

# BÜHLMANN fCAL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> turbo is FDA 510(k) cleared (K190784). For *in vitro* Diagnostic Use.  
CALEX<sup>®</sup> Cap: FDA 510(k) cleared (K191718). For *in vitro* Diagnostic Use.

 **BÜHLMANN**

## 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 20 to 8000 µg/g, takes only ten minutes, with automatic re-testing for highly concentrated samples.

| 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)<br>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    | 20-8000 µg/g   |
| Sample volume      | ~10 µL centrifuged fecal Extract (1:500)   |
| Time to result     | ~10 min<br>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](http://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 specificity 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 |



BÜHLMANN fCAL® and CALEX® are registered trademarks of BÜHLMANN in many countries.

Parts of the BÜHLMANN fCAL® kits are patent protected by:  
EP2947459(B1); US10620216(B2); AU2015261919(B2); JP6467436(B2)

Parts of the CALEX® Cap are patent protected by:  
EP2833795(B1); US9752967(B2); AU2016203121(B2); CA2997598(C); JP6307132(B2); KR10-1875862(B1)