AcroMetrix™ WNVRNA and AcroMetrix™ BB NAT WNV Negative Control

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 960500 AcroMetrix WNVRNA (10 x 1.4 mL)
960600 AcroMetrix BB NAT WNV Negative Control (10 x 1.4 mL)

This reagent must not be substituted for the mandatory positive and negative calibrator reagents provided with licensed test kits. Controls must be run every time the Procleix™ WNV Assay is performed per CLIA requirements (42 CFR 493). If the results of testing these 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 record.

Intended Use

AcroMetrix™ WNVRNA Control and AcroMetrix™ BB NAT WNV Negative Control are intended for use with the Procleix WNV Assay for the detection of West Nile Virus RNA (WNV RNA) in human plasma from donations of whole blood and blood components for transfusion. AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control are intended to provide a means of estimating precision and reproducibility of the Procleix WNV Assay and have the potential for detecting systematic deviations of Procleix WNV Assay for the qualitative determination of WNV RNA.

Summary and Explanation

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

Principles of the Procedure

AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control have been designed to maintain quality assurance and for the purpose of assessing assay performance of the Procleix WNV RNA Assay. AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control contain preserved processed human plasma. The reagents have been formulated to ensure stability of the final product.

Each lot of AcroMetrix WNVRNA Control is designed to produce a reactive result within a target range established by the laboratory. Each lot of AcroMetrix BB NAT WNV Negative Control is designed to produce a nonreactive result within a target range established by each laboratory. AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control should be analyzed in the same manner as donor specimens, according to the Procleix WNV Assay package inserts.

Reagents

Catalog Number	Designation	Control Type*	Number of Tubes	Volume per Tube
960500	WNV POS (+)	AcroMetrix WNVRNA Control	10	1.4 mL
960600	WNV NEG (-)	AcroMetrix BB NAT WNV Negative Control	10	1.4 mL

* AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control DO NOT HAVE ASSIGNED VALUES. Each testing laboratory should independently establish a target range for each control.

Reagent Names

AcroMetrix WNVRNA Control

West Nile Virus, grown in culture, inactivated, and diluted in defibrinated, delipidized normal human plasma (NHP).

The defibrinated, delipidized normal human plasma used in the production of AcroMetrix WNVRNA Control was previously tested and found to be negative for WNV RNA, HBV DNA, HCV RNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, HBsAg, antibodies to HCV and HTLV I-II.

AcroMetrix BB NAT WNV Negative Control

Defibrinated, delipidized normal human plasma tested and found to be negative for WNV RNA, HBV DNA, HCV RNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, HBsAg, antibodies to HCV and HTLV I-II.

AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Control contain 0.05% sodium azide and 0.05% gentamicin sulfate as preservatives.

Material Provided

AcroMetrix BB NAT WNV Negative Control (960600)
AcroMetrix WNVRNA Control (960500)

AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control are intended for use with only the Procleix WNV Assay, and should be treated like donor specimens. Please see the Procleix WNV Assay instructions for appropriate specimen preparation and testing procedures.

⚠ Precautions and Warning

WARNING: AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control contain human blood products and ≤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 WNV Negative Control, should be considered biohazardous. Observe the universal precautions for prevention of transmission of infectious agents when handling this material[1, 2, 3, 4].

Although the defibrinated, delipidized normal human plasma used in the production of these controls was determined to be negative for WNV RNA, HBV DNA, HCV RNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, HIV-1 antigen, HBsAg, antibodies to HCV and HTLV I-II, all controls should be handled as if capable of transmitting infectious agents.

Performance of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Controls when used in testing cadaveric blood specimens has not been established; therefore, each laboratory should establish its own ranges.

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 ribonuclease contamination of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control. Use of filtered disposable pipette tips is strongly recommended.

Material Safety Data sheets are available upon request.

Storage Instructions

AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control are stable when stored at -20°C or below. Discard any unused material after use. Any control that appears cloudy or contains precipitates after thawing should be discarded. Once thawed, AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Control are stable for up to 5 days if stored at 2°C to 8°C, and up to 24 hours if stored at room temperature (15° to 30°C). Do not use this product beyond the expiration date printed on the tube label.

Reagent Preparation

Thaw AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control at room temperature (15°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, AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control are stable for up to 5 days if stored at 2°C to 8°C, and up to 24 hours if stored at room temperature (15° to 30°C). Treat AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control like specimens as directed by the Procleix WNV Assay package insert.

