Quantum Blue® fCAL extended

Quantitative Lateral Flow Assay

For research use only.
Not for use in diagnostic procedures.

LF-CALE25-U 25 tests

Release date: 2025-12-04
Version A5

Manufacturer

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ENGLISH

INTENDED USE

The BÜHLMANN Quantum Blue® fCAL extended is a test for the quantitative determination of calprotectin in human stool specimens.

For research use only. Not intended for use in diagnostic procedures.

PRINCIPLE OF THE ASSAY

The test is designed for the selective measurement of calprotectin antigen by sandwich immunoassay. A monoclonal capture antibody (mAb) highly specific for calprotectin is coated onto the test membrane. A second monoclonal detection antibody conjugated to gold colloids is deposited onto the conjugate release pad and released into the reaction system after addition of the extracted and diluted stool sample. The calprotectin / anti-calprotectin gold conjugate binds to the anti-calprotectin antibody coated on the test membrane (test line) and the remaining free anti-calprotectin gold conjugate binds to the goat anti-mouse antibody coated on the test membrane (control line). The signal intensities of the test line (T) and the control line (C) are measured quantitatively in a non-automated test procedure by the Quantum Blue® Reader.

REAGENTS SUPPLIED AND PREPARATION

Reagents	Quantity	Code	Comments
Test Cassette	25 pieces	B-LFCALUS-TC	vacuum-sealed in a foil pouch
Extraction Buffer	1 bottle 125 mL	B-CAL-EX	Ready to use
Controls Low* / High*	2 vials 0.5 mL	B-CALE-CONSET	Ready to use
RFID Chip Card	1 piece	B-CALE-RCC	**White** plastic card
RFID Chip Card	1 piece	B-CALE-RCC720	**Green** plastic card
Barcode Card	1 piece	B-CALE-BCC	2D Barcode plastic card

Table 1

* The controls contain lot specific amounts of native human calprotectin. Refer to the additional QC data sheet for actual concentrations.

CHECK YOUR TEST KIT

BÜHLMANN products have been manufactured with the greatest of care and all possible efforts have been taken to ensure completeness of this test kit and its performance. Nevertheless, we advise you to verify your test kit for the condition of the test cassette and its pouch based on the following criteria:

- Expiration date
- The fault-free condition of the pouch (e.g. absence of any perforation that could be caused by improper handling).
- The fault-free condition of the test cassette (e.g. absence of scratches on the analytical membrane).

Should one of the test cassettes not fulfil the criteria mentioned above, please use another test cassette.

STORAGE AND SHELF LIFE OF REAGENTS

Unopened reagents	
Store at 2-8 °C. Do not use the reagents beyond the expiration date printed on the labels.	
Opened reagents	
Test Cassette	Test cassettes removed from the foil pouch must be used within 4 hours.
Extraction Buffer	Store for up to 6 months at 2-8 °C after opening.
Controls Low / High	Store for up to 6 months at 2-8 °C after opening.

Table 2

MATERIALS REQUIRED BUT NOT PROVIDED

- The devices described below are not delivered with the kit and must be ordered separately:

Devices	Quantity	Code
CALEX® Cap	Packages of 50, 200 or 500 tubes available, filled with 5 mL extraction buffer Ready to use	B-CALEX-C50 B-CALEX-C200 B-CALEX-C500
BÜHLMANN Smart-Prep	50 tubes consisting of spatulas and base caps	B-CAL-RD
Quantum Blue® Reader	1 unit	BI-POCTR-ABS

Table 3

- Vortex mixer for stool extraction
- Precision pipettes with disposable tips: 10-100 µL, 100-1000 µL and 250-2500 µL
- Centrifuge
- 5 mL polypropylene or polystyrene tubes for dilution of the extracts
- Timer (optional)
- Soft tissues or blotting paper

PRECAUTIONS

Safety precautions

- The controls of this test contain components of human origin. Although tested and found negative for HBV surface antigen, HCV and HIV1/2 antibodies, the reagents should be handled as if capable of transmitting infections and should be handled in accordance with Good Laboratory Practices (GLP) using appropriate precautions.
- The extraction buffer and controls of this kit contain components classified in accordance with the Regulation (EC) No. 1272/2008: 2-methyl-4-isothiazolin-3-one hydrochloride (conc. ≥ 0.0015 %), thus the reagents may cause allergic skin reactions (H317).
- Specimens should be handled as if capable of transmitting infections and should be handled in accordance with Good Laboratory Practice (GLP) using appropriate precautions.

