510(k) Summary AMPLITROL III
Amended October 15th, 2006
BK060052

(1) Submitter:

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(2) Device Name:

Product Trade Name:	AmpliTrol III™
Common or Usual Name:	Positive Quality Control for use with *in vitro* diagnostic tests
Classification Name:	Multi-Analyte Controls (assayed and unassayed)

(3) Device to Which Substantial Equivalence is Claimed:

Accurun 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control, Series 150 (*BK040064*)
Boston Biomedica, Inc.
West Bridgewater, MA 02379

(4) Device Description:

AmpliTrol III is an unassayed quality control reagent, positive for HIV-1 RNA, HCV RNA and HBV DNA, intended for use with *in vitro* diagnostic procedures that detect HIV-1 RNA, HCV RNA and HBV DNA in human serum or plasma from donations of whole blood and blood components for transfusion.

AmpliTrol III is prepared by diluting virus derived from cultured HIV type 1, sub-type B, Strain III virus; human serum or plasma reactive for HCV RNA and human serum or plasma reactive for HBV DNA in defibrinated normal human plasma non-reactive for HIV-1 RNA, HCV RNA and HBV DNA. AmpliTrol III contains stabilizers and preservatives (0.1% ProClin 300 (v/v) and 0.2% Gentamicin (v/v)).

(5) Intended Use:

AmpliTrol III is intended for use as an unassayed positive control for use with *in vitro* diagnostic tests for the detection of HIV-1 RNA, HCV RNA and HBV DNA in human serum or plasma from donations of whole blood and blood components for transfusion. This control is not intended to be substituted for the positive and negative control reagents provided with licensed test kits.

AmpliTrol III will be made available to clinical laboratory professionals for use with *in vitro* diagnostic tests for the detection of HIV-1 RNA, HCV RNA and HBV DNA in human serum or plasma.

(6) Comparison of Technological Features and Characteristics:

AmpliTrol III positive quality control reagent has the same intended use as the predicate device, ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control (series 150), 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, HBV and HCV nucleic acid (RNA and/or DNA). Both devices are intended to be used in a manner similar to unknown specimens in a test run for qualitative detection of HIV-1, HBV and HCV nucleic acid and do not have an assigned value. Additionally, both control devices utilize a similar base matrix prepared from defibrinated human plasma. Technological features and characteristics of these two devices are summarized in the following table:

Comparison of Technological Features and Characteristics of New and Predicate Device.		
Attribute	AmpliTrol III Quality Control Reagent	ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control (Predicate Device BK040064)
Intended Use	For use as an unassayed control reagent with *in vitro* diagnostic assay procedures for the detection of HIV, HBV and HCV nucleic acids in human serum or plasma from donations of whole blood and blood components for transfusion . To provide a means of monitoring assay functionality and have the potential for detecting systematic deviations from specific laboratory procedures.	For use with *in vitro* diagnostic test methods for the detection of HIV-1 RNA, HCV RNA and HBV DNA in human serum or plasma. To estimate laboratory precision and to detect errors in laboratory testing procedures
Matrix	Retroviral and viral hepatitis nucleic acid material derived from cultured human cell line or human serum or plasma sources diluted in defibrinated (normal) human plasma	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
Preparation for Use	Allow reagent to reach room temperature. Vortex to mix.	Bring to room temperature. Gentle pipetting to mix.
Instruction for Use	Include in a test run following the stepwise procedure provided by the test kit 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 Unexpected Results	Operator error Faulty performance of	Operator error Faulty performance of

	equipment Deterioration of test kit reagents Contamination of reagents	equipment Deterioration of test kit reagents Contamination of reagents
Assigned Values	AmpliTrol III does not have assigned values	ACCURUN 345 does not have an assigned value

Summary of Studies Performed:

Studies were performed to support product labeling, storage, stability (real-time and freeze-thaw) and expiry date conditions for AmpliTrol III.

Bench testing studies with AmpliTrol III were also conducted at several external sites that perform testing using different commercial assays and methodologies to assess consistency and performance under normal conditions for which the product is intended to be used.

Conclusions from Studies:

We have evaluated the performance of Amplitrol III under various environmental and actual user conditions. Real-time performance data available for AmpliTrol III demonstrate stability for up to twelve (12) months following the date of manufacture at the recommended refrigerated storage condition of 2 to 8°C. (Performance data also support stability for up to five (5) days at ambient temperatures and up to three (3) freeze/thaw cycles. However, storage at frozen, ambient or higher temperatures is not recommended for the product.)

A data summary of the overall results obtained from bench testing studies demonstrate that AmpliTrol III yields consistent performance that is 99% in agreement with the AmpliTrol III positive expected result and that the product is safe and effective for its intended use.

Product performance studies have been conducted by Blackhawk BioSystems, Inc. and by four external testing sites to validate performance of AmpliTrol III. The results of these studies document the safety and effectiveness of the reagent under normal conditions of use and also demonstrate that AmpliTrol III is substantially equivalent to ACCURUN 345 quality control product which shares the same intended use and similar performance characteristics.