ACCURUN® 365 SERIES 200

West Nile Virus RNA Positive Control

About this package insert

Thank you for your interest in this ACCURUN® product. This package insert consists of two pages.

The first page contains the product name, the SeraCare logo, and contact information.

The second page contains the complete package insert text. If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at info@seracare.com, or call us at +1.508.244.6400.

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SeraCare Life Sciences, Inc. | 37 Birch Street, Milford, MA 01757 USA
Phone: +1 508.244.6400 | info@seracare.com

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US | THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

ACCURUN® 365 Series 200 West Nile Virus RNA Positive Control

NAME AND INTENDED USE

ACCURUN controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 365 Series 200 West Nile Virus Positive Control is formulated for use with *in vitro* diagnostic test methods that detect West Nile Virus (WNV) RNA in human plasma from blood donors. Additional products for WNV RNA are available separately from SeraCare Life Sciences. *For In Vitro Diagnostic Use.*

SUMMARY

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. A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN 365 Series 200 West Nile Virus RNA Positive Control is designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 365 Series 200 West Nile Virus RNA Positive Control is prepared by diluting a cultured stock of intact WNV, Lineage 1 (WNV-NY2001-6263)[2,3], in WNV RNA negative defibrinated human plasma that is tested and found nonreactive for HBsAg and negative for antibodies to HIV 1 and 2, HCV and HTLV. The WNV stock was isolated from an encephalitis patient and amplified in cell culture. The culture derived virus was heat treated at 60° for 2 hours. The effectiveness of the heat treatment in inactivating virus was confirmed by using cell culture. ACCURUN controls do not have assigned values. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

REAGENTS

Item No. 2020-0107 — 10 vials, 1.5 mL per vial

ACCURUN 365 Series 200 West Nile Virus RNA Positive Control contains stabilizers and 0.09% sodium azide as preservative.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use

CAUTION: Handle ACCURUN controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 365 Series 200 West Nile Virus RNA Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HCV and HTLV with current FDA licensed tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human blood[4]. Do not pipette by mouth; do not smoke, eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens, controls, and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use ACCURUN controls beyond the expiration date. Avoid contamination of the controls when opening and closing the vials. To prevent formation of potentially explosive compounds due to reactions of sodium azide and copper or lead pipes, flush waste lines with large quantities of water.

STORAGE INSTRUCTIONS

For maximum stability, ACCURUN 365 Series 200 West Nile Virus RNA Positive Control should be stored at -70°C. If preferred, vials may be stored at -20°C for up to six months. Once thawed and opened, vials should not be reused. To prevent leakage, store vials upright.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN 365 Series 200 West Nile Virus RNA Positive Control is formulated to be reactive for West Nile Virus RNA and is prepared in a diluent that is tested and found nonreactive for HBsAg and negative for antibodies to HIV 1 and 2, HCV, and HTLV. This control contains intact, heat treated West Nile virus.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Thaw at room temperature and mix by gentle inversion before use. Once thawed, use immediately. ACCURUN controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens, including extraction. ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with manufactured test kits.

Quality Control

Since ACCURUN controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 365 Series 200 West Nile Virus RNA Positive Control may vary with different manufacturers' tests and different test kit lots. Since the control does not have an assigned value, the laboratory must establish a range for each lot of ACCURUN 365 Series 200 West Nile Virus RNA Positive Control. When results for ACCURUN 365 Series 200 West Nile Virus RNA Positive Control are outside the established acceptance range of values, it may be an indication of unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

LIMITATIONS OF THE PROCEDURE

ACCURUN CONTROLS MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN controls are not calibrators and should not be used for assay calibration. Performance characteristics for ACCURUN 365 Series 200 West Nile Virus RNA Positive Control have been established only for WNV RNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 365 Series 200 West Nile Virus RNA Positive Control DOES NOT HAVE AN ASSIGNED VALUE. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory. Each laboratory should establish its own range of acceptable values. For example, the acceptable range might include all values within 2 standard deviations of the mean of 20 data points obtained in 20 runs over a period of 30 days[5].

Table 1 lists typical data for the ACCURUN 365 Series 200 West Nile Virus RNA Positive Control. Additional products at different concentrations are available separately from SeraCare Life Sciences.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls are designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 365 Series 200 West Nile Virus RNA Positive Control is formulated to be reactive for West Nile Virus RNA and is prepared in a diluent that is tested and found nonreactive for HBsAg and negative for antibodies to HIV 1 and 2, HCV, and HTLV. ACCURUN controls do not have assigned values. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

REFERENCES

1. Green IV GA, Carey RN, Westgard JO, Carten T, Shablesky LA, Achord D, Page E, and Le AV. Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin. Chem. 43:9 1618-1621, 1997.
2. Huang C, Slater B, Rudd R, Parchuri N, Hull R, Dupuis M, and Hindenburg A. (2002) First isolation of West Nile Virus from a patient with encephalitis in the United States. Emerg. Infect. Dis. 8:1367-1371.
3. Lanciotti et al. (1999) Origin of the West Nile Virus Responsible for an Outbreak of Encephalitis in the Northeastern United States. Science Vol 286:2333-2337.
4. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
5. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Second Edition. NCCLS document C24-A2, 1999.

Table 1. Typical Data for ACCURUN 365 Series 200 West Nile Virus RNA Positive Control.

Manufacturer	Assay	Result
Grifols Diagnostic Solutions Inc.	Procleix® WNV Assay	Positive

For assistance, contact SeraCare Technical Support at +1 508.244.6400.

Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1881
Fax: +1.508.634.3334 | SeraCare.com