Quantum Blue®
Infliximab

Quantitative
Lateral Flow Assay

For *In Vitro* Diagnostic Use

LF-TLIF25	25 tests
LF-TLIF10	10 tests

Release date: 2023-02-20
Version A6

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ENGLISH

INTENDED USE

Quantum Blue® Infliximab is an *in vitro* diagnostic lateral flow immunoassay for the quantitative determination of trough levels of infliximab in serum samples. The assay serves as an aid to therapeutic drug monitoring in patients with inflammatory bowel disease (IBD) under infliximab therapy in conjunction with other clinical and laboratory findings. Quantum Blue® Infliximab is combined with the Quantum Blue® Reader.

For laboratory use.

PRINCIPLE OF THE ASSAY

The test is designed for the selective measurement of infliximab by a sandwich immunoassay. Recombinant tumor necrosis factor alpha (TNFα) is conjugated to gold colloids. On the test cassette the gold conjugate is released from a pad into the reaction system as the sample is applied. Infliximab present in the sample will bind to the gold conjugate. A monoclonal antibody, highly specific for the analyte, is immobilized on the test membrane and will capture the complex of gold conjugate and the infliximab analyte, resulting in a coloring of the test line (T). The remaining free TNFα/gold conjugate will bind to the control line (C). The signal intensities of the test line (T) and the control line (C) are measured quantitatively by the Quantum Blue® Reader.

REAGENTS SUPPLIED AND PREPARATION

Reagents	Quantity		Code	Comments
	LF-TLIF25	LF-TLIF10		
Test Cassette	25 pieces	10 pieces	B-LFTLIF-TC	Vacuum-sealed in a foil bag pouch
Chase Buffer	1 bottle 10 mL	1 bottle 10 mL	B-LFTLIF-CB	Ready to use
Controls Low* / High*	2 vials 0.5 mL	2 vials 0.5 mL	B-LFTLIF-CONSET	Ready to use
RFID Chip Card	1 piece	1 piece	B-LFTLIF-RCC	**White** plastic card
RFID Chip Card	1 piece	1 piece	B-LFTLIF-RCC15	**Green** plastic card
Barcode Card	1 piece	1 piece	B-LFTLIF-BCC	2D Barcode plastic card

Table 1

* The controls contain lot-specific amounts of infliximab. 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.
Chase 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

- Vortex mixer
- Timer (optional)
- Precision pipettes with disposable tips: 10-100 µL and 100-1000 µL
- Eppendorf tubes (or equivalent) for dilution of serum samples
- Quantum Blue® Reader available from BÜHLMANN (order code: BI-POCTR-ABS)
- Gloves and laboratory coat

PRECAUTIONS

Safety precautions

- None of the reagents of this test contains components of human origin.
- Patient specimens should be handled as if capable of transmitting infections and should be handled in accordance with Good Laboratory Practice (GLP) using appropriate precautions.
- The controls and chase buffer 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).
- 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.
- Unused solution should be disposed according to local state and federal regulations.

Technical precautions

Kit components

- The test must be performed at room temperature (20-26 °C).
- All reagents and test samples must be equilibrated to room temperature (20-26 °C) before starting the assay.
- Before performing the test, remove the test cassette from the foil pouch. Allow the test cassette to equilibrate in the laboratory environment (20-26 °C) for at least 2

minutes. Test cassettes removed from the foil pouch must be used within 4 hours.

- Mix well (e.g. vortex) the reagents before use.
- Components must not be used after the expiration date printed on the labels.
- Do not mix different lots of reagents.
- Do not disassemble the test cassettes.
- Test cassettes cannot be re-used.
- 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 procedure

- Read the instructions carefully prior to carrying out the test. Test performance will be adversely affected, if reagents are incorrectly diluted, handled or stored under conditions other than those 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® Infliximab assay. Load the assay method using the RFID chip card (B-LFTLIF-RCC or B-LFTLIF-RCC15), before starting the assay (see Quantum Blue® Reader manual).
- The QB3G must be switched on and programmed for the Quantum Blue® Infliximab assay either by using the barcode card (B-LFTLIF-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.
- Patient samples that are not properly handled may cause inaccurate results.
- Diluted samples should be stored at 2-8 °C and measured within 24 hours. The diluted samples cannot be stored for a longer period.
- Samples above 20 µg/mL (up to 183.6 µg/mL) may be additionally diluted 1:10 in chase buffer (1:200, in total) to obtain results within the measuring range of the test.

