BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

# LTA CHECK™ ✓

## Performance Monitoring Test Kit

REF 107117

IVD 2°C 8°C

## INSTRUCTIONS FOR USE

ENGLISH - EN

### PRODUCT DESCRIPTION

LTA Check™ ✓ is a system of reagents designed to verify the proper operation and performance of Light Transmission Aggregometers.

LTA Check™ ✓ Performance Monitoring Test Kit has been optimized for use with Light Transmission Aggregometers.

### INTENDED PURPOSE

LTA Check™ ✓ is a Performance Monitoring Test Kit used to verify the operation of Light Transmission Aggregometers (LTA) and provide instrument system quality control in the laboratory.

### DETECTION / MEASUREMENT

LTA Check™ ✓ reagents are used, in conjunction with the provided diluent, to measure changes in light transmission within a controlled test system.

### PRODUCT FUNCTION

LTA Check™ ✓ Performance Monitoring Test Kit is designed to verify the performance and proper operation of Light Transmission Aggregometers. The system generates defined aggregation and slope responses that enable evaluation of instrument functionality, precision, and reproducibility under controlled conditions.

### SPECIFIC INFORMATION PROVIDED

LTA Check™ ✓ Performance Monitoring Test Kit is not intended for the detection of a specific disorder, condition, or risk factor.

This test kit provides information related to the performance of Light Transmission Aggregometers, including the consistency, precision, and reproducibility of aggregation parameters generated under defined test conditions. The results reflect instrument system functionality and are used to verify proper operation of the aggregation system.

### AUTOMATION

LTA Check™ ✓ Performance Monitoring Test Kit is intended for use with semi-automated and automated Light Transmission Aggregometers (LTA).

### QUALITY / QUANTITY

There are no primary standards for LTA Check™ ✓ Performance Monitoring Test Kit. The responses generated by this system are concentration dependent.

LTA Check™ ✓ Performance Monitoring Test Kit comes packaged as 1 x 0.5 mL vial of Reagent 1, 1 x 4.0 mL vial of Reagent 2, 1 x 1.0 mL vial of Reagent 3, 1 x 10.0 mL vial of LTA Diluent, and 1 x 1.0 mL vial of Ultra Pure Water.

### SPECIMEN TYPE

No patient specimen is required for use with the LTA Check™ ✓ Performance Monitoring Test Kit. The test system utilizes the reagents and diluent provided within the kit to generate controlled reactions for performance verification of Light Transmission Aggregometers.

### TESTING POPULATION

LTA Check™ ✓ Performance Monitoring Test Kit is not intended for use with a patient population. The test kit is intended for use by trained laboratory personnel to verify the performance and proper operation of Light Transmission Aggregometers within professional laboratory settings.

### IN VITRO DIAGNOSTIC

LTA Check™ ✓ Performance Monitoring Test Kit is an in vitro diagnostic test kit intended for Professional Laboratory Use Only. It is not intended for injection or ingestion.

### INTENDED USER

LTA Check™ ✓ Performance Monitoring Test Kit is intended for Professional Laboratory Use by qualified personnel.

### TEST PRINCIPLE

LTA Check™ ✓ Performance Monitoring Test Kit evaluates the performance of Light Transmission Aggregometers by generating a controlled agglutination reaction within the test system. When the reagents are combined under defined conditions and stirred at 37°C, agglutination occurs, resulting in measurable changes in light transmission. The Light Transmission Aggregometer detects these changes and expresses the reaction as functional parameters, including Final Aggregation (FA) and Slope (PS), which represent the extent and rate of the reaction. These parameters are used to verify the proper operation and performance of the instrument system.

### CALIBRATORS AND CONTROLS

There are no external calibrators required for the LTA Check™ ✓ Performance Monitoring Test Kit. The reagents provided within the kit function as a performance monitoring system and are used to generate defined aggregation parameters for evaluation of instrument performance. Each laboratory should establish its own expected ranges and acceptance criteria for aggregation parameters when using this test kit.

