEX® tube for 10 min.

The prepared stool sample (1:500) is ready to use in the turbidimetric assay. The CALEX® Cap preparation highly correlates with the manual weighing method.

*Please see the full instructions for use (IFU) on buhlmannlabs.com for more detailed information prior to use

Use the established reference

BÜHLMANN fCAL® turbo standardization is based on the gold standard BÜHLMANN fCAL® ELISA, implemented globally in laboratories.

- **A trustful stable standardization of calprotectin**

  Our long experience with the complex protein and our large network in science and clinics guarantee a continuous quality of the assay.

- **Established cut-off for diagnosis and monitoring**

  Based on clinical experience over 10 years and clinical studies. Application of a cut-off **80 µg/g** means higher specificity with minor reduction in sensitivity facilitating the diagnosis of IBD with a major improvement of cost effectiveness. To keep the indecisive grey zone to a minimum, cut-off **160 µg/g** shows an ideal trade-off for a combination of specificity and better sensitivity for the studied patient cohort.

- **Clinically proven in more than 100 publications**

  Please, refer to our homepage or ask for reference literature.

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BÜHLMANN fCAL® turbo Ordering Codes:

Reagent Kit (~200 tests)	B-KCAL-RSET-US	R1 35 mL, R2 7 mL
Calibrator Kit	B-KCAL-CASET	6 levels, 1 mL each; Ready to use
Control Kit	B-KCAL-CONSET	3 x 2 levels, 1 mL each; Ready to use

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