

Summary of Safety and Effectiveness
ACCURUN® 365 West Nile Virus RNA Positive Quality Control
BK060022

1.0 Submitter's Name and Address

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2.0 Device Name

Product Trade Name: ACCURUN® 365 West Nile Virus RNA Positive Quality Control
Common or Usual Name: Run controls (for use with in vitro diagnostic tests)
Classification: Quality control kit for bloodborne pathogen testing of donors (MYZ)

3.0 Device to Which Substantial Equivalence is Claimed

AeroMetrix VeriSure Pro Positive EQC
AeroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
BK050061

4.0 Device Description

ACCURUN 365 West Nile Virus RNA Positive Quality Control is an independent, unassayed, external run control that is intended to be used with *in vitro* diagnostic test kits that detect West Nile Virus RNA in human plasma from blood donors.

ACCURUN 365 West Nile Virus RNA Positive Quality Control is formulated from a heat treated cultured stock of West Nile Virus, Lineage 1 (WNV-NY99), diluted in defibrinated plasma that is nonreactive for HBsAg and negative for antibodies to HIV 1 and 2, HCV, and HTLV. This product contains 0.09% sodium azide as preservative.

5.0 Intended Use

BBI Diagnostics intends to manufacture and market ACCURUN 365 West Nile Virus RNA Positive Quality Control, which is a culture and human blood based control designed to be used as an independent, unassayed, external run control with *in vitro* tests for the detection of West Nile Virus RNA. This control is not intended as a substitute for controls provided with licensed test kits.

This product will be made available to clinical laboratory professionals in blood banks for use with *in vitro* diagnostic tests for the detection of West Nile Virus RNA in human plasma.

6.0 Comparison of Technological Characteristics

ACCURUN 365 West Nile Virus RNA Positive Quality Control has the same intended use as the predicate device, AcroMetrix VeriSure Pro West Nile Virus RNA Positive EQC (one of the controls supplied in the VeriSure Pro West Nile Virus RNA External Quality Controls kit), which is to estimate laboratory precision and to detect problems in testing procedures with *in vitro* diagnostic test kits that are used to detect West Nile Virus RNA. Both devices share a similar matrix - cultured West Nile Virus diluted in defibrinated human plasma. In addition, both devices are intended to be used in a manner similar to unknown specimens in a test run. Neither device has an assigned value. Please refer to the table below for a summary of these two devices.

Comparison of Technological Characteristics of New and Predicate Device.

Attribute	ACCURUN 365 West Nile Virus RNA Positive Quality Control	AcroMetrix VeriSure Pro WNV RNA Positive EQC BK050061
Intended Use	To estimate laboratory precision and to detect errors in laboratory testing procedures. For use with <i>in vitro</i> diagnostic test methods for the detection of West Nile Virus RNA	To provide a means of estimating precision and reproducibility and to detect systematic deviations For use with the Procleix WNV Assay, an <i>in vitro</i> diagnostic test method.
Matrix	Inactivated West Nile Virus grown in culture, and diluted in defibrinated human plasma.	Inactivated West Nile Virus grown in culture, and diluted in defibrinated human plasma.
Preparation for Use	Thaw at room temperature Gentle inversion to mix	Thaw at room temperature Gentle inversion to mix

Comparison of Technological Characteristics of New and Predicate Device, continued.

Attribute	ACCURUN 365 West Nile Virus RNA Positive Quality Control	AcroMetrix VeriSure Pro WNV RNA Positive EQC BK050061
Instructions for Use	Include in a test run using exactly the same procedure provided by the test manufacturer for unknown specimens.	Include in a test run using exactly the same procedure provided by the test manufacturer for donor specimens.
Possible Causes of Discrepant Results	Operator error Faulty performance of equipment Deterioration of test kit reagents Contamination of reagents	Operator error Faulty performance of equipment Deterioration of test kit reagents Contamination of reagents
Assigned Values	ACCURUN 365 does not have an assigned value.	VeriSure Pro Positive EQC does not have an assigned value.

7.0 Summary of studies performed

Stability studies have been performed to support the labeling and storage conditions for ACCURUN 365 West Nile Virus RNA Positive Quality Control. These include real time, ambient temperature, freeze/thaw, and 37°C stress studies.

In addition, field studies were performed to evaluate the consistency and performance of ACCURUN 365 as an independent run control in situations where it is most likely to be used.

8.0 Conclusions drawn from studies

We have evaluated the stability of ACCURUN 365 West Nile Virus RNA Positive Quality Control under various environmental and user conditions. The data collected support two years storage at -70°C and 6 month storage at -20°C. The data demonstrate that ACCURUN 365 is not affected by multiple freeze/thaw cycles, and that ACCURUN 365 is stable for extended periods at ambient temperatures and under heat stress with no adverse effects.

The field study data demonstrate that ACCURUN 365 is safe and effective across multiple manufactured lots of product and in multiple testing laboratories.