### REAGENT LIMITATIONS

LTA Check™ ✓ Performance Monitoring Test Kit will perform as specified when the Instructions for Use are followed. The reagents must be used prior to the expiration date printed on each vial.

### REAGENTS PROVIDED

REF 107117:
1 vial of Reagent 1 (0.5 mL)
1 vial of Reagent 2 (4.0 mL)
1 vial of Reagent 3 (1.0 mL)
1 vial of LTA Diluent (10.0 mL)
1 vial of Ultra Pure Water (1.0 mL)

### REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

No additional reagents are required for use with the LTA Check™ ✓ Performance Monitoring Test Kit. All necessary reagents and diluents are provided.

### MATERIALS AND ACCESSORIES

- Platelet Aggregometer *(Follow the Manufacturer's Instructions for Use)*
- Electronic Pipette
- Pipette Tips ②
- Aggregometer Test Tubes *(Siliconized)* ②
- Aggregometer Stir Bars *(Plastic Coated)* ②
- Plastic Sample Tubes and Caps *(for Dilutions)* ②

*NOTE: DISPOSABLE ITEMS SUCH AS TEST TUBES, STIR BARS, SAMPLE TUBES, AND CAPS ARE FOR ONE TIME USE ONLY*

### STORAGE AND STABILITY

LTA Check™ ✓ Performance Monitoring Test Kit does not require temperature protection during shipment.

Upon receipt, store Reagent 1, Reagent 2, Reagent 3, LTA Diluent, and Ultra Pure Water at 2 – 8° C in their original packaging.

Reconstituted Reagent 1 is stable for 7 days when stored in its tightly capped, original container at 2 – 8° C.

Reconstituted Reagent 2 is stable for 30 days when stored in its tightly capped, original container at 2 – 8° C.

Reconstituted Reagent 3 is stable for 8 hours when stored in its tightly capped, original container at 2 – 8° C.

### STERILITY

LTA Check™ ✓ Performance Monitoring Test Kit is not a sterile product. Be careful not to contaminate the product when pipetting the reconstituted or aliquoted reagents.

### WARNINGS AND PRECAUTIONS

Wear PPE in accordance with laboratory policies and practices when handling LTA Check™ ✓ Performance Monitoring Test Kit.

Follow standard precautions when preparing test specimens and samples.

Handle LTA Check™ ✓ Performance Monitoring Test Kit with care to avoid contamination during use.

Avoid reagent evaporation by limiting air – liquid exchange surfaces.

To preserve reagent stability, store remaining reagent in its tightly capped, original container.

Dispose of post-test materials in accordance with applicable regulations and laboratory policies.

*NOTE TO USER: ANY SERIOUS INCIDENT THAT OCCURS IN RELATION TO THIS PRODUCT SHALL BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND / OR PATIENT ARE ESTABLISHED.*

## INFECTIOUS MATERIAL STATUS

LTA Check™ ✓ Reagent 1, LTA Diluent, and Ultra Pure Water do not contain any infectious materials. Reagent 2 and Reagent 3 contain plasma or platelets that have been screened at the source and confirmed negative for HIV-1 antigen (HIV-1Ag), anti-HIV-1/2 antibodies, Hepatitis B surface antigen (HBsAg), Hepatitis C antibodies, Human T-Lymphotropic Virus Type I and II (anti-HTLV I/II) antibodies, and Syphilis by serological testing. Nevertheless, due to their human origin, all plasma and platelets should be handled as potentially hazardous materials. After testing, test specimens and samples must be disposed of in compliance with applicable regulations and laboratory policies.

## SPECIAL FACILITIES

LTA Check™ ✓ Performance Monitoring Test Kit does not require the use of special facilities within a laboratory environment.

