

Summary of Safety and Effectiveness
ACCURUN® 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV)

1.0 Submitter's Name and Address

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2.0 Device Name

Product Trade Name: ACCURUN® 804 Nucleic Acid Negative Quality Control
(HIV, HCV, HBV, WNV)
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 Devices to Which Substantial Equivalence is Claimed

AcroMetrix VeriSure Pro Negative EQC
AcroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
BK05006I

ACCURUN® 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV)
BBI Diagnostics
375 West Street
West Bridgewater, MA 02379
BK040067

4.0 Device Description

ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV) is an independent, unassayed, external run control that is intended to be used with *in vitro* diagnostic test kits that detect HIV-1 RNA, HCV RNA, HBV DNA and WNV RNA.

ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV) is formulated from human serum or plasma negative for HIV-1 RNA, HCV RNA, HBV DNA and WNV RNA and 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

ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV) is intended to be used as an independent, unassayed, external run control with *in vitro* tests for the detection of HIV-1 RNA, HCV RNA, HBV DNA, and WNV 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, public health laboratories and clinical laboratories.

6.0 Comparison of Technological Characteristics

ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV) has the same intended use as two predicate devices: BBI Diagnostics ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) and AcroMetrix VeriSure ProWest Nile Virus RNA Negative EQC (one of the controls supplied in the VeriSure Pro West Nile Virus RNA External Quality Controls kit). ACCURUN 804, ACCURUN 803 and VeriSure Pro are all intended to estimate laboratory precision and to detect problems in testing procedures with *in vitro* diagnostic test kits. All three devices are intended to be used in a manner similar to unknown specimens in a test run. None of these devices has an assigned value. Please refer to the table below for a summary of these three devices.

Comparison of Technological Characteristics of New and Predicate Devices.

Attribute	ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV)	ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) BK040067	AcroMetrix VeriSure Pro WNV RNA Negative 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 HIV-1 RNA, HCV RNA, HBV DNA and WNV RNA	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 HIV-1 RNA, HCV RNA, and HBV DNA	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	Human serum or plasma.	Human serum or plasma.	Human plasma.
Preparation for Use	Thaw at room temperature Gentle inversion to mix	Thaw at room temperature Gentle inversion to mix	Thaw at room temperature Gentle inversion to mix
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 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	Operator error Faulty performance of equipment Deterioration of test kit reagents Contamination of reagents
Assigned Values	ACCURUN 804 does not have an assigned values.	ACCURUN 803 does not have an assigned values.	VeriSure Pro Negative 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 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV). 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 804 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 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV) under various environmental and user conditions. The data collected support two years storage at -20°C. The data demonstrate that ACCURUN 804 is not affected by multiple freeze/thaw cycles, and that ACCURUN 804 is stable for extended periods at ambient temperatures and under heat stress with no adverse effects.

The field study data demonstrate that ACCURUN 804 safe and effective across multiple manufactured lots of product and in multiple testing laboratories.