

Summary of Safety and Effectiveness

I. General Information

Device Generic Name: Rapid HIV-1 Antibody Test

Device Trade Name: Reveal™ Rapid HIV-1 Antibody Test

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Premarket Approval Application (PMA) Number: BP000023/0

Date of Notice of Approval to the Applicant: xxxxxxxxxxxxxx

II. Indications for Use

The Reveal™ Rapid HIV-1 Antibody Test is a single use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in human serum or plasma specimens. The Reveal™ Rapid HIV-1 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1. 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.

III. Device Description

The Reveal™ Rapid HIV-1 Antibody Test (Figures 1 and 2) consists of a unitized, leak-proof plastic test cartridge encasing the immunoreactive membrane, a Universal Buffer solution composed of Tris-buffered saline, synthetic polymers and an anti-microbial agent, a lyophilized MedMira Colorimetric Detection Agent, lyophilized MedMira HIV-1 Human Test Controls and disposable transfer pipettes. The immunoreactive test membrane is coated with a combination of synthetic peptides corresponding to conserved regions of HIV structural proteins to capture anti-HIV-1 antibodies present in human serum or plasma. The test cartridge and disposable pipette, vials of MedMira Colorimetric Detection Agent and vials of MedMira HIV-1 Human Test Controls are packaged in sealed Mylar pouches. The MedMira Universal Buffer bottle is packaged in a poly zipper bag with 12 disposable pipettes.

The Reveal™ Rapid HIV-1 Antibody Test is a unitized, ready-to-use test device that is packaged with all required test components in two different configurations. One box contains the following:

Component	Quantity for Catalogue # 815311000065	Quantity for Catalogue #815311009778
Test Cartridge Mylar pouch Each pouch contains: Test Cartridge (1) Disposable pipette (1) Desiccant packet (1)	50	15
Reagent Package Each 5"x7"poly zipper bag contains: MedMira Colorimetric Detection Agent Mylar pouch; Each pouch contains: <ul style="list-style-type: none"> 4 vials of lyophilized colorimetric detection agent comprised of protein A conjugated to colloidal gold in a buffered solution (Preservative: 0.1% sodium azide) Desiccant packet (1). 	1	1
MedMira HIV-1 Human Test Control Mylar pouch; Each pouch contains: <ul style="list-style-type: none"> 1 vial of MedMira Positive Test Control* (lyophilized, heat-inactivated human serum/plasma positive for HIV-1 antibodies and negative for Hepatitis B surface antigen and Hepatitis C antibodies, in a buffered solution). 1 vial of MedMira Negative Test Control* (lyophilized human serum/plasma negative for HIV antibodies and antigen, Hepatitis B surface antigen, and Hepatitis C antibodies, in a buffered solution). Desiccant packet (1) * MedMira HIV-1 Human Test Controls do not contain preservative	1	1
A 4"x6" poly zipper bag containing: <ul style="list-style-type: none"> One drop dispenser bottle containing 30 mL of MedMira Universal Buffer solution, composed of Tris-buffered saline, synthetic polymers and an anti-microbial agent (Preservative: 0.1% sodium azide). One 4"x4" poly zipper bag containing 12 disposable pipettes. 	1	1
Package Insert	1	1
Subject Information Brochure	50	15

The 50-test configuration is designed for use in clinical laboratories that run a minimum of eight (8) specimens per batch. **Caution: The 50-test configuration does not contain sufficient quantities of Test Controls for batch sizes of less than eight (8) specimens.** The 15-test configuration contains sufficient materials for clinical laboratories running less than eight (8) specimens per batch. **Additional MedMira HIV-1 Human Test Controls, MedMira Colorimetric Detection Agent, Medmira Universal Buffer and disposable pipettes can be purchased separately.**

