Section 5 – 510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a summary of Safety and Effectiveness for the use of the Reveal® G4 Rapid HIV-1/2 Antibody Test.

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Device Information:	
Trade Name:	Reveal® G4 Rapid HIV-1/2 Antibody Test
Common Name:	Reveal® G4
Classification Regulation:	860.3956
Classification Name:	Test, HIV detection
Classification Panel:	Microbiology
Device Classification:	Class II
Product Code:	QSU
Predicate Device:	Reveal® G4 Rapid HIV-1 Antibody Test

5.1 Device Description:

Reveal® G4 Rapid HIV-1/2 Antibody Test is a single-use, rapid, in vitro diagnostic immunoassay for the detection of antibodies to human immunodeficiency virus types 1 and 2 (anti-HIV-1/2). The test is composed of single-use test cartridge containing an immunoreactive test membrane coated with a combination of synthetic peptides corresponding to conserved regions of HIV structural proteins. The immunoreactive membrane functions to capture HIV-1 and HIV-2 antibodies present in human whole blood, serum and plasma when a drop of the specimen is applied to the membrane. In addition, the membrane has a procedural/ reagent control line comprised of protein A. Following the application of the specimen, captured HIV-1/HIV-2 antibodies are visualized through a reaction with the MedMira InstantGold™ Cap containing a proprietary protein A colloidal gold conjugate. A reactive test result occurs only when the protein A conjugate binds to the captured HIV-1/2 antibodies, producing a distinctive red dot in the test (T) zone of the membrane, along with a red vertical control line in the control (C) zone of the membrane validating the test procedure. A non-reactive result is indicated by the appearance of only the red vertical control line. If the red vertical control line does not appear on the membrane upon completion of the test, the test result is considered invalid and the test must be repeated using a new test device.

5.2 Intended Use:

Reveal® G4 Rapid HIV-1/2 Antibody Test (Reveal® G4) is a single use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Human Immunodeficiency Virus Type 2 (HIV-2) in human whole blood (venipuncture and fingerstick), serum, and plasma. Reveal® G4 is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and/or HIV-2. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid tests are available, this test should be used in appropriate multi-test algorithms.

5.3 Contraindications:

None

5.4 Technological Characteristics:

Reveal® G4 Rapid HIV-1/2 Antibody Test has the same technological characteristics as the predicate device Reveal® G4 Rapid HIV-1 Antibody Test. The intended use for Reveal G4 Rapid HIV-1/2 Antibody Test is the same as the predicate device, Reveal G4 Rapid HIV-1 Antibody Test, with the addition of the HIV-2 detection claim. The form, fit, function and method of operation are the same.

5.5 Performance Data:

Performance of the device with HIV-1 can be found in BP000023 and only information on performance with HIV-2 is included here.

Reproducibility Study:

The reproducibility of the Reveal® G4 Rapid HIV-1/2 Antibody Test with the HIV-2 samples was evaluated at three sites using three lots of the device on five different days, twice per day (morning and afternoon) by three operators per site. Blinded panels of 8 samples were used in this study. Each panel consisted of samples representing HIV-2 reactive whole blood at 1.5X LoD and 3X LoD and negative contrived whole blood. A total of 720 tests were performed (240 per site) with a total of 90 tests performed per panel member. There were three discordant samples; one Negative sample reported as positive and two positive samples (one each at 1.5X and 3X LoD) reported as negative. The overall reproducibility of the Reveal® Rapid HIV-1/2 Antibody Test was found to be 717/720 = 99.58% (95% CI 98.79 – 99.91).

Clinical Sensitivity of Reveal ® G4 Rapid HIV-1/2 Antibody Test in detection of HIV-2 antibodies.

The sensitivity of Reveal® G4 Rapid HIV-1/2 Antibody Test for the detection of anti-HIV-2 antibodies in plasma specimens was calculated using the results obtained from testing the 200 repository HIV-2 positive plasma samples, Table 1, and 500 leftover specimens collected from subjects seeking testing at a clinic located in an HIV-2 endemic area, Table 2.

Table 1. Detection of Antibodies to HIV-2 in Repository specimens by Reveal G4 Rapid HIV-1/2 Antibody Test

Population	Total Specimens	True HIV-2 Positive[1]	Reveal® G4 Reactive Results	Reveal® G4 Non-Reactive Results
Known HIV-2 Positive Repository Samples	200	200	200	0

[1]In order to be included in this study, all known positive HIV-2 repository samples were confirmed to be positive for HIV antibodies using Bio-Rad GS HIV-1/HIV-2 Plus O EIA, which does not differentiate between the antibodies and then for HIV-2 antibodies only using the Bio-Rad Multispot HIV-1/HIV-2 Rapid Test.

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Table 2. Detection of Antibodies to HIV by Reveal® G4 Rapid HIV-1/2 Antibody Test in 500 leftover specimens collected from individuals in a HIV-2 endemic setting.

		Comparator Test Results			
Reveal® G4 Test Results	**Reactivity**	Negative for HIV antibodies	Positive for HIV-1 antibodies[1,2]	Positive for HIV-2 antibodies[1,3]	Positive for HIV-1 and HIV-2 antibodies[1,4]
	Non-Reactive	190	0	0	0
	Reactive	0	279	9	22
	TOTAL	190	279	9	22

[1]Samples yielding positive results using Bio-Rad GS HIV-1/HIV-2 Plus O EIA were tested using Bio-Rad Multispot HIV-1/HIV-2 Rapid Test to confirm and differentiate EIA results.

[2]Samples found positive for HIV-1 antibodies only using Bio-Rad Multispot HIV-1/HIV-2 Rapid Test.

[3]Samples found positive for HIV-2 antibodies only using Bio-Rad Multispot HIV-1/HIV-2 Rapid Test.

[4]Samples found positive for HIV-1 and HIV-2 antibodies using Bio-Rad Multispot HIV-1/HIV-2 Rapid Test.

All 209 HIV-2 positive specimens; 200 HIV-2 repository specimens and 9 HIV-2 positive specimens, identified among the 500 leftover samples from the endemic population were found to be Reactive with Reveal® G4 Rapid HIV-1/2 Antibody Test. The overall sensitivity of the Reveal® G4 Rapid HIV-1/2 Antibody Test to detect HIV-2 Antibodies was calculated to be 209/209 = 100% (95% CI = 98.20% to 100.00%).

5.6 Summary of Substantial Equivalence:

Reveal® G4 Rapid HIV-1/2 Antibody Test device is substantially equivalent to the predicate device as confirmed through relevant performance tests.

5.7 Conclusion:

The results of non-clinical analytical and clinical performance studies demonstrate that the Reveal® G4 Rapid HIV-1/2 Antibody Test is as safe, as effective, and performs as well as the predicate device.

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