- Reagents: Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, irritation can occur.
- Reagents and chemicals have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.

Technical precautions

Kit components

- The test must be performed at room temperature (18-28 °C).
- All reagents and test samples must be equilibrated to room temperature (18-28 °C) before starting the assay.
- Once equilibrated to room temperature remove the test cassette from the foil pouch. Allow the test cassette to equilibrate in the laboratory environment for at least 2 minutes before starting the assay.
- Mix well (vortex) the reagents before use.
- Kit components must not be used after the expiry date printed on the labels.
- Do not mix different lots of reagents.
- The assay is designed for fecal extracts prepared using the extraction buffer provided in the kit or with the CALEX® Cap. The use of other extraction buffers could lead to incorrect results.
- Do not disassemble the test cassettes.
- Handle the test cassettes with care. Do not contaminate the sample loading port or read-out window via skin contact, other liquids, etc. (figure 1D).
- Ensure a flat, horizontal position of the test cassette while performing the assay.
- Test cassettes cannot be re-used.

Test procedure

- Read the instructions carefully prior to carrying out the assay. Assay performance will be adversely affected, if reagents are incorrectly diluted, handled or stored under conditions other than those as detailed in this instruction for use.
- Please note that there are two generations of readers: The Quantum Blue® Reader 2nd Generation with serial numbers between 1000 and 3000 (QB2) and Quantum Blue® Reader 3rd Generation with serial numbers above 3000 (QB3G).
- The QB2 must be switched on and programmed for the Quantum Blue® fCAL extended assay. Load the assay method using the RFID chip card (B-CALE-RCC or B-CALE-RCC720) before starting the assay (see Quantum Blue® Reader manual).
- The QB3G must be switched on and programmed for the Quantum Blue® fCAL extended assay either by using the barcode card (B-CALE-BCC) or by selecting from the test menu (Fast Track Mode only). For more information please refer to the Quantum Blue® Reader manual.
- Use the RFID chip card (QB2) / barcode card (QB3G) in order to change lot-specific test parameters.
- Samples that are not properly handled may cause inaccurate results.
- In order to receive reliable and quantitative results it is important to homogenize the stool sample entirely in the extraction buffer within the device.
- When using fecal extracts obtained by manual weighing method (BÜHLMANN Smart-Prep), it is important to centrifuge the extracts before storage. Centrifuge the tubes for 5 minutes at 3000 x g. After centrifugation the supernatant must be transferred into a fresh storage tube.

SPECIMEN COLLECTION, STORAGE, STABILITY

For the extraction procedure, less than 1 g of native stool specimen is required. Collect stool specimen into plain tubes.

Important: The specimen must be collected without any chemical or biological additives.

Specimen transport

Stool specimens should be received for processing by the laboratory within 3 days of collection. The specimens may be transported at room temperature or refrigerated.

Specimen storage

Stool specimens should be refrigerated at 2-8 °C and extracted within 3 days of receipt at the laboratory. Do not store samples at elevated temperatures.

Extract stability

Fecal calprotectin extracts obtained with the CALEX® Cap are stable at room temperature (23 °C) for 7 days and at 2-8 °C for up to 15 days. For longer storage, freeze extracts at -20 °C. Frozen extracts are stable for a period of up to 23 months.
CALEX® Cap extracts can be stored and frozen directly within the CALEX® Cap. Extracts can be subject to four freeze-thaw cycles. Prior to measurement, allow frozen extracts to equilibrate to room temperature. For re-use / re-measurement of the extracts see step 2 under the chapter assay procedure.
Fecal calprotectin extracts obtained by manual weighing method (e.g. BÜHLMANN Smart-Prep) are stable at 2-8 °C for ≤ 7 days or at -20 °C for 36 months.

ASSAY PROCEDURE

The assay procedure consists of three steps:

1. **Extraction of stool samples**

   The extraction is described in the instruction for use delivered with the respective devices.

