

Rapid Calprotectin Results with Quantum Blue[®]

Supports Clinical Decision Making



Rapid, Reliable Results



Although calprotectin testing has increased significantly many hospitals still batch samples for weekly testing or to send away to a referral laboratory for analysis. This means it can take several weeks before a result is available. Treatment decisions therefore often have to be made without the benefit of the calprotectin result or other more invasive and costly investigations are thus performed to determine the level of mucosal inflammation is present.

Faecal calprotectin concentrations are widely acknowledged to correlate to the degree of mucosal inflammation in the gut. However, the result is often not available at the point of decision making.

A study by Dr Derwa et al¹ from the University Hospital in Leeds regarding the factors effecting clinical decision making in IBD found that:

"Almost 60% of patients that were referred for investigation had no evidence of mucosal inflammation."

This obviously has cost and resource implications, but of greater concern is the fact that in addition, the study also highlighted that:

"36% of patients with IBD who were neither referred for investigation nor had treatment escalated had evidence of on-going mucosal inflammation"

The study went on to conclude that:

"Introduction of routine point-of-care faecal calprotectin testing could, potentially, improve the appropriateness of clinical decision-making, streamline resource allocation, reduce adverse events associated with injudicious use of medications and reduce costs."



The BÜHLMANN Quantum Blue® is a compact device that can be used in clinics or laboratories to give rapid quantitative faecal calprotectin results in a time frame to support clinical decision making.

The assays give a quantitative result, and there are two test ranges to choose from:

- High range faecal calprotectin 100 – 1800µg/g
- Extended range faecal calprotectin 30 - 1000µg/g

The Quantum Blue reader has a touch screen for rapid data input, and is LIMs compatible for reporting into the electronic patient records

Timely

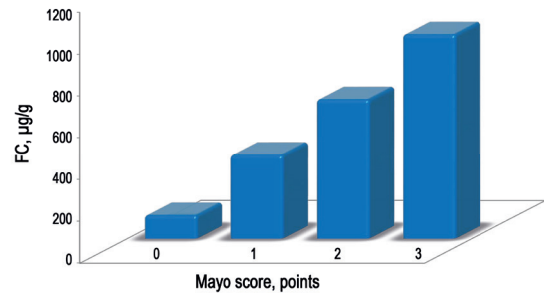
Quantitative results are available in just 15 minutes using the simple bench top reading device that can easily be used in the clinic setting making the result available to support the clinical decision making process:

*"This rapid bedside test can facilitate clinical decisions on hospital admission, such as deciding whether the IBD treatment should be intensified. Similarly, in the ambulatory setting, it is crucial when determining whether a patient should undergo endoscopy or not."*²

Accurate

Numerous studies have demonstrated the correlation of the result from BÜHLMANN calprotectin assays to the health of the gut and the clinical outcome.

"We observed that FC, measured both with fCAL ELISA and the rapid Quantum Blue, was able to discriminate between the different levels of endoscopic activity, as well as to detect the presence or absence of ulcers." ³



Mean Faecal calprotectin levels (determined using BÜHLMANN Quantum Blue fCAL and fCAL ELISA) in patients with UC compared to endoscopic score²

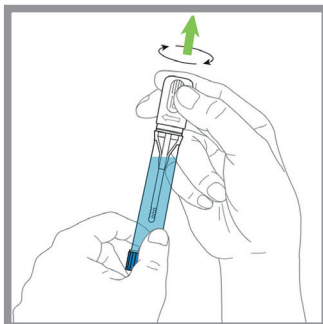
"FC appeared to be the optimal marker for identification of endoscopic postoperative recurrence, with high sensitivity and NPV. FC measurement is sufficiently sensitive in the postoperative setting after resection of all macroscopic disease to monitor for CD recurrence." ⁴

Simple

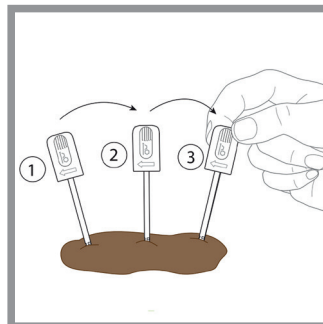
The BÜHLMANN Quantum Blue fCAL rapid tests combine the ease and speed of lateral flow technology with full quantification of the results by means of a small dedicated reading device.

