AcroMetrix™ BB NAT HIV-1 Positive Control

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 963602 AcroMetrix BB NAT HIV-1 Positive Control

This reagent must not be substituted for the mandatory positive and negative calibrator reagents provided with licensed test kits. External quality controls must be run every time the Procleix™ HIV-1/HCV Screening and Discriminatory Assays are performed per CLIA requirements (42 CFR 493). If the results of testing these external quality controls are outside the user-defined range, the test must be invalidated. However, positive results for test specimens must not be invalidated and remain the test result of record.

Intended Use

The AcroMetrix™ BB NAT HIV-1 Positive Control is intended for use with the Procleix HIV-1/HCV Screening and Discriminatory Assays and no other HIV-1 assay for the detection of human immunodeficiency virus, type 1 (HIV-1) RNA in human plasma from donations of whole blood and blood components for transfusion. The AcroMetrix BB NAT HIV-1 Positive Control is intended to provide a means of estimating precision and reproducibility of the Procleix HIV-1/HCV Screening and Discriminatory Assays and has the potential for detecting systematic deviations of the Procleix HIV-1/HCV assay for the qualitative determination of HIV-1 RNA. For In Vitro Diagnostic Use

Summary and Explanation

The AcroMetrix BB NAT HIV-1 Positive Control is designed to monitor assay performance. Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error. The AcroMetrix BB NAT HIV-1 Positive Control may be used to satisfy the appropriate CLIA requirements mandated in 42 CFR 493.

Principles of the Procedure

The AcroMetrix BB NAT HIV-1 Positive Control has been designed to maintain quality assurance and for the purpose of assessing assay performance of the Procleix HIV-1/HCV Screening and Discriminatory Assays. The AcroMetrix BB NAT HIV-1 Positive Control contains preserved processed human plasma and is supplied in single-use tubes. The reagents have been formulated to ensure stability of the final product.

Although the AcroMetrix BB NAT HIV-1 Positive Control DOES NOT HAVE AN ASSIGNED VALUE, each lot is designed to produce a reactive result within a target range established by each testing laboratory. The AcroMetrix BB NAT HIV-1 Positive Control should be analyzed in the same manner as donor specimens, according to the Procleix HIV-1/HCV Screening and Discriminatory Assay package inserts.

Reagents

10 tubes of AcroMetrix BB NAT HIV-1 Positive Control (P/N 963602). Store all reagents at -20°C or below.

Contents

Designation	Control Type*	Number of Tubes	Quantity per Tube
HIV-1 POS (+)	HIV-1 RNA Positive	10	1.4 mL

*The AcroMetrix BB NAT Controls DO NOT HAVE ASSIGNED VALUES. Each testing laboratory should independently establish a target range for each control.

Reagent Name

HIV-1 RNA Positive External Quality Control

Heat-inactivated HIV-1 grown in culture and diluted in defibrinated, delipidized normal human plasma. The defibrinated, delipidized normal human plasma used in the production of the AcroMetrix BB NAT HIV-1 Positive Control was previously tested and found to be negative for HBV DNA, HCV RNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, HBsAg, antibodies to HCV and antibodies to HTLV I-II.

The AcroMetrix BB NAT HIV-1 Positive Control contains 0.05% sodium azide and 0.05% gentamicin sulfate as preservatives.

⚠ Precautions and Warning

WARNING: The AcroMetrix BB NAT HIV-1 Positive Control contains human blood products. Contains ≤0.05% Sodium azide. No test method can offer complete assurance that products derived from human blood will not transmit infectious agents. All human blood sourced materials, including the AcroMetrix BB NAT HIV-1 Positive Control, should be considered potentially infectious. Although the AcroMetrix BB NAT HIV-1 Positive Control has been heat-inactivated, it should be considered potentially biohazardous. Observe the universal precautions for prevention of transmission of infectious agents when handling this material[1, 2, 3, 4].

Performance of the AcroMetrix BB NAT HIV-1 Positive Control when used in testing cadaveric blood specimens has not been established; therefore, each laboratory should establish its own ranges.

The AcroMetrix BB NAT HIV-1 Positive Control is designed for single use and excess material in each tube is to be appropriately discarded.

Do not pipette by mouth. Use personal protective equipment, including lab coats, gloves and safety glasses. Do not eat, drink or smoke in areas where controls and specimens are handled.

Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution or follow site procedures. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

This product contains 0.05% sodium azide as a preservative. Sodium azide is reported to form potentially explosive metal azides with lead or copper plumbing. Use caution when disposing of these materials and flush drains with sufficient water to prevent buildup of these azides in plumbing systems.

Avoid microbial and nuclease contamination of the AcroMetrix BB NAT HIV-1 Positive Control. Use of filtered disposable pipette tips is required.

Material Safety Data sheets are available upon request.

Storage Instructions

The AcroMetrix BB NAT HIV-1 Positive Control is stable when stored at -20°C or below. Discard any unused material after use. Any EQC that appears cloudy or contains precipitates after thawing should be discarded. Once thawed, the AcroMetrix BB NAT HIV-1 Positive Control is stable for up to 5 days if stored at 2°C to 8°C.