## PREPARATION FOR USE

⚠ *NOTE: LTA CHECK™ ✓ PERFORMANCE MONITORING TEST KIT MUST BE AT ROOM TEMPERATURE (15 – 28° C) PRIOR TO RECONSTITUTION. STORED REAGENTS MUST BE BROUGHT TO ROOM TEMPERATURE PRIOR TO USE.*

## RECONSTITUTION

- Reconstitute Reagent 1 with 0.5 mL of Ultra Pure Water.
- Reconstitute Reagent 2 with 4.0 mL of LTA Diluent.
- Reconstitute Reagent 3 with 1.0 mL of LTA Diluent.
- Cap each vial.
- Wait 5 minutes after reconstituting each vial.
- Invert each vial gently to mix.
- Allow each vial to stand at room temperature for 25 minutes.
- Invert each vial gently to ensure complete mixing and rehydration.
- Reconstituted vials should be kept capped prior to use.

⚠ *NOTE: TESTING MUST BE COMPLETED WITHIN 45 MINUTES OF REAGENT PREPARATION.*

## PATIENT PREPARATION

LTA Check™ ✓ Performance Monitoring Test Kit does not require patient preparation, as no patient specimens are used.

## SPECIMEN COLLECTION

LTA Check™ ✓ Performance Monitoring Test Kit does not require specimen collection, as no patient specimens are used.

☣ *PRACTICE STANDARD PRECAUTIONS THROUGHOUT THE SPECIMEN COLLECTION, SAMPLE PREPARATION, AND ANALYTICAL PROCESSES. DISPOSE OF SHARPS AND BIOHAZARDOUS WASTE IN ACCORDANCE WITH APPLICABLE REGULATIONS AND LABORATORY POLICIES.*

## SAMPLE PREPARATION

LTA Check™ ✓ Performance Monitoring Test Kit does not require preparation of patient specimens. Reagent preparation is described in the RECONSTITUTION section.

## ASSAY PROCEDURE

⚠ *NOTE: THIS IS A GENERAL PROCEDURE. FOLLOW THE INSTRUCTIONS FOR USE PROVIDED BY THE MANUFACTURER OF THE AGGREGOMETER IN USE.*

⚠ *NOTE: TESTING MUST BE COMPLETED WITHIN 45 MINUTES OF REAGENT PREPARATION.*

*FULL VOLUME PROCEDURE 500 µL*

Prepare a Blank

- Label a test tube with the letter “B” to identify the Blank
- Pipette 250 µL of Reagent 2 and 250 µL of LTA Diluent into the test tube *(DO NOT ADD A STIR BAR)*
- Invert gently to mix
- Let stand for 10 minutes
- Invert gently again to mix prior to use

Prepare Samples

- Label one to eight new test tubes with test well #
- Place the labeled test tubes into the correct well # 1 - 8 of the stirred sample incubation wells
- Add a stir bar to each test tube
- Incubate test tubes for one minute
- Pipette 50 µL of reconstituted Reagent 1 into each test tube in the stirred sample incubation wells *(MAKE SURE THERE ARE NO BUBBLES)*
- Pipette 400 µL of reconstituted Reagent 2 into each test tube in the stirred sample incubation wells *(MAKE SURE THERE ARE NO BUBBLES)*
- Select the on-screen timer for each stirred sample incubation well in use and the warming countdown will start
- The samples will incubate at 37° C for the pre-set time (2 Minutes)

Set the 100% baseline (Blank)

- Place the previously prepared Blank test tube into test well # 1
- Select BLANK to activate the test well
- The BLANK button will change to START
- Repeat the steps above for each test well being used for testing

Begin Testing

- Once the countdown timer reaches 0:00, press the timer button to stop each stirred sample incubation well
- Transfer the test tube in the stirred sample incubation well # 1 to test well # 1
- Repeat the step above for each test well, making sure all test tubes remain with their corresponding well #'s during transfer
- Close the pipette guides
- Select START for test well # 1
- Pipette 50 µL of Reagent 3 directly into the test tube in test well # 1 *(DO NOT ALLOW REAGENT TO RUN DOWN THE WALL OF THE TEST TUBE OR PERMIT PIPETTE TIP TO BREAK THE SURFACE OF THE SAMPLE)*
- Select INJECT for test well # 1
- Repeat the steps above for each test well being used for testing
- The test will now run for the pre-set time (5 Minutes) *(OTHER MANUFACTURER’S TEST PROCEDURES MAY SPECIFY DIFFERENT TIMES OR VOLUMES)*

