

AcroMetrix™ BB NAT Negative Control

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IVD For In Vitro Diagnostic Use

Rx Only

REF 963600 AcroMetrix BB NAT Negative 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 Negative Control is intended for use with the Procleix HIV-1/HCV Screening and Discriminatory Assays and no other assay for the detection of human immunodeficiency virus type 1 (HIV-1) RNA and hepatitis C virus (HCV) RNA in human plasma from donations of whole blood and blood components for transfusion. The AcroMetrix BB NAT Negative 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 and HCV RNA. This product is for *in vitro* diagnostic use.

Summary and Explanation

The AcroMetrix BB NAT Negative 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 Negative Control may be used to satisfy the appropriate CLIA requirements mandated in 42 CFR 493.

Principles of the Procedure

The AcroMetrix BB NAT Negative 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 Negative 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 Negative Control DOES NOT HAVE AN ASSIGNED VALUE, each lot is designed to produce a non-reactive result within a target range established by each testing laboratory. The AcroMetrix BB NAT Negative 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 Negative Control (P/N 963600). Store all reagents at -20°C or below.

Contents

Designation	Control Type*	Number of Tubes	Quantity per Tube
Negative (-)	Negative RNA (HIV-1/HCV)	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

Negative RNA (HIV-1/HCV) External Quality Control

Defibrinated, delipidized normal human plasma.

The defibrinated, delipidized normal human plasma used in the production of the AcroMetrix BB NAT Negative 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 Negative Control contains 0.05% sodium azide and 0.05% gentamicin sulfate as preservatives.

Precautions and Warning

The AcroMetrix BB NAT Negative Control contains human blood products. 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 Negative Control, should be considered potentially infectious. The AcroMetrix BB NAT Negative Control 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 Negative Control when used in testing cadaveric blood specimens has not been established; therefore, each laboratory should establish its own ranges.

The AcroMetrix BB NAT Negative 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 Negative Control. Use of filtered disposable pipette tips is required.

Storage Instructions

The AcroMetrix BB NAT Negative 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 Negative Control is stable for up to 5 days if stored at 2°C to 8°C.

Reagent Preparation

Thaw the AcroMetrix BB NAT Negative 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 Negative 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 Negative 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 Negative Control (P/N 963600)

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

Interpretation of Results

The AcroMetrix BB NAT Negative 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 Negative 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 Negative 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 Negative 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 Negative Control is for In Vitro Diagnostic Use.

Expected Results

Three lots of AcroMetrix BB NAT Negative Control were tested as unknown specimens in the Procleix HIV-1/HCV Assay according to the manufacturer's instructions. The mean, standard deviation (SD) and percent coefficient of variation (%CV) for Relative Luminescence Units (RLU) and Signal to Cutoff Ratios (S/Co), as well as the ranges for these values, were calculated for each External Quality Control (Table 1). These data are intended to be representative of typical test results. They are not intended to represent performance specifications of the AcroMetrix BB NAT Negative Control in the Procleix HIV-1/HCV Assay. Results may vary from these typical results based upon differences in EQC reagent lots, test kit lots, instruments and laboratories. The values shown in Table 1 should be used for informational purposes only. Each testing laboratory should establish its own target ranges with each lot of AcroMetrix BB NAT Negative Control.

Table 1. Representative AcroMetrix BB NAT Negative Control Data in the Procleix HIV/HCV Assay									
Lot	N	Analyte RLU			S/Co			Result Ranges +/- 3 SD	
		Mean	SD	%CV	Mean	SD	%CV	Analyte RLU	S/Co
1	75	5,905	1,622	27.5	0.15	0.04	26.7	1,039 to 10,771	0.03 to 0.27
2	55	6,139	1,394	22.7	0.16	0.04	25.0	1,957 to 10,321	0.04 to 0.28
3	35	6,395	1,236	19.3	0.17	0.03	17.6	2,687 to 10,103	0.08 to 0.26
All	165	6,087	1,476	24.2	0.16	0.04	25.0	1,659 to 10,515	0.04 to 0.28

Specific Performance Characteristics

The reproducibility and precision of the AcroMetrix BB NAT Negative 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 Negative 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 2. In the same study, the AcroMetrix BB NAT Negative Controls were also tested the same number of times in the Procleix HIV-1 and HCV Discriminatory Assays (Tables 3 and 4, respectively).

Although the AcroMetrix BB NAT Negative Control DOES NOT HAVE AN ASSIGNED VALUE, each lot of AcroMetrix BB NAT Negative Control is designed to produce a non-reactive result when tested as an unknown specimen according to the instructions provided with the Procleix HIV-1/HCV.

Table 2. Reproducibility of AcroMetrix BB NAT Negative Control in the Procleix HIV-1/HCV Screening Assay							
Lot	N	RLU			S/Co		
		Mean	SD	%CV	Mean	SD	%CV
1	119	7,577	3,500	46.2	0.17	0.07	44.6
2	120	8,549	2,817	33.0	0.19	0.06	33.1
3	117	6,740	2,899	43.0	0.16	0.07	41.5

Table 3. Reproducibility of AcroMetrix BB NAT Negative Control in the Procleix HIV-1 Discriminatory Assay							
Lot	N	RLU			S/Co		
		Mean	SD	%CV	Mean	SD	%CV
1	30	6,648	2,914	43.8	0.16	0.07	43.5
2	30	6,440	2,670	41.5	0.16	0.06	40.0
3	30	6,010	2,885	48.0	0.15	0.07	46.2

Table 4. Reproducibility of AcroMetrix BB NAT Negative Control in the Procleix HCV Discriminatory Assay							
Lot	N	RLU			S/Co		
		Mean	SD	%CV	Mean	SD	%CV
1	30	5,695	4,623	81.2	0.11	0.08	79.7
2	30	5,127	4,133	80.6	0.09	0.07	77.1
3	29	4,931	3,834	77.8	0.09	0.07	72.2

This clinical data is intended to be representative of typical test results. They are not intended to represent performance specifications of the AcroMetrix BB NAT Negative Control in the Procleix HIV-1/HCV Screening or Discriminatory Assays. Results may vary from these typical results based upon differences in EQC reagent lots, test kit lots, instruments, operators and laboratories.

References

- Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
- 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.
- 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.
- 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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