

Quantum Blue® fCAL Assays

Rapid Testing of Fecal Calprotectin
in IBD Diagnosis and Monitoring



Quantum Blue® Calprotectin Assays

The Unique Values of Quantum Blue®

- Rapid:** The quantitative fecal calprotectin result is obtained within 12-15 minutes.
- Simple:** Using an easy extraction method in combination with a simple lateral flow test cassette, makes it an ideal tool for clinicians to determine the fecal calprotectin level of patients immediately.
- Reliable:** BÜHLMANN Quantum Blue® fCAL assays have been shown in clinical literature to correlate highly with endoscopic and histologic findings in IBD patients^{1,2}.

Innovative Combination of Assay and Readout Technology

- Lateral Flow Technology:** Quantum Blue® relies on the established lateral flow technology.
- Quantum Blue® Reader:** Test line intensities are detected by state of the art image analysis and translated into a quantitative result.
- Highly Specific:** Specific monoclonal antibody captures calprotectin in the patient sample more specifically than polyclonal approaches.
- Quantitative:** The Quantum Blue® test result is a quantitative read-out and lot-specific standard curves are loaded via a simple barcode by the system camera.



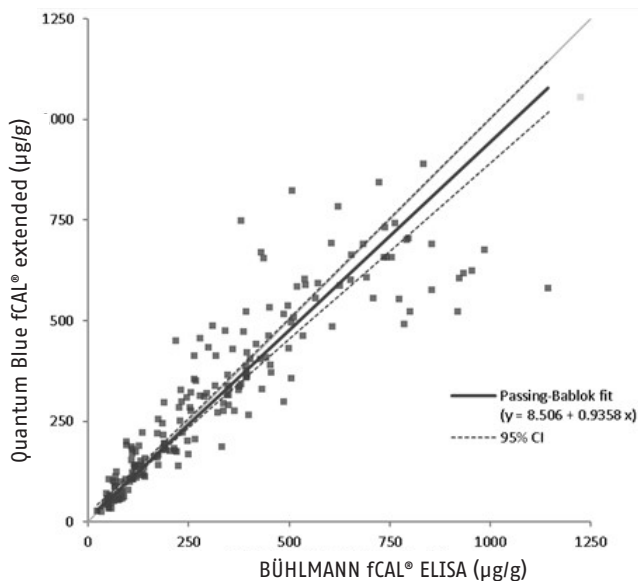
Lateral flow test cassette

Quantum Blue® fCAL Assays

Test	Quantum Blue® fCAL extended	Quantum Blue® fCAL high range
Range	30 – 1000 µg/g	100 – 1800 µg/g
Time to Result	12 min	15 min
Sensitivity	<30 µg/g	<100 µg/g
Order Code	LF-CALE25	LF-CHR25
Lot-specific Control Set	B-CALE-CONSET	B-CHR-CONSET

Quantum Blue® Calprotectin Assays

Method Comparison to the BÜHLMANN fCAL® ELISA



All Quantum Blue® fCAL assays are standardised against the BÜHLMANN fCAL® ELISA.

4 Easy Steps to a Quantitative Result with Quantum Blue®

Easy extraction



1. The Quantum Blue® fCAL assays are fully compatible with the BÜHLMANN stool extraction device CALEX® Cap.

Simple sample loading



2. A defined amount of stool extract is loaded onto the sample loading port of the test cassette.

Quick measurement



3. Immediately after loading, the test can be started. An internal timer controls the incubation time and starts the reading process automatically.

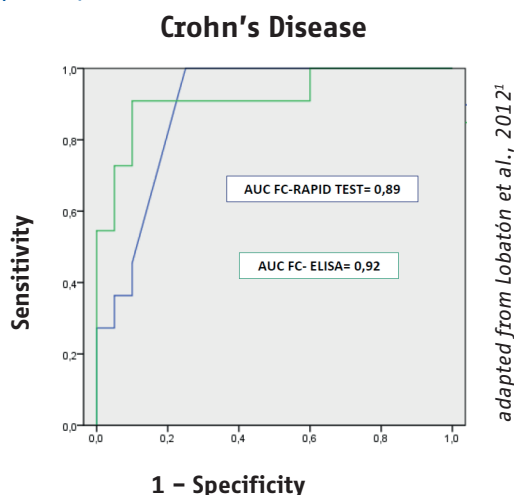
Immediate result



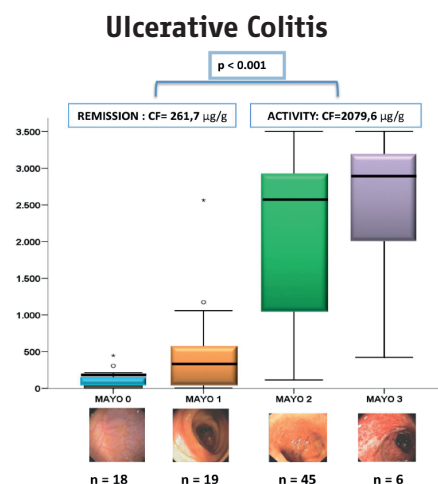
4. At the end, the test result is displayed in µg/g. The Quantum Blue® Reader is ready for the next sample.

Excellent Clinical Validity

The Quantum Blue® fCAL rapid test shows high sensitivity and specificity in detecting relapses in both, Ulcerative Colitis and Crohn's Disease and compares very well to the clinical performance of the BÜHLMANN fCAL® ELISA (Lobatón et al., 2012):



ROC Analysis demonstrating the accuracy of the Quantum Blue® (blue) and BÜHLMANN fCAL® ELISA (green) in predicting endoscopic activity.



Accuracy of Quantum Blue® fCAL testing to predict endoscopic Mayo score in Ulcerative Colitis.

Simplified Stool Extraction – BÜHLMANN CALEX® Cap

Stool Extraction with CALEX® Cap

All Quantum Blue® fCAL assays are fully compatible with CALEX® Cap.

Efficient: The 1:500 dilution offers excellent efficiency in extraction.

Convenient: CALEX® Cap uses a convenient and reliable sampling pin. The device is pre-filled with extraction buffer.

Stable: Extracts remain stable for 7 days at room temperature or 15 days at 2-8 °C. Long-term storage at -20 °C is possible for at least 23 months, allowing for up to 4 freeze/thaw cycles.

Hygienic: CALEX® Cap is a closed system offering safe handling, storage and transport.



CALEX® Cap

References:

¹Lobatón, T. et al., 2013, A new rapid test for fecal calprotectin predicts endoscopic remission and post-operative recurrence in Crohn's disease, Journal of Crohn's & Colitis

²Lobatón Ortega, T. et al., 2013, A New Rapid Quantitative Test for fecal Calprotectin Predicts Endoscopic Activity in Ulcerative Colitis, Inflammatory bowel diseases

For further references please consult the BÜHLMANN Calprotectin Key Literature List.



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Parts of the BÜHLMANN fCAL® and Quantum Blue® 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)

Order Codes:

Quantum Blue® Reader
Quantum Blue® fCAL extended
Quantum Blue® fCAL high range
CALEX® Cap

BI-POCTR-ABS
LF-CALE25
LF-CHR25
B-CALEX-C50
B-CALEX-C200
B-CALEX-C500

Related Products:

Quantum Blue® Infliximab LF-TLIF10 / LF-TLIF25
Quantum Blue® Anti-Infliximab LF-ADIF10 / LF-ADIF25
Quantum Blue® Adalimumab LF-TLAD10 / LF-TLAD25
Quantum Blue® Anti-Adalimumab LF-ADAD10 / LF-ADAD25

CE-marked products