SPECIMEN COLLECTION AND STORAGE

Collect blood into plain venipuncture tubes without any additives and avoid hemolysis. Perform serum preparation according to manufacturer's instructions. Decant the serum. Undiluted serum samples can be stored unrefrigerated (temperatures up to 28 °C) or at 2-8 °C for up to 10 days. For longer storage, keep undiluted serum samples at ≤-20 ºC. These samples are stable for at least 21 months at ≤-20 ºC.

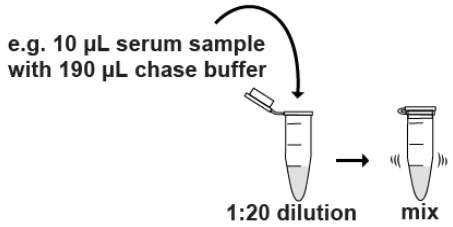
ASSAY PROCEDURE

For the assay use only reagents equilibrated to room temperature (20-26 °C). The test cassette must be removed from the foil pouch prior to assay start.

The assay procedure consists of two steps:

1. Dilution of serum samples with chase buffer

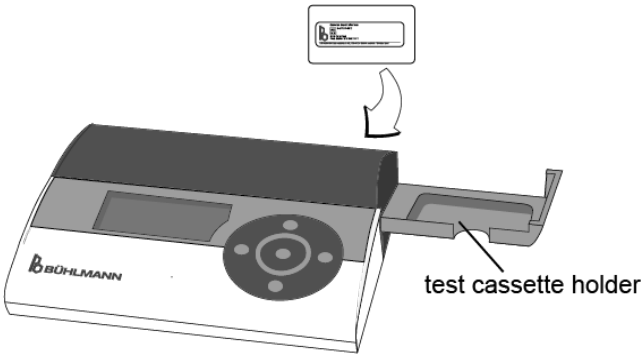
Prior to measurement dilute the serum sample 1:20 with chase buffer (B-LFTLIF-CB) (e.g. mix 10 µL serum sample with 190 µL chase buffer) in a test tube and mix it by vortexing, pipetting or shaking.



2. Lateral flow assay procedure and readout

QB2

Two alternative methods can be loaded from the respective RFID chip card: B-LFTLIF-RCC15 (with internal timer) or B-LFTLIF-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 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.

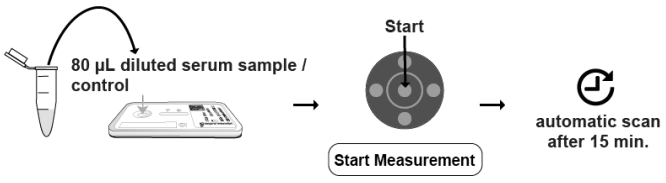
2.1. Method with internal timer

QB2: use the green RFID chip card B-LFTLIF-RCC15

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. Allow the test cassette to equilibrate in the laboratory environment for at least 2 minutes.
- Add 80 µL of the diluted serum sample onto the sample loading port of the test cassette (figure 1D).
- Insert the test cassette into the test cassette holder of the Quantum Blue® 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 15 minutes.
- For low / high controls: Repeat step 2.1 using 80 µL of control instead of diluted serum.



2.2. Method without internal timer

QB2: Use the white RFID chip card B-LFTLIF-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. Allow the test cassette to equilibrate in the laboratory environment for at least 2 minutes.
- Add 80 µL of the diluted serum sample onto the sample loading port of the test cassette (figure 1D).
- Incubate for 15 ± 1 minute (set a timer manually).
- Insert the test cassette into the test cassette holder of the Quantum Blue® 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 2.2 using 80 µL of control instead of diluted serum.

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.
- Result of the self-test of the Quantum Blue® Reader performed at the startup of the instrument has to be valid.