⚠ *NOTE: EACH LABORATORY SHOULD ESTABLISH AND VALIDATE ITS OWN TEST PROTOCOL AND VERIFY THE RESULTING PERFORMANCE OF ITS TEST SYSTEM (REAGENTS, INSTRUMENT, AND TEST PROTOCOL).*

*HALF VOLUME PROCEDURE 250 µL*

Prepare a Blank

- Label a test tube with the letter “B” to identify the Blank
- Pipette 125 µL of Reagent 2 and 125 µL of LTA Diluent into the test tube *(DO NOT ADD A STIR BAR)*
- Invert gently to mix
- Let stand for 10 minutes
- Invert gently again to mix prior to use

Prepare Samples

- Label one to eight new test tubes with test well #
- Place the labeled test tubes into the correct well # 1 - 8 of the stirred sample incubation wells
- Add a stir bar to each test tube
- Incubate test tubes for one minute
- Pipette 25 µL of reconstituted Reagent 1 into each test tube in the stirred sample incubation wells *(MAKE SURE THERE ARE NO BUBBLES)*
- Pipette 200 µL of reconstituted Reagent 2 into each test tube in the stirred sample incubation wells *(MAKE SURE THERE ARE NO BUBBLES)*
- Select the on-screen timer for each stirred sample incubation well in use and the warming countdown will start
- The samples will incubate at 37° C for the pre-set time (2 Minutes)

Set the 100% baseline (Blank)

- Place the previously prepared Blank test tube into test well # 1
- Select BLANK to activate the test well
- The BLANK button will change to START
- Repeat the steps above for each test well being used for testing

Begin Testing

- Once the countdown timer reaches 0:00, press the timer button to stop each stirred sample incubation well
- Transfer the test tube in the stirred sample incubation well # 1 to test well # 1
- Repeat the step above for each test well, making sure all test tubes remain with their corresponding well #'s during transfer
- Close the pipette guides
- Select START for test well # 1
- Pipette 25 µL of Reagent 3 directly into the test tube in test well # 1 *(DO NOT ALLOW REAGENT TO RUN DOWN THE WALL OF THE TEST TUBE OR PERMIT PIPETTE TIP TO BREAK THE SURFACE OF THE SAMPLE)*
- Select INJECT for test well # 1
- Repeat the steps above for each test well being used for testing
- The test will now run for the pre-set time (5 Minutes) *(OTHER MANUFACTURER’S TEST PROCEDURES MAY SPECIFY DIFFERENT TIMES OR VOLUMES)*

⚠ *NOTE: EACH LABORATORY SHOULD ESTABLISH AND VALIDATE ITS OWN TEST PROTOCOL AND VERIFY THE RESULTING PERFORMANCE OF ITS TEST SYSTEM (REAGENTS, INSTRUMENT, AND TEST PROTOCOL).*

## QUALITY CONTROL

Quality control is achieved by generating defined aggregation parameters, including Final Aggregation (FA) and Primary Slope (PS), and evaluating the precision and reproducibility of these results under consistent test conditions.

Testing should be performed periodically, with new reagent lots, and following instrument maintenance to verify consistent system performance. Each laboratory should

establish its own expected ranges and acceptance criteria for aggregation parameters and verify ongoing system performance.

## RESULTS

Results are expressed as functional parameters generated by the Light Transmission Aggregometer, including Final Aggregation (FA) and Primary Slope (PS), which represent the extent and rate of the reaction.

Results should be evaluated based on the precision and reproducibility of these parameters under defined test conditions. Consistent results indicate proper instrument performance, while variability may indicate issues with instrument function, reagent handling, or test conditions.

