Summary of Safety and Effectiveness
ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control

1.0 Submitter's Name and Address

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Date Prepared: October 14, 2004

2.0 Device Names

Product Trade Name: ACCURUN® 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control, Series 150
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 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control 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 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control is prepared by diluting cultured HIV-1 type B virus (8E5), human serum or plasma reactive for HCV RNA and human serum or plasma reactive for HBV DNA in defibrinated plasma that is nonreactive for antibodies to HIV 1 and 2, HTLV, and HCV and nonreactive for HIV-1 RNA, HCV RNA and HBV DNA. This control contains stabilizers and 0.09% sodium azide as preservative.

5.0 Intended Use

ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control is intended to be used as an independent, unassayed, external run control with *in vitro* blood donor screening 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 for use with *in vitro* blood donor screening test for the detection of HIV-1 RNA, HCV RNA and HBV DNA in human serum and plasma.

6.0 Comparison of Technological Characteristics

ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control has the same intended use as the predicate device, 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 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control	Procleix HIV-1 and HCV External Quality Controls (Predicate Device BK010003)
Intended Use	To estimate laboratory precision and to detect errors in laboratory testing procedures. For use with *in vitro* 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 *in vitro* diagnostic test method.
Matrix	Cell derived virus culture, human serum or plasma reactive for HCV RNA and human serum or plasma reactive for HBV DNA diluted in defibrinated human plasma.	HIV-1 RNA positive or HCV RNA positive plasma diluted in defibrinated human plasma

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

Attribute	ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control	Procleix HIV-1 and HCV External Quality Controls (Predicate Device BK010003)
Preparation for Use	Bring to room temperature Gentle pipetting to mix	Bring to room temperature Gentle invert 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.
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 345 does not have an assigned value.	Procleix HIV-1 and HCV External Quality Controls do not have assigned values.

7.0 Summary of studies performed

Stability studies have been performed to support the labeling and storage conditions for ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control. These include real time, ambient temperature, and freeze/thaw studies.

In addition, field studies were performed at several clinical laboratories to evaluate the consistency and performance of ACCURUN 345 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 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control under various environmental and user conditions. The data collected thus far support three years storage at -70°C and 6 months at -20°C. The data demonstrate that ACCURUN 345 is not affected by multiple freeze/thaw cycles and is stable at ambient temperatures for several days with no adverse effects, but is not stable under heat stress.

The field study data demonstrate that ACCURUN 345 is safe and effective across multiple manufactured lots of product and in multiple testing laboratories.