Quantum Blue®

Rapid Testing for Diagnosis and Monitoring of Inflammatory Diseases

BÜHLMANN

BI044ML-02E

Quantum Blue® Reader

The BÜHLMANN Quantum Blue® Reader is a compact and easy to use dedicated reader for *in vitro* lateral flow assays. It uses a state of the art camera based image analysis system to measure BÜHLMANN's lateral flow assay portfolio. The Quantum Blue® Reader enables fast result reporting close to the clinical environment, allowing immediate decision making leading to an optimized clinical care. The assay menu of rapid tests for fecal calprotectin (fCAL) and therapeutic drug monitoring (TDM) of anti-inflammatory biologics provides an indispensable toolset in diagnosis and monitoring of inflammatory diseases such as Inflammatory Bowel Disease (IBD).

Fecal Calprotectin

Fecal calprotectin has proven itself as the key non-invasive biomarker to identify intestinal inflammation throughout the gastrointestinal tract. Its excellent correlation with clinical endoscopy and histology scores makes it the surrogate marker of choice to discriminate between organic diseases like Inflammatory Bowel Disease (IBD) and non-organic disorders such as Irritable Bowel Syndrome (IBS). Further, fecal calprotectin has shown to be a good predictor of relapse and remission in IBD patients. The Quantum Blue® fCAL product line offers lateral flow-based quantitative calprotectin test results for diagnosis and therapy follow-up of IBD patients within 12 to 15 minutes.

The Quantum Blue® fCAL extended and the Quantum Blue® fCAL high range assays are designed with highly specific monoclonal antibodies to capture the calprotectin molecule. This allows for quantitative measurement of fecal calprotectin. Both assays correlate very well with the BÜHLMANN fCAL® ELISA and BÜHLMANN fCAL® turbo as gold standard laboratory methods.

Quantum Blue® fCAL extended

The Quantum Blue® fCAL extended assay offers a quantitative measurement of fecal calprotectin with a range of 30-1000 µg/g. This makes it the tool of choice to support IBD diagnosis and monitoring.

Quantum Blue® fCAL high range

The Quantum Blue® fCAL high range assay allows for a quantitative measurement of fecal calprotectin with an extended range of 100-1800 µg/g. The high range makes it the perfect addition to the fCAL extended assay, since this higher range is often needed in IBD monitoring.

Therapeutic Drug Monitoring

Infliximab and adalimumab are the most commonly used biologic drugs that target TNF-alpha in a range of different chronic inflammatory diseases such as Inflammatory Bowel Disease (IBD) or Rheumatoid Arthritis (RA). Therapeutic Drug Monitoring (TDM) encompasses measuring drug levels in patients blood (trough) and the occurrence of antibodies that block the drug (anti-drug antibodies). With the Quantum Blue® TDM assays, BÜHLMANN offers a menu of rapid tests for fast and reliable determination of biologic trough levels and anti-drug antibodies. The time to result of 15 minutes allows for quick decision making and optimization of patient's treatment.

Quantum Blue® Infliximab

The Quantum Blue® Infliximab assay is designed for the quantitative measurement of infliximab trough levels in patient serum within minutes for immediate decision making and potential drug dose adjustments. The assay range is from 0.4 to 20 µg/mL infliximab in serum covering the desired therapeutic window of 3-7 µg/mL for infliximab measurements during induction and acute phase. With an additional dilution the range can be extended to 180 µg/mL for patients in the induction phase. The assay is standardized against the first WHO international standard for infliximab (NIBSC 16/170). It is validated for the originator drug as well as for many biosimilars.

Quantum Blue® Anti-Infliximab

The Quantum Blue® Anti-Infliximab qualitative rapid test allows for a highly specific detection of antibodies against infliximab in patient serum. The high amount of anti-drug antibodies (ADA) against infliximab may diminish the beneficial effect of the drug. As drug-sensitive assay it enables the measurement of free antibodies with an excellent specificity of 95%.

Quantum Blue® Adalimumab

The Quantum Blue® Adalimumab assay is designed for the quantitative measurement of adalimumab trough levels in patient serum within minutes for drug dose adjustments. The assay range is from 1.3 to 35 µg/mL adalimumab in serum covering the desired therapeutic window of 5-12 µg/mL. The assay is standardized against the first WHO international standard for adalimumab (NIBSC 17/236). It is validated for the originator drug as well as for its biosimilar.

Quantum Blue® Anti-Adalimumab

The Quantum Blue® Anti-Adalimumab qualitative rapid test allows for reliable detection of antibodies against adalimumab in patient serum. The presence of anti-drug antibodies (ADA) against adalimumab may diminish the beneficial effect of the drug. As a drug-sensitive assay it enables the measurement of free antibodies to adalimumab.

The BÜHLMANN Quantum Blue® Assay Portfolio

Test	Quantum Blue® fCAL extended	Quantum Blue® fCAL high range	Quantum Blue® Infliximab	Quantum Blue® Anti-Infliximab	Quantum Blue® Adalimumab	Quantum Blue® Anti-Adalimumab
Sample Type	Feces	Feces	Serum	Serum	Serum	Serum
Range	30–1000 µg/g	100–1800 µg/g	0.4–20 µg/mL 180 µg/mL with dilution	qualitative assay cut-off 1.3 μg_{eq}/mL	1.3–35 µg/mL	qualitative assay cut-off 0.2 μg_{eq}/mL
Time to Result	12 min	15 min	15 min	15 min	15 min	15 min
Order Code	LF-CALE25	LF-CHR25	LF-TLIF25/LF-TLIF10	LF-ADIF25/LF-ADIF10	LF-TLAD25/LF-TLAD10	LF-ADAD25/LF-ADAD10

Quantum Blue® Reader Key Features

- Intuitive navigation with touch screen
- Easy step-by-step tutorial screens
- Additional Fast Track Mode allows for reading test cassettes in a quick sequential way
- Results can be directly sent to Laboratory and Hospital Information Systems

BÜHLMANN

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Ordering Codes:

Quantum Blue® Reader	BI-POCTR-ABS
Quantum Blue® fCAL extended	LF-CALE25
Quantum Blue® fCAL high range	LF-CHR25
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

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