   CALEX® Cap: Liquid stool samples can be pipetted directly into the CALEX® Cap. Unscrew the blue cap and pipet 10 µL of stool sample into the device. Recap the CALEX® Cap and proceed with vortexing step according to the extraction procedure described and illustrated in the instruction for use delivered with the CALEX® Cap.

2. **Sample processing**

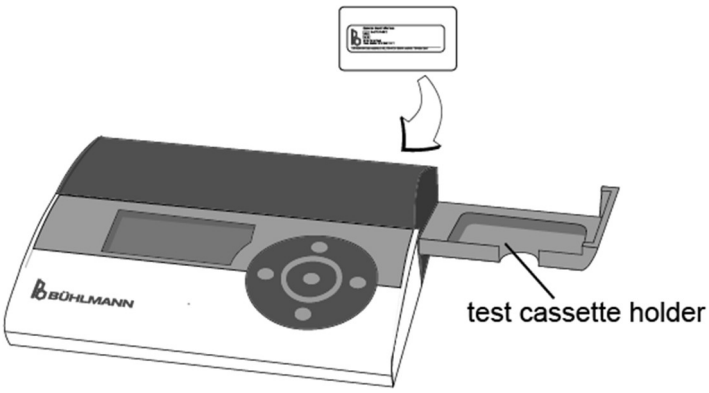
- Manual weighing method (BÜHLMANN Smart-Prep): Let the stool extract settle for 10 minutes after extraction. Dilute the supernatant 1:10 with extraction buffer (e.g. 50 µL stool extract and 450 µL extraction buffer) and mix well. Let the samples equilibrate for at least 5 minutes at 18-28 °C prior to proceeding to the next step (step no. 3).

- CALEX® Cap: After extraction, let the stool extract settle for 10 minutes with the white head of the device down. Unscrew the blue cap. The supernatant can be used without further dilution in the lateral flow assay.

3. Lateral flow assay procedure and readout

QB2

Two alternative methods can be loaded from the respective RFID chip card: B-CALE-RCC720 (with internal timer) or B-CALE-RCC (without internal timer). Select one of the RFID chip cards before starting the experiments. Load the test method from the RFID chip card on the Quantum Blue® Reader.



QB3G

Two different modes of operation are available from BÜHLMANN to measure samples with the QB3G: Fast Track Mode or Fail Safe Mode. Before starting the assay, please inform yourself in which operation mode your reader is working.
The test method can be loaded from the barcode card (Fast Track and Fail Safe Mode) or, if previously used, selected from the test menu (Fast Track Mode only). Measurements can be performed with or without an internal timer in the Fast Track Mode. Measurements in the Fail Safe Mode can be performed with internal timer only.
Follow the instructions provided on the screen of the QB3G. You may also refer to the QB3G Quick Guides for the Fast Track and Fail Safe Mode.

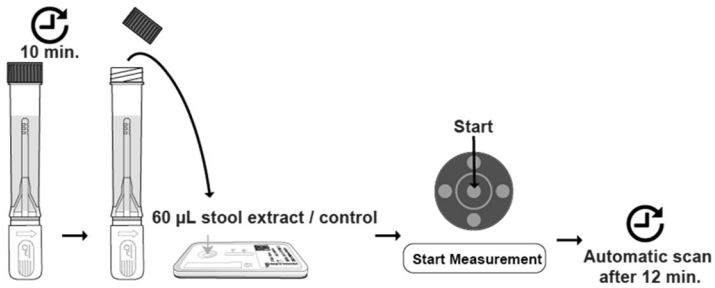
3.1. Method with internal timer

QB2: use the green RFID chip card B-CALE-RCC720

QB3G (Fast Track Mode): when prompted by the QB3G to skip the incubation time, select “NO”

QB3G (Fail Safe Mode): default setting

- Unpack the test cassette and equilibrate it for at least 2 minutes in the laboratory environment.
- Add 60 µL of stool extract onto the sample loading port of the test cassette.
- Load the test cassette onto the test cassette holder of the reader.
- Close the test cassette holder and start the measurement by pressing the start button on the QB2 or the “Start Measurement” option on the QB3G.
- The scan starts automatically after 12 minutes (720 seconds).
- For low / high controls: Repeat step 3.1 with 60 µL controls instead of stool extract.