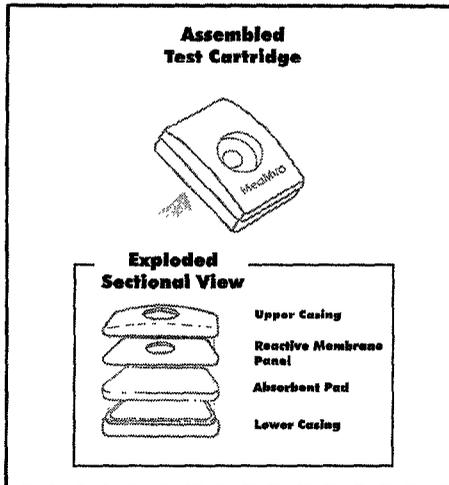


Figure 1. Assembled Test Cartridge

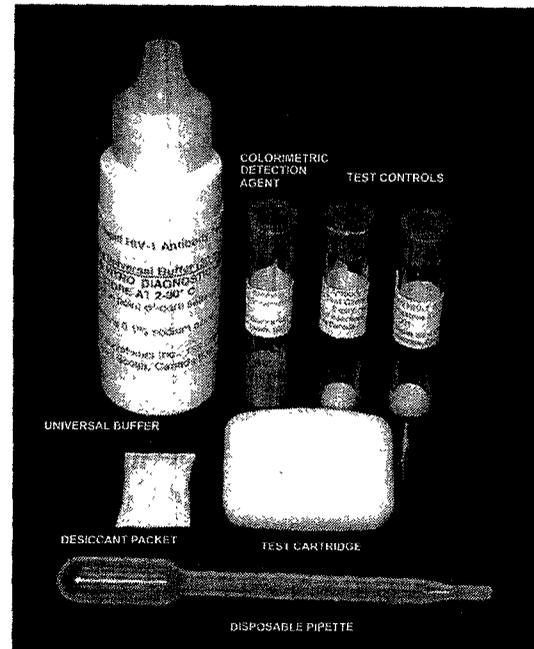


Figure 2. Components of the *Reveal*™ Rapid HIV-1 Antibody Test

To perform the test, the disposable pipette is used to deposit 1 drop (30-40 μ l) of specimen onto the primed immunoreactive membrane of the test cartridge followed by 3 drops (90-120 μ l) of Universal Buffer to wash away any non-specifically bound antibodies. Four drops (120-160 μ l) of reconstituted Colorimetric Detection Agent is then added to the test cartridge to visualize the captured HIV-1 antibodies in a specimen in the form of a distinctive red dot on the test membrane, representing a Reactive test result. The presence of a red dot on the test membrane, regardless of intensity, indicates that anti-HIV-1 antibodies **have been detected** in the specimen. The absence of a red dot on the test membrane indicates that anti-HIV-1 antibodies **were not detected**. A uniform, faint pinkish background may be visible on the test membrane. An Invalid test result indicates that there has been a problem, either with the test device or the specimen, during the testing procedure. **An Invalid result cannot be interpreted.** If an Invalid test result is obtained, the testing procedure should be repeated using a new test cartridge and specimen. The test results should be read immediately after the completion of the test procedure.

A MedMira Positive and Negative Test Control must be run in parallel with each batch of tests.

IV. Restrictions

- Sale of the *Reveal*™ Rapid HIV-1 Antibody Test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.
- The *Reveal*™ Rapid HIV-1 Antibody Test is approved for use only by an agent of a clinical laboratory.
- Test subjects must receive the "Subject Information Brochure" prior to specimen collection, and appropriate information when test results are provided.
- The *Reveal*™ Rapid HIV-1 Antibody Test is not approved for use to screen donors of blood, plasma, cells or tissues.

V. Warnings

For *In Vitro* Diagnostic Use

1. Read the package insert completely and carefully prior to use of the *Reveal*™ Rapid HIV-1 Antibody Test. If the directions are not followed exactly, inaccurate test results may occur.
2. The United States Food and Drug Administration has approved this test for use with serum or plasma specimens only. Use of this test with specimens other than those specifically approved for use with the *Reveal*™ Rapid HIV-1 Antibody Test may result in inaccurate test results.
3. Perform the *Reveal*™ Rapid HIV-1 Antibody Test at room temperature (15-27°C).