STANDARDIZATION AND METROLOGICAL TRACEABILITY

- Calibrator values of the standard curve are assigned according to a value transfer protocol (ref. 1). The calibrator material comprises infliximab in a human serum matrix.
- Quantum Blue® Infliximab is standardized against the WHO International Standard for Infliximab (NIBSC code: 16/170). The value of the reference material is transferred to product calibrators allowing generation of test results traceable to the standard. The 95% confidence interval of the combined uncertainty of the product calibrators is lower than 20%, the combined uncertainty of the controls lower than 25%.
- The Quantum Blue® Reader uses a lot-specific calibration curve to calculate the infliximab concentration. The measuring range is between 0.4 and 20.0 µg/mL.

VALIDATION OF RESULTS

- For a valid test result, the control line (C) must be visible in any case (see figure 1A and figure 1B). It is used as a 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 15 minutes of incubation time (figure 1A), the concentration of infliximab present in the serum sample is below the detection limit. If a test line (T) is detectable after 15 minutes of incubation time (figure 1B), the infliximab concentration present in the serum sample is calculated by the Quantum Blue® Reader.
- If only the test line (T) is detectable after 15 minutes of incubation time (figure 1C), the test result is invalid and the Quantum Blue® Infliximab assay has to be repeated using another test cassette.

- If neither the control line (C) nor the test line (T) are detectable after 15 minutes of incubation time (figure 1D), the test result is invalid and the Quantum Blue® Infliximab 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) line, an additional validity check of the control line (C) is undertaken. If the signal intensity of the control line (C) is below a specific preconfigured threshold after 15 minutes of incubation time, the test result is invalid and the Quantum Blue® Infliximab assay has to be repeated using another test cassette.

LIMITATIONS

- The reagents supplied with this kit are optimized to measure trough levels of infliximab in diluted serum samples.
- Samples from patients switching from certolizumab (Cimzia®) therapy should not be tested directly with Quantum Blue® Infliximab, as cross-reactivity may occur. Allow certolizumab (Cimzia®) trough levels to fall at least below 1.7 µg/mL.
- Quantum Blue® Infliximab test results should be interpreted in conjunction with other clinical and laboratory findings. These may include the determination of IBD disease activity, presence of anti-drug antibodies, as well as information on patient's adherence to therapy (ref. 2).
- Infliximab trough levels between 3 and 7 µg/mL are considered the consensus therapeutic window for best treatment efficacy (ref. 2, 6). Optimal trough levels, however, may be individual and may differ depending on the treatment target as well as the disease phenotype (ref. 2).

EXPECTED VALUES

The determination of infliximab trough levels in serum samples can support therapy monitoring and has been associated with improved clinical outcomes for IBD patients (ref. 3-8).

Values below 3 µg/mL

Sub-therapeutic infliximab levels in serum suggest pharmacokinetic failure. Therapy adjustment, taking into account available clinical and laboratory findings, should be considered (ref. 2, 3).

Values between 3 – 7 µg/mL

Therapeutic infliximab trough levels may serve as an indication for continuing therapy with the current dosage, in patients in IBD disease remission (ref 2, 3).

Values above 7 µg/mL

Supra-therapeutic infliximab trough levels may serve as an indication for dose reduction in conjunction with the clinical picture, in patients in IBD disease remission (ref 2). It was shown that dose de-escalation to reach the optimal therapeutic window (3-7 µg/mL) has no effect on CRP values nor on Harvey Bradshaw or Mayo scores in Crohn's or ulcerative colitis patients, respectively (ref. 3).

PERFORMANCE CHARACTERISTICS

The following performance characteristics have been established with the Quantum Blue® Reader 2nd Generation and were verified on the Quantum Blue® Reader 3rd Generation.

Indicated performance characteristics apply for both Reader generations.

Method comparison

Bias at 3 µg/mL: -0.7% (95% CI: -6.9% – 3.1%)

Bias at 7 µg/mL: -3.8% (95% CI: -8.3% – -0.7%)

The method comparison study was performed according to the CLSI guideline EP09-A3. One hundred and ten (110) clinical samples were measured in triplicate using two test cassette lots of Quantum Blue® Infliximab over three days. Reference values, with a final concentration interval of 1.2 – 22.2 µg/mL were established with a commercially available infliximab ELISA test (ref. 9). Bias was determined using a Passing-Bablok linear regression analysis. The results are summarized in figure 2.

Recovery: 83 – 100%

Six clinical specimens including infliximab levels close to clinical decision points were spiked with 3.2 µg/mL infliximab in serum-based calibrator material. "Baseline" samples were spiked with the corresponding volume of analyte-free specimen. "Baseline" and "baseline + spike" samples were measured in ten replicates with one reagent lot. The results are shown in table 3.

