#406 13251 Delf Place
Richmond, BC Canada V6V 2A2

510(k) Summary

510(k) #: BK261388

Contact Details

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Device Name

Device Trade Name	INSTI HIV-1/HIV-2 Antibody Test (90-1019)
Common Name	Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test
Classification Name	Point Of Care HIV Serology Diagnostic And/Or Supplemental Test
Registration Number	866.3956
Product Code(s)	QSU

Legally Marketed Predicate Devices

Predicate #	BP090032
Predicate Trade Name	INSTI HIV-1/HIV-2 Antibody Test
Product Code	QSU

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Device Description Summary

The INSTI HIV-1/HIV-2 Antibody Test is a single-use, rapid, qualitative in vitro immunoassay intended for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in human venous whole blood, fingerstick whole blood, or plasma specimens. The test is intended for use by trained healthcare professionals in point-of-care and laboratory settings as an aid in the diagnosis of HIV infection.

How the device functions

The test utilizes a disposable membrane-based test device together with proprietary liquid reagents to process the specimen and generate a visual result. Following specimen application and sequential addition of the supplied reagents, the sample migrates through the membrane where target antibodies, if present, are captured by immobilized assay reagents. A visible colored reaction develops at designated locations on the membrane, allowing qualitative interpretation of the test and control results without the need for instrumentation.

Scientific basis

The device is based on flow-through immunoassay technology. HIV-specific antibodies present in the specimen bind to immobilized HIV antigens within the test device. An integrated control reaction confirms proper test function and supports result validity. The assay produces a visually detectable colorimetric signal that is interpreted according to the Instructions for Use.

Physical and performance characteristics

The test kit consists of a single-use membrane-based test device housed within a plastic cartridge, proprietary reagent solutions, and specimen collection components appropriate for the specimen type. The test does not require external instrumentation or electrical power and provides a qualitative visual result in approximately one minute following completion of the test procedure.

Intended Use/Indications for Use

The INSTI HIV-1/HIV-2 Antibody Test is a single use, rapid, in vitro qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 and/or Type 2 (HIV-1/HIV-2) in human venipuncture whole blood, fingerstick blood, or plasma specimens. The test is intended for use by trained personnel in point of care and laboratory situations to aid in the diagnosis of HIV infections. If multiple rapid HIV tests are available, this test is suitable for use in appropriate multi-test algorithms.

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Indications for Use Comparison

The indications for use are the same as the approved device.

Technological Comparison

The primary technological characteristics and intended use of the INSTI HIV-1/HIV-2 Antibody Test remain the same as the predicate device, the approved INSTI HIV-1/HIV-2 Antibody Test (BP090032).

The INSTI HIV-1/HIV-2 Antibody Test is a manual, visually interpreted, flow-through immunoassay intended for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in human whole blood (fingerstick or venipuncture) and plasma specimens. The test is based on membrane immunoassay technology and utilizes a disposable test device with integrated assay reagents and a visual colorimetric detection system. The device includes assay and control components that enable detection of HIV-specific antibodies and verification of proper test performance.

The device operates using the same immunological principles as the predicate device, in which HIV-specific antibodies present in the specimen are captured by immobilized assay reagents and generate a visible signal. The procedure control provides confirmation that the test was performed appropriately and that the device functioned as intended.

The modified device maintains the same design, materials, principle of operation, energy requirements, and performance characteristics as the predicate device. No changes have been made to the intended use, assay principle, or fundamental technological characteristics of the device.

Table 1: Similarities and differences between INSTI HIV-1/HIV-2 Antibody Test and the predicate device

Device & Predicate Device(s):	Subject Device INSTI HIV-1/HIV-2 Antibody Test	Predicate Device INSTI HIV-1/HIV-2 Antibody Test
Device Trade Name	INSTI HIV-1/HIV-2 Antibody Test	Same
General Device Characteristic Similarities		

Intended Use/Indications For Use	The INSTI HIV-1/HIV-2 Antibody Test is a single use, rapid, in vitro qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 and/or Type 2 (HIV-1/HIV-2) in human venipuncture whole blood, fingerstick blood, or plasma specimens. The test is intended for use by trained personnel in point of care and laboratory situations to aid in the diagnosis of HIV infections. If multiple rapid HIV tests are available, this test is suitable for use in appropriate multi-test algorithms.	Same
Assay format	Manual, visually read, flow-through immunoassay.	Same
Detection method	Colorimetric: visible blue dot formation on nitrocellulose membrane via Protein A-indigo dye conjugate.	Same
Membrane material	Nitrocellulose	Same
Test spot antigen	HIV-1 and HIV-2 recombinant proteins	Same
Specimen volume	50 µL	Same
Reagent formulations	Sample Diluent (Tris-Glycine buffer with cell lysis reagents), Color Developer (borate-buffered chromatic indicator), Clarifying Solution (Tris-Glycine buffer).	Same
Result Reading	Visual interpretation of control and test dot formation.	Same

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Kit components	Blotted Membrane Unit (BMU), Sample Diluent, Color Developer, Clarifying Solution, lancet, capillary pipette, alcohol swab and Instructions for Use (IFU).	Same
Shelf life	15 months at 2 to 30°C	Same
General Device Characteristic Differences		
BMU manufacturing process	Addition of (b) (4) BMU assembly line (b) (4) as an alternative process in the manufacturing process. (b) (4) remain as an alternative in the manufacturing process.	BMU is manufactured by (b) (4).
BMU Pouching process	Addition of (b) (4) as an alternative process. (b) (4) remain as an alternative in the manufacturing process.	(b) (4)
Finished kit packaging	Addition of automated packaging line. The kit is packaged in tray format with sealed lid.	Manual assembly. The kit is packaged in pouch format.
BMU Pouch Dimensions	189 x 114mm	280 x 111 mm

Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-clinical verification and validation activities were conducted to assess the proposed changes to the (b) (4) BMU Assembly Line, (b) (4) Automated Packaging Line, BMU pouch dimensions, and finished-kit packaging format. Equipment and process qualifications, including installation, operational, cleaning, and performance qualification, demonstrated acceptable equipment functionality, environmental controls, cleaning

effectiveness, BMU manufacturing and pouching processes, seal and package integrity, component placement, packaging accuracy, reject detection, and process consistency.

Comparative analytical studies evaluated key performance characteristics, including limit of blank and limit of detection, sample volume, result reading time, repeatability, operating temperature and humidity, analytical sensitivity using seroconversion and low-titer panels, and in-use stability. These studies demonstrated equivalent performance between BMUs manufactured using the previously cleared (b) (4) process and those manufactured using the proposed (b) (4) process.

Real-time stability studies demonstrated equivalent stability between (b) (4)-manufactured and (b) (4)-manufactured BMUs and supported the 15-month shelf-life claim at 2–30°C. Real-time, and post-shipping, studies of finished kits assembled using the Automated Packaging Line met all predefined acceptance criteria at the available timepoints. Overall, all completed verification and validation activities and available stability data met their applicable predefined acceptance criteria, demonstrating that the proposed manufacturing and packaging changes do not adversely affect the safety, effectiveness, performance, or claimed shelf-life of the INSTI HIV-1/HIV-2 Antibody Test.

Clinical performance evaluation

Clinical performance evaluation was completed as part of BP090032. There are no changes to the assay reagents.

Conclusion

The results of the performance qualification and analytical studies demonstrate that the INSTI HIV-1/HIV-2 Antibody Test kits manufactured on automated assembly line and packaged line is as safe, as effective, and performs as well as the predicate device.