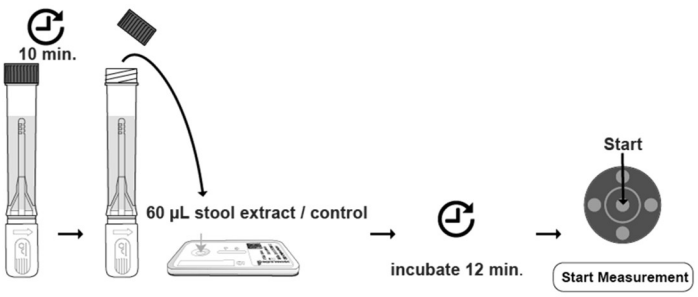
3.2. Method without internal timer

QB2: Use the white RFID chip card B-CALE-RCC

QB3G (Fast Track Mode): when prompted by the QB3G to skip the incubation time, select “YES”

QB3G (Fail Safe Mode): option not available

- Unpack the test cassette and equilibrate it for at least 2 minutes in the laboratory environment.
- Add 60 µL of stool extract onto the sample loading port of the test cassette.
- Incubate for 12 minutes +/- 1 minute (set a timer manually).
- Load the test cassette onto the test cassette holder of the reader.
- Scan the test cassette with the Quantum Blue® Reader immediately by pressing the start button on the QB2 or the “Start Measurement” option on the QB3G.
- For low / high controls: Repeat step 3.2 with 60 µL of controls instead of stool extract.



Remark: Please refer to your Quantum Blue® Reader manual to learn about the basic functions and how to initialize and operate the Quantum Blue® Readers, especially how to select test methods and how to load lot-specific parameters from the RFID chip card (QB2) / barcode card (QB3G) on the Quantum Blue® Reader. Ensure the correct insertion of the test cassette into the Quantum Blue® Reader, with the read-out window first (figure 1D).

QUALITY CONTROL

- If the performance of the assay does not correlate with the established limits and repetition excludes errors in technique, check the following issues: i) pipetting, temperature controlling and timing ii) expiration dates of reagents and iii) storage and incubation conditions.
- The result of the self-test of the Quantum Blue® Reader performed at startup has to be valid.

VALIDATION OF RESULTS

- For a valid test result, the control line (C) must be visible in any case (see figures 1A and 1B). It is used as functional test control only and cannot be used for the interpretation of the test line (T). If the test line (T) is not detectable after 12 minutes of incubation time (figure 1A), the concentration of calprotectin present in the stool sample is below the detection limit. If a test line (T) is detectable after 12 minutes of incubation time (figure 1B), the calprotectin concentration present in the stool sample is calculated by the Quantum Blue® Reader.
- If only the test line (T) is detectable after 12 minutes of incubation time (figure 1C), the test result is invalid and the assay has to be repeated using another test cassette.
- If neither the control line (C) nor the test line (T) are detectable after 12 minutes of incubation time (figure 1D), the test result is invalid and the assay has to be repeated using another test cassette.
- As the Quantum Blue® Reader allows a quantitative evaluation of the test (T) and control (C) lines, an additional validity check of the control line (C) is undertaken. If the signal intensity of the control line (C) is below a threshold after 12 minutes of incubation time, the test result is also invalid and the assay has to be repeated using another test cassette.

STANDARDIZATION

- There are no internationally or nationally recognized reference materials or reference measurement procedures for the calprotectin analyte in stool specimen. The Quantum Blue® fCAL extended is standardized with the BÜHLMANN fCAL® ELISA (order code: EK-CAL), which is standardized using internal reference material.
- The Quantum Blue® Reader uses a lot-specific standard curve to calculate the calprotectin concentration. The 95% confidence interval of the combined uncertainty of the product calibrator is lower than 20.0 %, the combined uncertainty of the controls lower than 30.0 %.
- The assay range is between 30 and 1000 µg/g.
- To receive quantitative results for calprotectin concentration between 850-1800 µg/g, high samples reading above 850 µg/g can be re-tested with the Quantum Blue® high range test (order code: LF-CHR25).