VI. Limitations of the Test

1. The *Reveal*™ Rapid HIV-1 Antibody Test must be used in accordance with this package insert to ensure accurate results.
2. The FDA has approved the *Reveal*™ Rapid HIV-1 Antibody Test for serum or plasma specimens only. Use of other types of specimens may not yield accurate results.
3. Test results are to be read and interpreted **immediately** following the final washing step with Universal Buffer. A delay in reading test results may yield inaccurate results.
4. Specimens that do not pass through the membrane within thirty (30) seconds after centrifugation (see **Testing Procedure, step 2**) are unsuitable for testing with the *Reveal*™ Rapid HIV-1 Antibody Test.
5. Lipemic samples or specimens contaminated with bacteria may not pass through the membrane within thirty (30) seconds, and therefore may be unsuitable for testing with the *Reveal*™ Rapid HIV-1 Antibody Test.
6. Limited studies were conducted to determine the potential effect of interfering substances and unrelated medical conditions on the performance of the *Reveal*™ Rapid HIV-1 Antibody Test.
7. The specificity of the *Reveal*™ Rapid HIV-1 Antibody Test for serum specimens in low-risk populations has not been evaluated.
8. Limited studies were conducted to determine the performance of the *Reveal*™ Rapid HIV-1 Antibody Test on fresh serum and plasma specimens.
9. A Reactive test result using the *Reveal*™ Rapid HIV-1 Antibody Test suggests the presence of anti-HIV-1 antibodies in the specimen. The *Reveal*™ Rapid HIV-1 Antibody Test is intended to be used as an aid in the diagnosis of infection with HIV-1. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. Results of the MedMira *Reveal*™ Rapid HIV-1 Antibody Test should not be used in isolation, but in conjunction with the clinical status, history, and risk factors of the individual being tested.
10. The intensity of the red dot (Reactive test result) does not necessarily correlate with the antibody titre of the specimen.
11. A Non-Reactive test result with the *Reveal*™ Rapid HIV-1 Antibody Test indicates the absence of detectable antibodies to HIV in the specimen. However, a Non-Reactive test result does not exclude the possibility of exposure to, or infection with HIV. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels, during which time testing for antibodies to HIV will not be indicative of true infection status. A comprehensive risk history and clinical judgement should be considered before concluding that an individual is not infected with HIV.

VII. Alternative Practices and Procedures

The detection of antibodies to HIV-1 in humans is primarily performed using laboratory-based assays for serum, plasma, oral fluid or urine. The majority of these tests use principles similar to that of the *Reveal*™ Rapid HIV-1 Antibody Test; utilizing peptides, recombinant antigens, isolated proteins or viral lysate immobilized onto a solid phase support to capture antibodies in a patient sample. In many cases, the detection of the captured antibodies is accomplished using an instrument to reveal a coloured or chemiluminescent endpoint from enzymatic reactions. All reactive screening test results require supplemental, more specific testing.

The *Reveal*™ Rapid HIV-1 Antibody Test differs from traditional laboratory-based testing in that it requires no extra instrumentation, and a protein A-colloidal gold conjugate colorimetric detection agent is used for qualitative visual interpretation of test results.

VIII. Marketing History

There is no marketing history for the *Reveal*™ Rapid HIV-1 Antibody Test. This product has not been marketed domestically or internationally.

IX. Potential Adverse Effects of the Device on Health

There have been no adverse effects of the *Reveal*™ Rapid HIV-1 Antibody Test indicated during studies performed to date.

X. Summary of Preclinical Studies

Sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test in the Detection of HIV-1 From Various Geographic Regions
The sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test for the detection of antibodies to HIV-1 Group M subtypes (A,B,C,D,E,F,G) from various geographic regions was assessed by testing 1026 confirmed HIV-1 antibody positive serum and plasma specimens obtained from various parts of the world. Of these 1026 specimens, 1024 were Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test. Two confirmed HIV-1 antibody positive specimens from Canada were Non-Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test.