The CALEX Cap is a stool extraction device that provides rapid, clean and consistent sample preparation every time.

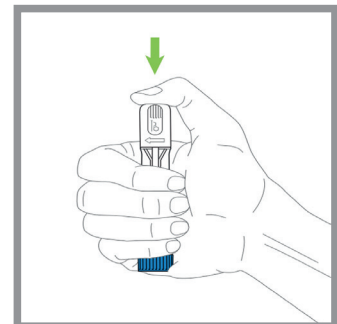
CALEX Cap can be given to patients instead of collection pots so that the calprotectin in the sample is stabilised immediately in the extraction buffer to prevent degradation before testing. CE marked collection packs are available including stool collection sheets and patient instructions to help with this.



1) Remove the CALEX Cap sampling pin



2) Dip into the sample 3 times



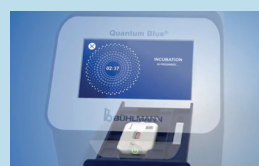
3) Put the cap back into CALEX device

Prepare the CALEX Cap extraction device as above

Transfer 60µl of extract to the circular loading port on the cassette

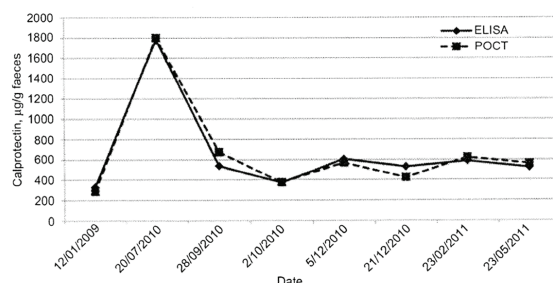
A timer on the Quantum Blue reader controls the incubation time and starts the reading process automatically

The test result is displayed in µg/g. The reader is ready for the next sample



Standardised

BÜHLMANN has specialised in calprotectin assays for more than 10 years and has the broadest range of faecal calprotectin assays available, enabling testing across the healthcare network.



Comparison of ELISA and POCT FC concentrations in follow-up of a patient.⁵

BÜHLMANN assays are standardised across the range to give consistent results and cut-off values enabling testing in both POC and laboratory settings (see graph), and even patient self testing with the IBDoc, supporting testing across the healthcare network to suit individual requirements.

Reliable

The BÜHLMANN Quantum Blue® faecal calprotectin assays are individually packaged to ensure the quality of the test is maintained until it is required. This means no batching of samples is necessary. If you want to do a single test then you can – the other test cassettes remain sealed until you are ready to use them.

The new Quantum Blue III reader has LIMs connectivity enabling reporting into electronic patient records eliminating transcription errors.

Flexible

The Quantum Blue reader can be used with a number of different assays to give quantitative results in a time frame that can impact the clinical decision.

Description	Assay Range	Code
Faecal Calprotectin High Range	100-1800µg/g	LF-CHR25
Faecal Calprotectin Extended Range	30-1000µg/g	LF-CALE25
Serum Calprotectin	0.42-10µg/ml	LF-MRP25
Infliximab Serum Trough levels	0.4-20µg/ml	LF-TLIF25
Infliximab Anti-drug Antibody	-	LF-ADIF25
Adalimumab Serum Trough levels	1-35µg/ml	LF-TLAD25
Adalimumab Anti-drug Antibody	-	LF-ADAD25

References:

1. Derwa et al Therapeutic Advances in Gastroenterology 2018.
2. Moniuszko. A et al. Polish Archives of Internal Medicine 2017. Rapid fecal calprotectin test for prediction of mucosal inflammation in ulcerative colitis and Crohn disease: a prospective cohort study.
3. Lobaton. T et al. J of Crohn's and Colitis 2013. A new rapid test for faecal calprotectin predicts endoscopic remission and postoperative recurrence in Crohn's disease.
4. Wright. E et al. Inflammatory Bowel Disease 2016. Comparison of Faecal Inflammatory Markers in Crohn's Disease
5. Coorevits. L. et al. CCLM / FESCC 2012. Faecal calprotectin: Comparative study of the Quantum Blue rapid test and an established ELISA method.



Flexibility to Test Across the Healthcare Network
Supporting Rapid Decision Making to Influence Patient Pathways