LIMITATIONS

- Reagents delivered with the Quantum Blue® fCAL extended kit are intended for the determination of calprotectin levels in human stool samples only.
- In rare cases, when calprotectin levels are extremely high (above 5000 µg/g, e.g. in acute UC), the test system may be prone to a high dose hook effect, that can result in values below the expected 1000 µg/g assay range limit.

PERFORMANCE CHARACTERISTICS

The presented performance characteristics have been established on the Quantum Blue® Reader 3rd Generation, with the excepton of linearity presented for both reader generations.

Quantum Blue® fCAL extended was validated on both Quantum Blue® Reader 2nd and 3rd Generation instruments. The indicated performance characterstic specifications apply to both reader generations.

Method comparison

Mean bias: ≤ 15 %

The method comparison study was performed according to the CLSI guideline EP09-A3. One-hundred and eighty-three (183) stool samples extracted with the CALEX® Cap were measured over 10 days with three Quantum Blue® fCAL extended reagent lots. Reference values, with a final calprotectin concentration interval of 30.5 to 925.8 µg/g were established in a study with the BÜHMANN fCAL® ELISA using the manual weighing and extraction method. The results are summarized in tables 4 and 5.

Accuracy / Recovery: within 80-120 %

Eight stool specimen extracts were spiked with 60.2 µg/g and 120.4 µg/g calprotectin in calibrator material of human stool origin, at 5 % and 10 % of the specimen extract volume, respectively. “Baseline” samples were spiked with the corresponding volume of extraction buffer. “Baseline” and “baseline + spike” samples were measured in 13 replicates. The results are summarized in table 6.

Repeatability: **≤ 25 % CV**

Within-laboratory precision: ≤ 25 % CV

Repeatability and within-laboratory precision were established according to the CLSI guideline EP05-A3 using the standardized 20 days x 2 runs x 2 replicates study design. Six pooled stool specimen extracts with calprotectin concentrations ranging from 49.9-485.0 µg/g were tested. The results are summarized in table 7.

Between-lot precision: ≤ 25 % CV

Between-lot precision was established according to the CLSI guideline EP05-A3 using a 3 lots x 5 days x 5 replicates study design. Six pooled stool specimen extracts with calprotectin concentrations ranging from 55.3-552.5 µg/g were tested. The results are summarized in table 8.

Between-instrument reproducibility: ≤ 25 % CV

Between-instrument precision was established according to the CLSI guideline EP05-A3 using a 3 instruments x 5 days x 5 replicates study design. Six pooled stool specimen extracts with calprotectin concentrations ranging from 48.5-502.8 µg/g were tested. The results are summarized in table 9.

Limit of Detection (LoD): ≤ 30 µg/g

The LoD was established according to the CLSI guideline EP17-A2 using the classical approach, parametric analysis and a LoB <20 µg/g, determined using a non-parametric analysis.

Limit of Quantification (LoQ): ≤ 30 µg/g

The LoQ was established according to the CLSI guideline EP17-A2, based on 90 determinations and a precision goal of 25 % CV.

Linearity: 25.2 to 908.9 µg/g

The linear range of the Quantum Blue® fCAL extended was determined according to CLSI guideline EP06-A. Measurements were performed in 10 replicates on a total of four reagent lots. A maximum deviation from linearity of 20 % or 15 µg/g, for samples below 75 µg/g, was allowed. The results are summarized in table 10.

High dose hook effect

High dose hook effect testing was performed on two reagent lots. Samples with calprotectin concentrations up to 5000 µg/g were correctly indicated as above 1000 µg/g for all replicates. For samples with higher calprotectin concentration values (6308.2-11214.4 µg/g) replicates with values below 1000 µg/g (643.4 µg/g lowest) were observed.

PREANALYTICS

CALEX® Cap extraction reproducibility ≤ 30 % CV

The extraction reproducibility was established according to the CLSI guideline EP05-A3 using a 2 days x 2 operators x 3 CALEX® Cap lots x 2 extractions x 3 replicates study design. Eight (8) stool specimens with calprotectin concentrations ranging from 51.2-615.3 µg/g were assayed. The results are summarized in table 11.