Reactivity with Seroconversion Panels

Seven seroconversion panels were tested in comparison to a licensed anti-HIV-1,2 EIA. Each panel consisted of a series of sequential specimens obtained from a single individual undergoing seroconversion. Five of the 7 panels were obtained from a commercial source, while the remaining 2 were from clinical settings. The 7 seroconversion panels consisted of 36

specimens. In this study, the Reveal™ Rapid HIV-1 Antibody Test detected seroconversion similarly to the FDA-licensed HIV-1,2 EIA (Table 1).

Table 1. Performance of the Reveal™ Rapid HIV-1 Antibody Test with Seroconversion Panels

Specimen Information		Reveal™ test	Licensed anti-HIV-1,2 EIA
Panel	Relative Day of Bleed		
AF	1	NR	NR
	3	NR	NR
	8	NR	NR
	10	NR	NR
	16	R	NR
	29	R	RR
	34	R	RR
	36	R	RR
D	43	R	RR
	1	NR	NR
	22	NR	NR
	50	R	NR
	93	R	RR
H	100	R	RR
	1	NR	NR
	8	NR	NR
	13	NR	NR
	20	NR	NR
	27	NR	NR
M	29	R	RR
	1	NR	NR
E	23	R	RR
	1	NR	NR
	8	NR	NR
	22	NR	NR
	36	NR	NR
	43	NR	NR
	50	NR	NR
	64	NR	NR
	85	NR	NR
	92	NR	RR
TORONTO PANEL 1	127	R	RR
	1	NR	RR
TORONTO PANEL 6	22	R	RR
	1	R	NR
	72	R	RR

NR= Non-Reactive; R=Reactive; RR=Repeatedly Reactive

Reactivity with Low Titre HIV-1 Antibody Performance Panel

A low titre HIV-1 antibody panel consisting of 15 specimens, obtained from a commercial source, was tested in comparison with licensed anti-HIV EIA tests. The results of the study are shown in Table 2. The Reveal™ Rapid HIV-1 Antibody Test was capable of detecting antibodies to HIV-1 similarly to the licensed anti-HIV EIA tests.

Table 2: Comparison of the Reveal™ Rapid HIV-1 Antibody Test and Licensed Anti-HIV EIA Tests Using a Low Titre HIV-1 Antibody Performance Panel

Panel Member	Reveal™ Test	Licensed Anti-HIV EIA Tests				
		EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
1	NR	NR	RR	RR	NR	NR
2	R	NR	RR	RR	RR	NR
3	R	NR	RR	NR	NR	NR
4	R	RR	RR	RR	RR	NR
5	NR	NR	NR	NR	NR	NR
6	R	RR	RR	RR	RR	NR
7	NR	NR	RR	RR	NR	NR
8	NR	NR	RR	NR	RR	NR
9	NR	NR	RR	NR	NR	NR
10	R	RR	RR	RR	RR	RR
11	R	RR	RR	RR	RR	RR
12	NR	NR	RR	NR	NR	NR
13	NR	NR	RR	RR	NR	NR
14	R	RR	RR	RR	RR	RR
15	R	RR	RR	RR	RR	RR

