BIO/DATA CORPORATION

LTA CHECK™

Performance Monitoring System
REF 107117

PRODUCT DESCRIPTION

The LTA Check✓Kit is a system of reagents used to verify the operation of Light Transmission Aggregometers and to provide instrument system quality control in the laboratory. FOR PROFESSIONAL LABORATORY USE ONLY.

INTENDED USES

Performance Verification, Light Transmission Aggregometer the LTA Check ✓Kit is a combination of three reagents produced to generate an established range of Slopes and Final Aggregation results when the test is performed properly on a Light Transmission Aggregometer. Test results provide channel to channel and analyzer to analyzer CVs.

PRINCIPLE

System functionality is determined by the ability of a plasma and ristocetin to induce agglutination of a standardized platelet suspension. The agglutination may be defined by two parameters: Aggregation and Slope (rate of reaction). These parameters when generated on a periodic basis may be used to evaluate the aggregation test system in the laboratory. Evaluation of the Aggregation and Slope of a test run using the materials provided on a periodic basis will generate information as to the functionality of the instrument test system. Ranges and limits for quality control and system functionality may be recorded by each laboratory and these results may be used to verify the functionality of the system on a "Channel to Channel" and a "Performance to Performance" basis. The laboratory is responsible for the establishment of the performance ranges of each lot and for each instrument in the laboratory.

PRECAUTIONS

The LTA Check✓Kit is for RESEARCH USE ONLY (RUO) AND NOT FOR INJECTION OR INGESTION. The plasma and platelets have been tested at the source and found to be negative for HIV-1Ag, anti-HIV-1/2, Hepatitis B surface antigen, Hepatitis C antibody, Human T-Lymphotropic Type I and II (anti-HTLV I/II) and negative by a serological test for Syphilis. All plasma and platelets of human origin should be handled as being potentially hazardous.

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.

MATERIALS PROVIDED

1. Reagent 1, 1 X 0.5 mL
2. Reagent 2, 1 X 4.0 mL
3. Reagent 3, 1 X 1.0 mL
4. LTA Diluent, 1 X 10.0 mL, ready to use.
5. Ultrapure Water, 1 X 1.0 mL.

REAGENT STORAGE

Reagent kits are stored at 2°C to 8°C prior to use.
Stored reagent must be brought to room temperature prior to use.

Upon completion of testing, all prepared, unused reagents must be discarded.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Light Transmission Aggregometer (LTA)
2. Pipettors and tips
3. Disposable Stir Bars
4. Siliconized test tubes or cuvettes

RECONSTITUTION

Allow vials to warm to room temperature before reconstitution. Reconstitute the vials as follows:

1. Add 0.5mL Ultrapure Water to Reagent 1.
2. Add 4.0mL LTA Diluent to Reagent 2.
3. Add 1.0mL LTA Diluent to Reagent 3.

Wait 5 minutes and then invert each vial to assure that all contents are rehydrated and allow the vial to stand an additional 25 minutes. Prior to use invert the vial an additional time to assure complete mixing and rehydration.

PREPARATION OF THE AGGREGOMETER BLANK

The blank is prepared by mixing 1 part of Reagent 2 with 1 part of LTA Diluent. Volumes used are determined by the requirements of the instrument being used. ***AFTER PREPARING BLANK LET STAND FOR 10 MINUTES BEFORE USE. ALWAYS REMIX BLANK IMMEDIATELY PRIOR TO USE.***

For full volume (500 µL)		For half volume (250 µL)	
Reagent 2	LTA Diluent	**Reagent 2**	LTA Diluent
250 µL	250 µL	125 µL	125 µL

PERFORMING TESTS

The user must follow the test instructions provided by the instrument manufacturer.

REAGENT USAGE IS IN THE FOLLOWING PROPORTION

Aggregation for full volume (500 µL)	Aggregation for half volume (250 µL)
50 µL Reagent 1	25 µL Reagent 1
400 µL Reagent 2	200 µL Reagent 2
50 µL Reagent 3	25 µL Reagent 3

Testing must be completed within 45 minutes of reagent preparation.

1. Place the appropriate number of test tubes required for testing into the incubation wells
2. Add a stir bar.
3. Incubate test tubes for one minute.
4. Add Reagent 1 into pre-warmed test tube for each test.
5. Add Reagent 2 into each tube, being careful to avoid splashing or the introduction of air bubbles.
6. Incubate the sample at 37ºC for 2 minutes with stirring.
7. Set the 100% baseline (Blank) as required by the instrument .
8. Place the test tube mixture into the test well and add Reagent 3.
   a. Do not allow reagent to run down the side of the tube.
   b. Be careful not to spike the contents of the tube with pipetting technique.
9. Allow the test to run for 5 minutes and STOP when complete.

EXPECTED RESULTS

Because the intended use is a verification of the LTA system performance, expected results should be evaluated on precision and reproducibility between test parameters (final aggregation (FA) and slope (PS)). The operator's proficiency may also be evaluated on the precision and reproducibility of the test results. Expected precision ranges are shown below.

		Expected CV (vs. average of established range)
* Expected Slope	25-50	± 10%
* Expected Agglutination	60-110%	± 10%

* Performed on Bio/Data Corporation's Platelet Aggregation Profiler, Model PAP-8E. Other instruments or models may show different results.

NOTE: LTA Check✓Performance Monitoring Software C/N 107149 is available for purchase. This software program accepts data generated from the aggregometer, calculates and prepares printable Levey-Jennings charts to evaluate and review. The Levey-Jennings chart is a graphical method used to display control or similar results for visual assessment of whether a process is in or out of specified limits as established by the laboratory. Utilizing Westgard analysis, a common set of statistical control rules will maximize error detection and minimize false rejections.

Bibliography/Reference List

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4. Westgard JO, Hunt MR. Use and interpretation of common statistical tests in method comparison studies. Clin Chem 1973;19:49-57.

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