Repeatability: 16.3 – 25.0% CV

Within-laboratory precision: 18.5 – 25.3% 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. Seven, pooled, patient serum samples with infliximab concentrations covering the measuring range of the assay and clinical decision points were tested. The results are summarized in table 4.

Reproducibility: 22.6 – 29.3% CV

Reproducibility was established according to the CLSI guideline EP05-A3 by performing measurements using a 3 operators x 3 instruments/lots x 5 days x 5 replicates study design. Seven, pooled, patient serum samples with infliximab concentrations covering the measuring range of the assay and clinical decision points were tested. The results are summarized in table 5.

Limit of Detection (LoD): <0.21 µg/mL infliximab

The LoD was established according to the CLSI guideline EP17-A2 and with proportions of false positives (α) less than 5% and false negatives (β) less than 5% based on 120 determinations, with 60 blank and 60 low level replicates; and a **LoB of <0.10 µg/mL**.

Lower Limit of Quantitation (LLoQ): 0.32 µg/mL

Upper Limit of Quantitation (ULoQ): 22.7 µg/mL

The LLoQ and ULoQ were established according to the CLSI guideline EP17-A2 based on 60 determinations and a relative total error goal of 30.0%.

Linear range: 0.14 – 20.37 µg/mL
Linear range (additional dilution): 2.6 – 183.6 µg/mL

The linear range of the Quantum Blue® Infliximab test was determined according to the CLSI guideline EP06-A. Both samples prepared using the standard procedure as well as samples additionally diluted 1:10 in chase buffer were assessed. The linear range was defined as the interval of concentration levels in which coefficients of the second and third order fits were determined as not significant. Results for one test cassette lot, for the standard procedure, are shown in figure 3.

High dose hook effect

Samples exceeding the measuring range with concentrations of up to 200 µg/mL will be correctly indicated as above 20 µg/mL.

Biosimilars

The Quantum Blue® Infliximab test specifically recognizes the infliximab originator drug (Remicade®) as well as the infliximab biosimilars, CT-P13 (Remsima®; Inflectra®) (ref. 10), SB2 (FLIXABI®) (ref. 11) and GP1111 (Zessly®), in serum. The recovery of Zessly® values compared to expected values, based on IgG determination of drug concentrations and dilution factor in negative serum, were found in the range of 89.5% to 102.5%.

Cross-reactivity

Spiked serum with TNFα blockers, such as adalimumab (Humira®), etanercept (Enbrel®), golimumab (Simponi®), and certolizumab (Cimzia®) up to 100 µg/mL resulted in a read out below the limit of blank.

INTERFERING SUBSTANCES

The susceptibility of the Quantum Blue® Infliximab test to interfering substances was assessed according to the CLSI-approved guideline EP07-A2. Interfering substances were tested at concentrations three-fold higher than those reported or expected in clinical samples or at concentration levels recommended by the CLSI guideline EP07-A2. Bias exceeding 30% was considered interference.

Within-class switch

TNFα blockers were tested at concentrations exceeding the lowest, recommended drug trough levels by three-fold. No interference was detected up to 10 µg/mL for adalimumab (Humira®), etanercept (Enbrel®) and golimumab (Simponi®). Interference was detected with certolizumab (Cimzia®) with bias criteria not exceeded at a concentration of 1.7 µg/mL.

Serum indices

No interference was detected with the following substances up to the listed concentrations: Triglycerides (Intralipid® 1320 mg/dL), conjugated bilirubin (342 µmol/L; 28.8 mg/dL), unconjugated bilirubin (342 µmol/L; 20.0 mg/dL), hemoglobin (50 µmol/L; 322 mg/dL), TNFα (0.15 nmol/L; 2.6 ng/mL) and rheumatoid factors (497.3 IU/mL).

Immunosuppressive co-medication

No interference was detected with immunosuppressive co-medication such as azathioprine (216 µmol/L; 6.0 mg/dL), 6-mercaptopurine (216 µmol/L; 3.7 mg/dL), and methotrexate (3000 µmol/L; 136.3 mg/dL).

All performance characteristics, unless otherwise indicated, were assessed with infliximab (Remicade®, MSD).