Each laboratory should establish its own expected ranges and acceptance criteria for aggregation parameters and use these to assess system performance.

## LIMITATIONS

The performance of the LTA Check™ ✓ Performance Monitoring Test Kit is dependent on proper instrument operation, reagent handling, and adherence to specified test conditions.

Variability may occur due to differences in instrument configuration, environmental conditions, and operator technique.

This test kit is intended for performance verification of Light Transmission Aggregometers and does not provide information related to patient conditions.

## EXPECTED VALUES

Expected results should be evaluated based on the precision and reproducibility of aggregation parameters. Typical performance characteristics are shown below.

Expected CV (vs. average of established range):

- Expected Primary Slope: 25–50 (± 10%)
- Expected Final Aggregation: 60–110% (± 10%)

These values were established using Bio/Data Corporation's Platelet Aggregation Profiler, Model PAP-8E. Other instruments or models may yield different results. Each laboratory should establish its own expected ranges and acceptance criteria.

## ANALYTICAL PERFORMANCE

LTA Check™ ✓ Performance Monitoring Test Kit is designed to evaluate the functionality of Light Transmission Aggregometers under controlled conditions. The test system generates aggregation responses that are measured as functional parameters, including Final Aggregation (FA) and Primary Slope (PS).

The performance of the system is dependent on proper instrument operation, reagent handling, and adherence to specified test conditions. Variability may be introduced by factors such as instrument configuration, environmental conditions, and operator technique.

Precision and reproducibility are assessed through the consistency of aggregation parameters generated during repeated testing. The following performance characteristics are typical for the system:

| | |
|---|---|
| Test to Test Reproducibility: | less than ± 7.5% |
| Instrument to Instrument Reproducibility: | less than ± 15.0% |
| Reagent Lot to Lot Variability: | less than ± 10.5% |
| Laboratory to Laboratory (System to System) | less than ± 12.5% |

## OPTIONAL SOFTWARE

LTA Check™ ✓ Performance Monitoring Software (C/N 107149) is available for use with this test kit. The software accepts data generated by the Light Transmission Aggregometer and provides automated analysis, including the generation of printable Levey-Jennings charts for evaluation and review of system performance.

Levey-Jennings charts provide a graphical representation of results over time, allowing for visual assessment of whether performance remains within laboratory-established limits. The software supports the application of Westgard rules to enhance error detection and reduce false rejection of valid results.

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## REVISION HISTORY

Document No: 107135 Revision: AA, May 2026

- Modified Testing Instructions
- Implemented IVDR Regulatory Requirements
- Reformatted and Reconfigured to Enhance Operator Use

**For a complete product catalog, please visit our website at www.biodatacorp.com or contact our Customer Service Department.**

THE BIO/DATA CORPORATION PRODUCT LINE INCLUDES GENERAL PURPOSE, PROFESSIONAL LABORATORY USE REAGENTS INTENDED TO INDUCE AND REPORT PLATELET FUNCTION ACTIVITY AND RESPONSES. THIS PRODUCT IS WARRANTED TO PERFORM AS DESCRIBED IN ITS LABELING INCLUDING THE INSTRUCTIONS FOR USE. BIO/DATA CORPORATION MAKES NO CLAIM OR WARRANTY, EXPRESSED OR IMPLIED, OF THE CAPABILITY, FITNESS, OR MERCHANTABILITY FOR ANY OTHER PURPOSE. IN NO EVENT SHALL BIO/DATA CORPORATION BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES ARISING OUT OF AFORESAID EXPRESSED WARRANTY.

## SYMBOLS


**Bio-Hazardous**

**Catalog Number**


**Caution**


**CE Marked & Registered Product**


**Consult Instructions For Use**

**European Union Representative**

**In Vitro Diagnostic Device**


**Manufacturer**


**Must Read**

**Non-Sterile**


**Single Use Only**


**Temperature Limitations**

**United Kingdom Marked & Registered Product**

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