INTERFERING SUBSTANCES

The susceptibility of the Quantum Blue® fCAL extended assay to oral pharmaceuticals, nutritional supplements, haemoglobin as well as entheropathological microorganisms was assessed according to the CLSI guideline EP07-A2. Bias in results exceeding 20 % was considered interference.

No interference was detected with listed substances, in table 12, up to the indicated concentrations.
No interference was detected with entheropathological microorganisms, listed in table 13, up to the indicated amounts of colony forming units (CFU) per mL of stool specimen extract.

TABLES AND FIGURES

Test Results

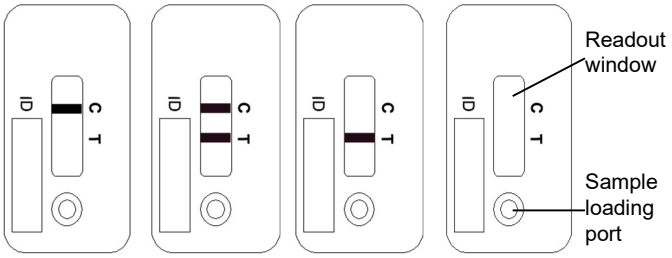


Figure 1A Figure 1B Figure 1C Figure 1D

Figure 1

Method Comparision

Passing-Bablok Regression Analysis						
Slope (95 % CI)	Intercept [µg/g] (95 % CI)	Bias at 80 µg/g (95 % CI)	Bias at 100 µg/g (95 % CI)	Bias at 160 µg/g (95 % CI)	Bias at 300 µg/g (95 % CI)	r
1.123 (1.045, 1.221)	-2.7 (-11.3, 3.6)	8.9 % (4.2 %, 15.3 %)	9.6 % (4.6 %, 16.8 %)	10.6 % (4.3 %, 19.2 %)	11.4 % (3.8 %, 21.1 %)	0.900

Table 4

Bland-Altman Analysis		
Mean bias (95 % CI)	Lower LoA (95 % CI)	Upper LoA (95 % CI)
9.7 % (4.9 %, 14.5 %)	-54.6 % (-62.8 %, -46.4 %)	74.0 % (65.8 %, 82.2 %)

Table 5

Recovery

ID	Spike value [µg/g]	Mean baseline [µg/g]	Expected baseline + spike [µg/g]	Observed baseline + spike [µg/g]	Recovery rate [%]
#1	60.2	52	112	110	99
#2	60.2	63	123	127	103
#3	60.2	63	123	131	107
#4	60.2	78	138	137	99
#5	60.2	115	175	179	102
#6	120.4	149	270	272	101
#7	120.4	221	341	341	100
#8	120.4	469	589	559	95

Table 6

Within-Laboratory Precision

ID	Mean [µg/g]	n	Within-run (Repeatability) %CV	Between-run %CV	Between-day %CV	Total precision %CV
S1	49.9	80	18.2	0.0	5.3	18.9
S2	87.1	80	17.0	0.0	2.9	17.2
S3	135.7	80	11.7	8.9	0.0	14.7
S4	213.2	80	14.5	6.5	1.8	16.0
S5	337.4	80	14.8	3.2	5.0	15.9
S6	485.0	80	21.4	0.0	0.0	21.4

Table 7

Between-Lot Precision

ID	Mean [µg/g]	n	Within-run (Repeatability) %CV	Between-day %CV	Between-lot %CV	Total precision %CV
S1	55.3	75	16.6	10.0	0.0	19.4
S2	94.4	75	16.4	8.7	0.0	18.5
S3	155.2	75	20.1	2.6	2.1	20.4
S4	227.0	75	17.3	2.8	0.0	17.5
S5	361.5	75	16.9	2.5	4.8	17.7
S6	552.5	75	17.3	6.8	4.6	19.1

Table 8

Between-Instrument Precision

ID	Mean [µg/g]	n	Within-run (Repeatability) %CV	Between-day %CV	Between-instrument %CV	Total precision %CV
L1	48.5	75	16.9	2.4	4.3	17.6
L2	86.9	75	12.4	5.6	0.0	13.6
L3	151.6	75	19.4	3.2	0.0	19.7
L4	224.1	75	17.5	4.2	3.5	18.3
L5	355.0	75	17.0	4.9	0.0	17.7
L6	502.8	75	19.8	7.3	4.5	21.6