TABLES AND FIGURES

Test Results

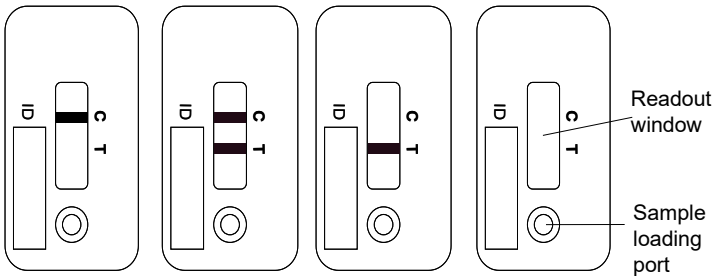


Figure 1A Figure 1B Figure 1C Figure 1D

Method Comparison

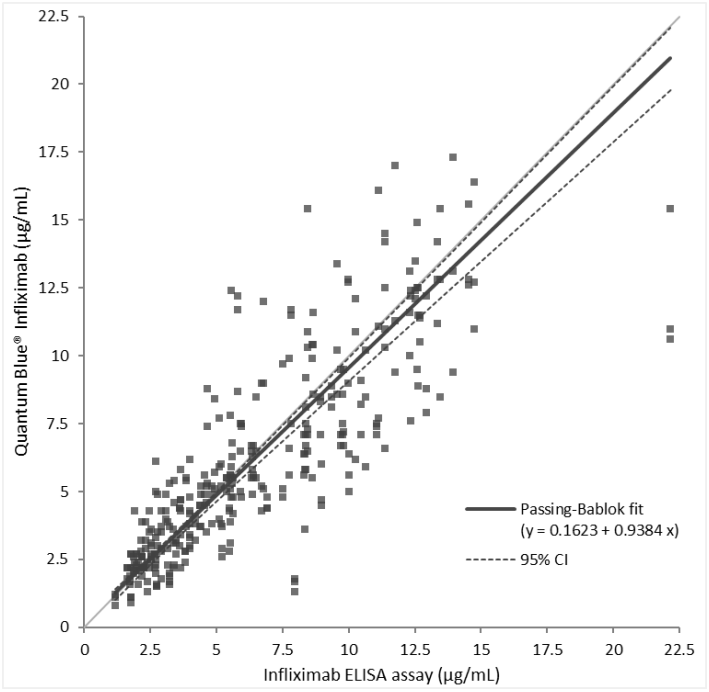


Figure 2

Recovery

Sample	Base [µg/mL]	Spike [µg/mL]	Expected Base + Spike [µg/mL]	Observed Base + Spike [µg/mL]	Recovery [%]
S1	1.5	3.2	4.7	3.9	83
S2	2.0	3.2	5.3	5.1	98
S3	2.9	3.2	6.1	6.1	100
S4	4.3	3.2	7.6	7.2	95
S5	6.5	3.2	9.7	9.3	96
S6	9.9	3.2	13.2	11.8	89

Table 3

Repeatability / Within-Laboratory Precision

Mean IFX Conc. [µg/mL]	Repeatability CV [%]	Between-run Precision CV [%]	Between-day Precision CV [%]	Within-lab Precision CV [%]
0.42	16.3	3.7	7.9	18.5
1.44	25.0	0.0	3.6	25.2
3.02	20.3	5.1	5.1	21.5
4.78	21.0	0.0	0.0	21.0
7.26	17.0	7.5	4.5	19.2
9.37	20.4	0.0	2.7	20.6
11.71	23.5	9.5	0.0	25.3

Table 4

Reproducibility

Mean IFX Conc. [µg/mL]	Within-run CV [%]	Between-day precision CV [%]	Between-lot / instrument / operator precision CV [%]	Within-lab precision CV [%]
0.42	21.1	3.0	15.4	26.3
1.43	21.7	5.5	15.9	27.4
2.86	21.9	16.4	10.5	29.3
4.73	24.5	10.1	4.2	26.8
7.13	25.0	9.8	10.1	28.7
9.71	18.5	9.7	8.9	22.6
12.33	27.5	0.0	5.1	28.0

