BK040006

Summary of Safety and Effectiveness
ACCURUN 315 HIV-1 RNA Positive Quality Control

1.0 Submitter's Name and Address

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2.0 Device Names

Product Trade Name: ACCURUN 315 HIV-1 RNA Positive Quality Control
Common or Usual Name: Run controls (for use with in vitro diagnostic tests)
Classification Name: Single (Specified) 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 Dr.
San Diego, CA 92121
510(k) Number: BK010003

4.0 Device Description

ACCURUN 315 HIV-1 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 HIV-1 RNA.

ACCURUN 315 HIV-1 RNA Positive Quality Control is prepared by diluting cultured HIV-1 type B virus (8E5) in human serum or plasma that is nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV, and HCV. The 8E5 virus contains an intact, but defective viral genome. This control contains stabilizers and 0.09% sodium azide as preservative.

5.0 Intended Use

ACCURUN 315 HIV-1 RNA Positive Quality Control is intended to be used as an independent, unassayed, external run control with *in vitro* diagnostic tests for

the detection of HIV-1 RNA 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 315 HIV-1 RNA Positive Quality Control has the same intended use as the predicate device, Procleix HIV-1 External Quality 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. 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 315 HIV-1 RNA Positive Quality Control (New Device BK040006)	Procleix HIV-1 External Quality Control (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 that detect and quantitate HIV-1 RNA	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 culture derived virus diluted in human serum or plasma	Heat inactivated HIV-1 RNA positive plasma diluted in defibrinated human plasma
Preparation for Use	Bring to room temperature Gentle inversion to mix	Bring to room temperature Gently 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 315 does not have an assigned value.	Procleix HIV-1 External Quality Control does not have an assigned value.

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7.0 Summary of studies performed

Stability studies have been performed to support the labeling and storage conditions for ACCURUN 315 HIV-1 RNA Positive Quality Control. These include real time, ambient temperature, and freeze-thaw studies.

In addition, field studies were performed at two external clinical laboratories to evaluate the consistency and performance of ACCURUN 315 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 315 HIV-1 RNA Positive Quality Control under various environmental and user conditions. The data supports three years storage at -70°C and 6 months at -20°C. The data demonstrates that ACCURUN 315 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 315 is safe and effective across multiple manufactured lots of product and in multiple testing laboratories.