Reagent Preparation

Thaw the AcroMetrix BB NAT HIV-1 Positive Control at room temperature (15°C to 30°C) and mix thoroughly by gentle inversion to avoid foaming. Tap the control tubes on the bench top to remove any liquid trapped in the cap before decapping the tubes. Once thawed, the AcroMetrix BB NAT HIV-1 Positive Control is stable for up to 5 days if stored at 2°C to 8°C, and 12 hours if stored at room temperature. Treat the AcroMetrix BB NAT HIV-1 Positive Control like a donor specimen as directed by the Procleix HIV-1/HCV Screening and Discriminatory Assay package inserts.

Procedure

According to CLIA requirements (42 CFR 493), external quality controls should be included with every Procleix HIV-1/HCV Screening and Discriminatory Assay run where donor specimens are tested to screen the blood supply.

Material Provided

AcroMetrix BB NAT HIV-1 Positive Control (P/N 963602)

The AcroMetrix BB NAT HIV-1 Positive Control is intended for use with only the Procleix HIV-1/HCV Screening and Discriminatory Assays, and should be treated like a donor specimen. Please see the Procleix Assay instructions for appropriate specimen preparation and testing procedures.

Quality Control

Since the AcroMetrix BB NAT HIV-1 Positive Control does not have an assigned value, it is recommended that each laboratory validate the use of each lot of AcroMetrix BB NAT HIV-1 Positive Control with its specific assay system prior to use in routine blood testing.

Interpretation of Results

The AcroMetrix BB NAT HIV-1 Positive Control DOES NOT HAVE AN ASSIGNED VALUE.

It is recommended that each laboratory establish its own target ranges with each lot of AcroMetrix BB NAT HIV-1 Positive Control. Target ranges may be established by performing replicate assays with each lot using a statistically valid number of test points. In order to minimize the risk of underestimating variability when establishing a target range, each laboratory should include replicate determinations from multiple test runs, multiple test kit lots and multiple operators whenever possible. The laboratory should use results from replicate determinations to calculate basic statistical parameters such as mean and standard deviation from which an acceptable target range can then be established. Although individual values may not be identical to an established mean value, results obtained in the laboratory should fall within its target ranges.

Failure to achieve the expected results may be an indication of unsatisfactory test performance. Possible sources of error include reagent deterioration, operator error, faulty performance of equipment, or contamination of test reagents.

Limitations

The AcroMetrix BB NAT HIV-1 Positive Control does not have an assigned value and must not be substituted for the mandatory calibrators provided with the Procleix Assay. Tests must be performed and results interpreted according to procedures provided with each individual test kit. Deviations from these procedures may produce unreliable results. The AcroMetrix BB NAT HIV-1 Positive Control is provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated external quality controls and/or reagents may produce erroneous results. The AcroMetrix BB NAT HIV-1 Positive Control is for In Vitro Diagnostic Use.

Specific Performance Characteristics

The reproducibility and precision of the AcroMetrix BB NAT HIV-1 Positive Controls were evaluated at two clinical testing sites using one lot of Procleix HIV-1/HCV Assay reagents. At each site, 2 operators tested each of 3 lots of AcroMetrix BB NAT HIV-1 Positive Control in 3 independent runs of the Procleix HIV-1/HCV Screening Assay (a total of 9 runs per site). The results of this evaluation are summarized in Table 1. In the same study, the AcroMetrix BB NAT HIV-1 Positive Controls were also tested the same number of times in the Procleix HIV-1 and HCV Discriminatory Assays (Tables 2 and 3, respectively).

Although the AcroMetrix BB NAT HIV-1 Positive Control DOES NOT HAVE AN ASSIGNED VALUE, each lot of AcroMetrix BB NAT HIV-1 Positive Control is designed to produce a reactive result when tested as an unknown specimen according to the instructions provided with the Procleix HIV-1/HCV Screening and HIV-1 Discriminatory Assays, and a non-reactive result when tested in the Procleix HCV Discriminatory Assay. Each laboratory should implement a quality assurance program and procedures for monitoring test performance on a regular basis.

Table 1. Reproducibility of AcroMetrix BB NAT HIV-1 Positive Control in the Procleix HIV-1/HCV Screening Assay

Lot	N	RLU			S/CO		
		Mean	SD	%CV	Mean	SD	%CV
1	117	828,931	138,028	16.7	18.30	3.43	18.7
2	119	829,621	119,234	14.4	18.44	2.64	14.3
3	120	801,149	146,638	18.3	19.26	3.55	18.4

Table 2. Reproducibility of AcroMetrix BB NAT HIV-1 Positive Control in the Procleix HIV-1 Discriminatory Assay

Lot	N	RLU			S/CO		
		Mean	SD	%CV	Mean	SD	%CV
1	30	720,245	178,497	24.8	17.65	4.28	24.2
2	30	708,666	170,365	24.0	17.40	4.22	24.2
3	30	754,438	162,907	21.6	18.49	3.97	21.5

Table 3. Reproducibility of AcroMetrix BB NAT HIV-1 Positive Control in the Procleix HCV Discriminatory Assay

Lot	N	RLU			S/CO		
		Mean	SD	%CV	Mean	SD	%CV
1	45	5,862	4,802	81.9	0.11	0.08	78.6
2	30	5,566	4,457	80.1	0.10	0.08	80.0
3	30	5,097	3,848	75.5	0.10	0.07	75.0

References

1. Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
2. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.
3. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.
4. 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; Final Rule, Federal Register, Vol. 56, No. 235, December 6, 1991.

Glossary:

http://www.thermofisher.com/symbols-glossary

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