

Quantum Blue®

SUPPORTS IBD/IBS SCREEN
& THERAPY MONITORING WITH
CALPROTECTIN QUANTITATIVE RAPID TESTS

- Quantitative
- Rapid
- RFID Technology

IBD/IBS Screening & Therapy Monitoring

Quantum Blue® Calprotectin Rapid Tests

Two rapid Calprotectin tests are now offered by BÜHLMANN.

- **The lower range Quantum Blue® LF-CAL** has been developed to cover a calprotectin level range of **30 to 300 µg/g**. It is a sensitive tool to pre-select patients requiring colonoscopy for further diagnostic confirmation of organic bowel disease, or to exclude IBD. The cut off of 50 µg/g for this application lies within the defined measuring range.
- **The high range Quantum Blue® LF-CHR** has been developed to cover a calprotectin level range of **100 to 1800 µg/g**. In addition to other biomarkers like CRP, this is an ideal tool to support the follow up of IBD patients during their therapy. By regularly testing, a patient calprotectin profile can provide valuable information about inflammation and prediction of relapses.

Within 12 to 15 minutes only, the results are presented as a quantitative readout of calprotectin concentration in µg/g, comparable to commonly used tests like the BÜHLMANN Calprotectin ELISA, EK-CAL, (refer to the correlation data on the back page).

The BÜHLMANN Quantum Blue® tests rely on the simple and established technology of lateral flow assays, including an easy to use reader system allowing for quantitative read out.

This innovation detects the intensity of appearing bands through optical measurement. Thus the application of Quantum Blue® Calprotectin avoids possible subjective misinterpretations of reading by eye, and simplifies the operator's work and interpretation of results.

As further asset, cartridges and readers are equipped with RFID chips (Radio Frequency Identification) for synchronization of the reader to the test kit lot.

Thus Quantum Blue® tests are the ideal quantitative tools for rapid and easy calprotectin measurements.

Quantum Blue® Calprotectin

Innovations and advantages

Simplicity: Ideally suited for every medical professional. No special equipment is required. The combination with the extraction devices Smart-Prep and Sche-Bo® Quick-Prep (see separate documentations) allow for user friendly sample preparation and analysis.

Rapid: Depending on the test in use, results will be available within 12 or 15 minutes once the sample has been loaded.

Quantification: The application of the Quantum Blue® reader provides quantitative results of calprotectin concentrations.

RFID Technology: The perfect assistant for the operator: No need to worry about lot to lot standardization differences and set ups.

Clinical Evaluations

Quantum Blue® Calprotectin is nowadays a routine tool in many hospitals. Numerous published clinical evaluations confirm the diagnostic utility of this rapid and quantitative assay.

Sydora et al. confirm in JCC that « Quantum Blue® Calprotectin exhibits a fast and reliable way to identify IBD ».

Coorevits et al. and Hessels et al. conclude that it is a reliable test in differential diagnosis and seems to be reliable in the follow up of IBD patients. It also « has demonstrated better performance than the CalDetect test in reducing the number of colonoscopies ».

Finally Lobaton et al. conclude that « Quantum Blue® Calprotectin predicts mucosal healing in IBD patients accurately ».



Interpretation of results

Estimation of faecal Calprotectin is a reliable and easy way to distinguish organic from functional gastrointestinal diseases as well as a means of IBD patients' therapy follow up.

Normal values below 50 µg/g:

Calprotectin values <50 µg/g are not indicative of inflammation. Patients with low levels are likely not to be in need of further invasive procedures.

It is recommended re-testing samples in the grey zone between 30 and 70 µg/g, which corresponds to the 2.5th – 97.5th percentile of imprecision around the cut-off of 50 µg/g.

Elevated values between 50 and 200 µg/g:

Calprotectin values between 50 and 200 µg/g can represent mild organic disease such as inflammation caused by NSAIDs, mild diverticulitis and IBD in remission phase.

Elevated values above 200 µg/g:

Calprotectin values > 200 µg/g are indicative of active organic disease with inflammation in the gastrointestinal tract. Appropriate further investigative and curative procedures by specialists are suggested.

Quantitative Lateral Flow Test Format



1. Sample preparation for measurement: Dilute the stool extract in a fresh microtube with the respective buffer. Vortex and centrifuge for 5 min at 3'000 x g. Alternatively, the extract can be sedimented for 10 minutes. The supernatant is to be used afterwards.



2. Process the stool extract according to the instruction for use of the respective kit. Load stool extract onto the sample loading port of the Test Cartridge with a precision pipette.



3. Immediately after loading, start the timer by pressing the Enter Button of the reader. To avoid contamination of the reader's optical device, close the tray after about 30 seconds.



4. At the end of the incubation time, the test cartridge is automatically read and the result is displayed in $\mu\text{g/g}$ Calprotectin.

Quantum Blue® Reader

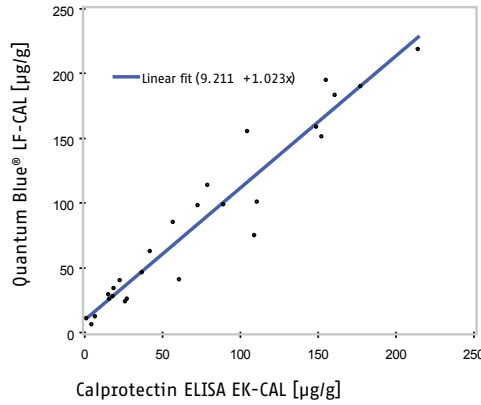


Method Comparison

Sample Extraction

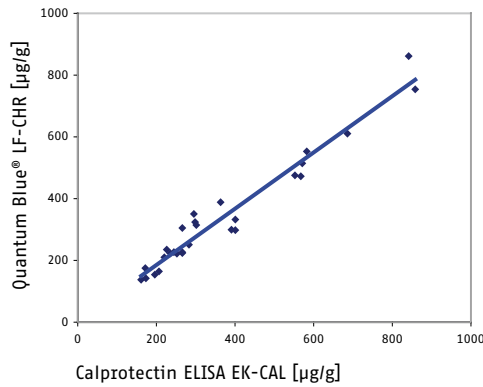
Lower range Quantum Blue® LF-CAL vs Calprotectin ELISA - EK-CAL

$r^2 = 0.93$



High range Quantum Blue® LF-CHR vs Calprotectin ELISA - EK-CAL

$r^2 = 0.952$



Lower range Quantum Blue® LF-CAL and high range Quantum Blue® LF-CHR provide within minutes quantitative results from 30 to 300 µg/g or 100-1800 µg/g calprotectin respectively, which can be compared directly to the well established and highly precise ELISA results.

The integrated lot-specific standard curve guarantees independence of inter-technician and inter-lot variations.



1)

ScheBo® Quick-Prep™

Smart-Prep

Extraction devices to be ordered separately: ScheBo® Quick-Prep™: pre-filled; Smart-Prep: empty.

2)

Take the stool sample and dissolve in extraction buffer using the respective device.

3)

Homogenize the sample on a Vortex mixer and perform the lateral Flow test after appropriate sample processing.

Requirements

- Lab coat and gloves
- Pipettes (4 ml, variable pipettes 10-100 µl and 100-1000 µl)
- Vortexer

Ordering Codes:

Quantum Blue® Reader
BI-POCTR-ABS

Quantum Blue® Calprotectin
LF-CAL25
LF-CHR25



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