Table 5

Linearity Plot

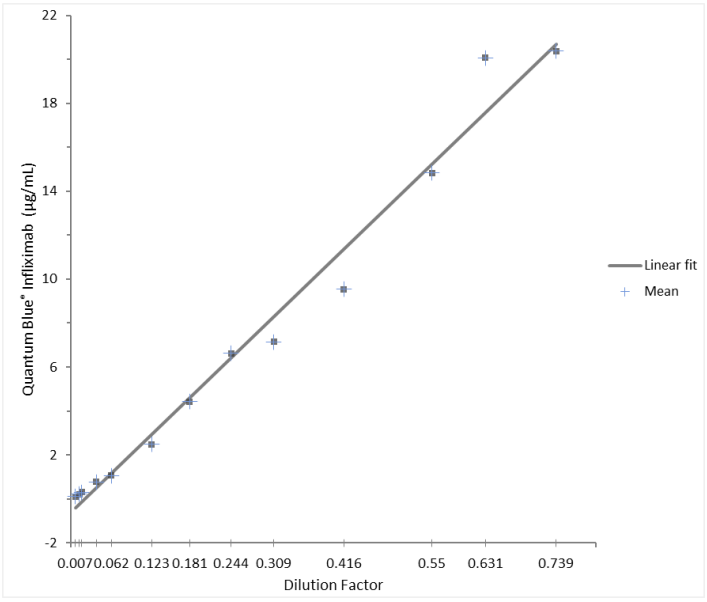


Figure 3

REFERENCES

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INCIDENT REPORTING IN EU MEMBER STATES

If any serious incident in relation to this device has occurred, please report without delay to the manufacturer and competent authority of your Member State.

SHIPPING DAMAGE

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

CHANGELOG

Date	Version	Change
2023-02-20	A6	Removal of biosimilars in chapter *Intended use* Update to chapter *Precautions* Revision of chapter *Specimen collection and storage* Division of the subsection *Specificity/ cross-reactivity* into *Biosimilars* and *Cross-reactivity* in chapter *Performance characteristics* Revision of chapter *Symbols* Inclusion of notified body number to CE-mark – conformity assessment procedure according to IVDR 2017/746

SYMBOLS

BÜHLMANN use symbols and signs listed and described in ISO 15223-1. In addition, the following symbols and signs are used:

Symbol	Explanation
TC	Test Cassette
BUF|CHASE	Chase Buffer
CONTROL|L	Control Low
CONTROL|H	Control High
RCC	RFID Chip Card
BCC	Barcode Card
	**EN**: electronic instruction for use available in different languages at:/ **BG**: електронни инструкции за употреба на различни езици на адрес:/ **CS**: elektronický návod k použití dostupný v různých jazycích na adrese:/ **DA**: elektronisk brugsanvisning på forskellige sprog på:/ **DE**: elektronische Gebrauchsanweisung in verschiedenen Sprachen verfügbar unter:/ **EL**: ηλεκτρονικές οδηγίες χρήσης διαθέσιμες σε διάφορες γλώσσες στη διεύθυνση:/ **ES**: instrucciones de uso electrónicas disponibles en diferentes idiomas en:/ **ET**: elektrooniline kasutusjuhend, mis on saadaval erinevates keeltes aadressil:/ **FR**: un mode d'emploi électronique disponible en différentes langues à l'adresse:/ **HU**: különböző nyelveken elérhető elektronikus használati utasítás a következő címen:/ **IT**: istruzioni elettroniche per l'uso disponibili in diverse lingue su:/ **LT**: elektroninės naudojimo instrukcijos įvairiomis kalbomis:/ **LV**: dažādās valodās pieejama elektroniska lietošanas instrukcija:/ **NO**: elektronisk instruksjon for bruk tilgjengelig på forskjellige språk på:/ **PL**: elektroniczna instrukcja obsługi dostępna w różnych językach na stronie:/ **PT**: instrução electrónica para utilização disponível em diferentes línguas em:/ **RO**: instrucțiuni electronice de utilizare disponibile în diferite limbi la adresa:/ **SK**: elektronický návod na použitie dostupný v rôznych jazykoch na:/ **SL**: elektronska navodila za uporabo so na voljo v različnih jezikih na:/ **SR**: elektronsko uputstvo za upotrebu dostupno na različitim jezicima na:/ **SV**: elektronisk bruksanvisning på olika språk på följande adress: **www.buhlmannlabs.ch/support/downloads/**

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