Procedure

According to CLIA requirements (42 CFR 493), Controls should be included with every Procleix WNV Assay run where donor specimens are tested to screen the blood supply.

Quality Control

Since AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control do not have assigned values, it is recommended that each laboratory validate the use of each lot of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control with its specific assay system prior to use in routine blood testing.

Interpretation of Results

It is recommended that each laboratory establish its own target ranges with each lot of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV 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

AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control do not have assigned values and must not be substituted for the mandatory calibrators provided with the Procleix WNV Assay. Tests must be performed and results interpreted according to procedures provided with each individual test kit. The deviations from these procedures may produce unreliable results. AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control are 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 controls and/or reagents may produce erroneous results. AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control are for *in vitro* diagnostic use.

Expected Values

Nine (9) lots of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control were tested as unknown specimens in the Procleix WNV 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 control lot (Tables 1 and 2). This data is intended to be representative of typical test results. It is not intended to represent performance specifications of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control on the Procleix WNV 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 Tables 1 and 2 should be used for informational purposes only. Each testing laboratory should establish its own target ranges with each lot of AcroMetrix WNVRNA Control and AcroMetrix BB NAT WNV Negative Control.

Table 1. Representative AcroMetrix WNVRNA Control Data using the Procleix WNV Assay

Lot	N	Analyte RLU			S/Co			Result Ranges +/- 3 SD	
		Mean	SD	%CV	Mean	SD	%CV	Analyte RLU	S/Co
1	140	1,319,183	107,636	8.2	29.85	1.864	6.2	996,275 to 1,642,091	24.26 to 35.44
2	130	1,249,446	172,190	13.8	30.35	4.016	13.2	732,876 to 1,766,016	18.30 to 42.40
3	149	1,354,122	188,652	13.9	32.45	3.615	11.1	788,166 to 1,920,078	21.61 to 43.30
4	20	1,234,092	20,488	1.7	31.47	0.522	1.7	1,172,628 to 1,295,556	29.90 to 33.04
5	20	1,230,494	70,068	5.7	26.72	1.522	5.7	1,020,290 to 1,440,698	22.15 to 31.29
6	20	1,141,157	167,992	14.7	28.95	4.261	14.7	637,181 to 1,645,133	16.17 to 41.73
7	20	1,088,039	90,028	8.3	28.69	2.374	8.3	817,955 to 1,358,123	21.57 to 35.81
8	20	1,216,393	54,350	4.5	29.65	1.325	4.5	1,053,343 to 1,379,443	25.68 to 33.63
9	20	1,202,165	81,011	6.7	29.95	2.018	6.7	959,132 to 1,445,198	23.90 to 36.00
All	539	1,282,235	162,706	12.7	30.55	3.388	11.1	794,117 to 1,770,353	20.39 to 40.71

Table 2. Representative AcroMetrix BB NAT WNV Negative Control Data using the Procleix WNV Assay

Lot	N	Analyte RLU			S/Co			Result Ranges +/- 3 SD	
		Mean	SD	%CV	Mean	SD	%CV	Analyte RLU	S/Co
1	140	1,486	2,268	152.6	0.03	0.070	233.3	0 to 8,290	0.00 to 0.24
2	139	1,081	1,141	105.6	0.02	0.025	125.0	0 to 4,504	0.00 to 0.10
3	149	1,107	1,080	97.6	0.02	0.024	120.0	0 to 4,347	0.00 to 0.09
4	20	1,001	646	64.5	0.02	0.018	90.0	0 to 2,939	0.00 to 0.07
5	20	3,433	2,346	68.3	0.07	0.052	74.3	0 to 10,471	0.00 to 0.23
6	20	847	903	106.6	0.02	0.022	110.0	0 to 3,556	0.00 to 0.09
7	20	2,226	3,162	142.0	0.05	0.081	162.0	0 to 11,712	0.00 to 0.29
8	20	1,074	622	57.9	0.02	0.016	80.0	0 to 2,940	0.00 to 0.07
9	18	3,861	1,186	30.7	0.09	0.030	33.3	303 to 7,419	0.00 to 0.18
All	546	1,400	1,746	124.7	0.03	0.047	156.7	0 to 6,638	0.00 to 0.17

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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