

**Summary of Safety and Effectiveness**  
**ACCURUN® 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV)**

**1.0 Submitter's Name and Address**

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**2.0 Device Names**

Product Trade Name: ACCURUN® 803 Nucleic Acid Negative Quality Control  
(HIV,HCV,HBV)  
Common or Usual Name: Run controls (for use with in vitro diagnostic tests)  
Classification Name: Multi-Analyte Controls, (Assayed and Unassayed)

**3.0 Device to Which Substantial Equivalence is Claimed**

Procleix™ HIV-1 and HCV External Quality Controls  
Gen-Probe Incorporated  
10210 Genetic Center Drive  
San Diego, CA 92121  
BK010003

**4.0 Device Description**

ACCURUN 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV) 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 and HBV DNA.

ACCURUN 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV) is formulated from human serum or plasma negative for HIV-1 RNA, HCV RNA and HBV DNA, and nonreactive for HBsAg and antibodies to HIV 1 and 2, HCV and HTLV. This control contains stabilizers and 0.09% sodium azide as preservative.

**5.0 Intended Use**

ACCURUN 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV) is intended to be used as an independent, unassayed, external run control with *in vitro* diagnostic tests for the detection of HIV-1 RNA, HCV RNA and HBV DNA in human serum or plasma. This control is not intended to be used as a substitute for controls provided with licensed test kits.

This control will be made available to clinical laboratory professionals in blood banks, public health laboratories and clinical laboratories.

## 6.0 Comparison of Technological Characteristics

ACCURUN 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV) has the same intended use as the predicate device, Procleix Negative External Control (one of the controls supplied in the Procleix HIV-1 and HCV External Quality Controls), which is to estimate laboratory precision and to detect problems in testing procedures with *in vitro* diagnostic test kits that are used to detect HIV-1 RNA and HCV RNA. Both devices share a similar matrix – 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 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV)	Procleix Negative External Quality Controls (Predicate Device BK010003)
<b>Intended Use</b>	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 potentially detect systematic deviations from laboratory testing procedures.  For use with the Procleix HIV-1/HCV Assay, an <i>in vitro</i> diagnostic test method.
<b>Matrix</b>	Human serum or plasma.	Defibrinated human plasma.
<b>Preparation for Use</b>	Bring to room temperature Gentle inversion to mix	Bring to room temperature Gentle inversion to mix
<b>Instructions for Use</b>	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.

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

<b>Attribute</b>	<b>ACCURUN 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV)</b>	<b>Procleix HIV-1 and HCV External Quality Controls (Predicate Device BK010003)</b>
<b>Possible Causes of Discrepant Results</b>	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
<b>Assigned Values</b>	ACCURUN 803 does not have an assigned value.	Procleix Negative External Quality Control 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 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV). These include real time, ambient temperature, freeze/thaw, 37°C stress, and open vial studies.

In addition, field studies were performed at several testing laboratories to evaluate the consistency and performance of ACCURUN 803 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 803 Nucleic Acid Negative Quality Control (HIV,HCV,HBV) under various environmental and user conditions. The data collected thus far support three years storage at -20°C. The data demonstrate that ACCURUN 803 is not affected by multiple freeze/thaw cycles and that a single vial can be reused up to three times, with refreezing between uses. ACCURUN 803 is stable for extended periods at ambient temperatures and under heat stress with no adverse effects.

The field study data demonstrate that ACCURUN 803 is safe and effective across multiple manufactured lots of product and in multiple testing laboratories.