ACCURUN® 365
West Nile Virus RNA Positive Quality Control
Series 200

BBI Diagnostics
A SeraCare Company
TEL: (508) 580-1900
US Toll Free:(800) 676-1881
FAX: (508) 580-2202

June 2006

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

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 West Nile Virus Positive Quality Control Series 200 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 BBI Diagnostics. *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 West Nile Virus RNA Positive Quality Control Series 200 is designed for use with *in vitro* assay procedures for the purpose of monitoring test performance. ACCURUN 365 West Nile Virus RNA Positive Quality Control Series 200 is prepared by diluting a cultured stock of intact WNV, Lineage 1 (WNV-NY99)[2] 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 infected bird 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 manufacturer's assays, different procedures, different lot numbers and different laboratories.

REAGENTS

Cat. No. A365-5227	10 vials, 1.0 ml per vial
Cat. No. A365-5228	10 vials, 1.5 ml per vial

ACCURUN 365 West Nile Virus RNA Positive Quality Control Series 200 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 West Nile Virus RNA Positive Quality Control Series 200 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.[3] 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 West Nile Virus RNA Positive Quality Control Series 200 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 West Nile Virus RNA Positive Quality Control Series 200 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 West Nile Virus RNA Positive Quality Control Series 200 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 West Nile Virus RNA Positive Quality Control Series 200. When results for ACCURUN 365 West Nile Virus RNA Positive Quality Control Series 200 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 West Nile Virus RNA Positive Quality Control Series 200 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 West Nile Virus RNA Positive Quality Control Series 200 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[4]

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

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 365 West Nile Virus RNA Positive Quality Control Series 200 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. *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.*
3. CDC *recommendations for prevention of HIV transmission in health care settings.* MMWR 36 (supp. 2), 1987.
4. *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 West Nile Virus RNA Positive Quality Control Series 200

Manufacturer	Assay	Mean Value
Gen-Probe Incorporated	Procleix® WNV Assay	Positive

For assistance, contact BBI Diagnostics Technical Support

BBI Diagnostics
A SeraCare Company
375 West Street, West Bridgewater, MA 02379 USA
e-mail: info@seracare.com, website: www.seracare.com

June 2006
10864-03