Table 9

Linearity

Dilution Series	Lot	Measuring Interval [µg/g]	R2	p-value for non-linear coefficient	Linear range [µg/g]
1	M0527	15.5 to 939.1	0.911	< 0.0001*	15.5 to 939.1
2	M2128	16.1 to 908.9	0.927	< 0.0001*	25.2 to 908.9
3	M3048	11.7 to 972.9	0.856	0.018*	11.7 to 972.9
4	M4851	24.3 to 1004.2	0.939	< 0.0001*	24.3 to 1004.2

Table 10: *significant

Pre-analytics extraction reproducibility

ID	Mean [µg/g]	n	Within-run %CV	Between-				Total %CV
				extraction %CV	day %CV	lot %CV	operator %CV	
S1	51.2	72	11.7	6.1	10.2	0.0	0.0	16.7
S2	63.5	72	19.0	9.9	4.3	0.0	0.0	21.9
S3	87.4	72	13.2	12.4	1.8	4.6	1.2	18.8
S4	159.5	72	16.6	0.0	5.0	0.0	2.1	17.5
S5	181.4	72	11.6	11.0	0.0	3.5	11.0	19.7
S6	270.5	72	15.1	12.5	6.6	9.6	6.4	23.7
S7	570.8	72	16.9	8.1	5.7	2.0	0.0	19.6
S8	615.3	72	17.0	8.9	9.3	0.0	0.0	21.3

Table 11

TABLES AND FIGURES

Interfering substances

Trade Name	Active Component	Concentration mg/50 mg stool
Duofer Fol	Iron (II) sulfate (contains 0.4 mg folic acid)	0.11
Prednisone	Prednisone	0.31
Imurek	Azathioprine	0.19
Salofalk	Mesalamine; 5-ASA	5.21
Agopton	Lansoprazole	0.18
Asacol	Mesalamine; 5-ASA	2.50
Vancocin	Vancomycin	2.00
Bactrim	Sulfamethoxazole + Trimethoprim	1.7 + 0.35
Ciproxine	Ciprofloxacin	1.25
Vitamin E	DL-α-Tocopherol Acetate	0.30
Berocca	*B1 (1.4 mg), B2 (1.6 mg), B6 (2 mg), B12 (1 µg), C (60 mg), folic acid (200 mg), nicotinamid (18 mg), pantothensäure (6 mg), biotin (0.15 mg), calcium (120 mg), magnesium (120 mg), zink (9.5 mg)*	1.06
Hemoglobin	Hemoglobin	1.25

Table 12

Name	Final Concentration (CFU/mL)
Escherichia coli	2.9×10^6
Salmonella enterica subsp. enterica	8.2×10^6
Klebsiella pneumoniae subsp. pneumonia	4.5×10^6
Citrobacter freundii	5.5×10^6
Shigella flexneri	5.0×10^6
Yersinia enterocolitica subsp. enterocolitica	5.3×10^6

Table 13

CHANGELOG

Date	Version	Change
2025-12-04	A5	Update to chapter *Principle of the Assay* Removal of chapter *Reagents & Materials supplied supplementary* and extension of chapter *Materials required but not provided* Update to chapters *Precautions; Specimen Collection, Storage, Stability* and *Assay Procedure* Introduction of a *Changelog* Revision of chapter *Symbols*

SHIPPING DAMAGE

Please notify your distributor, if this product was received damaged.

SYMBOLS

BÜHLMANN use symbols and signs listed and described in ISO 15223-1.
For definition of symbols see the symbol glossary at:
www.buhlmannlabs.ch/support/downloads/
In addition the following symbols and signs are used:

Symbol	Explanation
TC	Test Cassette
BUF|EX	Extraction buffer
CONTROL|L	Control Low
CONTROL|H	Control High
RCC	RFID Chip Card
BCC	Barcode Card

Parts of the kit are patent protected by EP2947459(B1); US10620216(B2); AU2015261919(B2); JP6467436(B2)