NR=Non-Reactive, R=Reactive, RR=Repeatedly Reactive

Interfering Substances and Unrelated Medical Conditions

The effects of anticoagulants, potentially interfering medical conditions, seromarkers and abnormal blood chemistry on the outcome of Reveal™ Rapid HIV-1 Antibody Test were assessed using a total of 276 HIV-1 antibody positive serum and plasma specimens. Of these, 155 specimens were from confirmed cases of HIV-1 infection and 121 specimens were spiked with HIV-1 antibody positive specimens. These 276 HIV-1 antibody positive specimens represented the following conditions: EDTA (n=73), heparin (n=89), sodium citrate (n=20), hemolyzed (n=2), icteric (n=2), lipemic (n=1), HBsAg (n=3), anti-HBc (n=3), anti-HBs (n=4), anti-HCV (n=3), EBV (n=5), CMV (n=6), measles (n=6), HSV (n=5), rubella (n=4), varicella (n=3), RA (n=5), C reactive protein (n=5), infectious mononucleosis (n=4), antistreptolysin O (n=2), and H. pylori (n=5). The effect of multiple elevated analytes on the sensitivity of the Reveal™ Rapid HIV-1 Antibody Test was assessed using pairs of specimens (with elevated analyte levels and normal analyte levels) spiked with an HIV-1 positive specimen. Specimens contained elevated levels of the following (n=26): AST (range of elevated levels tested, 96 to 1764 U/L; reference range, 0 to 37 U/L), ALT (136 to 2296 U/L; reference, 0 to 37 U/L), ALP (297 to 550 U/L; reference, 36 to 125 U/L), total bilirubin (34 to 65 µmol/L; reference, 0 to 20 µmol/L), LD (350 to 600 U/L; reference, 90 to 180 U/L), uric acid (600 to 940 µmol/L; reference, 150-450 µmol/L). Multiple elevated analytes were: AST, ALT, ALP (1); ALT, total bilirubin (4); AST, ALT (2); AST, ALT, total bilirubin (2); AST, ALT, ALP, Uric Acid (1); ALT, LD, AST, ALP (2); ALT, ALP (1).

The results indicated that none of the above conditions interfered with the Reveal™ Rapid HIV-1 Antibody Test.

The effects of anticoagulants, potentially interfering medical conditions and seromarkers on the outcome of Reveal™ Rapid HIV-1 Antibody Test were assessed using a total of 271 serum and plasma specimens from known HIV antibody negative individuals. These 271 specimens contained the following: EDTA (n=79), heparin (n=20), sodium citrate (n=26), HBsAg (n=4), anti-HBc (n=4), anti-HBs (n=3), anti-HCV (n=10), HTLV-1 (n=10), CMV (n=10), measles (n=10), HSV (n=10), rubella (n=10), varicella (n= 10), RA (n=10), C reactive protein (n=10), infectious mononucleosis (n=10), antistreptolysin O (n=15), mycoplasma (n=10), and syphilis reagent antibodies (n=10).

The results indicated that none of the above conditions interfered with the Reveal™ Rapid HIV-1 Antibody Test.

REPRODUCIBILITY

The reproducibility of the Reveal™ Rapid HIV-1 Antibody Test was studied at three sites using three lots of the device on three different days by three operators per site. Coded panels of 15 samples were used in triplicate for this study. Each panel consisted of strongly and weakly Reactive HIV-1 antibody serum/plasma samples, as well as HIV-1 antibody negative specimens. In addition, three lots of MedMira Positive and Negative Test Controls were included in the panel. A total of 810 tests were performed (270 per site) with a total of 54 tests performed per panel member. The overall reproducibility of the Reveal™ Rapid HIV-1 Antibody Test was found to be 810/810 = 100%.

XI. Summary of Clinical Studies

SENSITIVITY

Serum Specimens

Sensitivity studies were performed using repository HIV-1 antibody positive serum specimens from individuals known to be infected with HIV-1 and freshly collected serum specimens from routine clinical settings in high-risk populations at four clinical sites. Serum specimens were obtained from 483 individuals known to be infected with HIV-1, as well as 2914 serum specimens from previously untested individuals from high-risk populations. All 483 serum specimens from

known HIV-1 antibody positive individuals that were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA and were HIV-1 antibody Western blot positive gave Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 2914 previously unscreened serum specimens from individuals from a high-risk population, 124 were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA, 123 were confirmed positive by Western blot (1 indeterminate result), and 122 were Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test. The results of these studies are shown in Table 3A.

Table 3A. Detection of Anti-HIV-1 Antibodies in Serum Specimens Obtained From Known HIV-1 Antibody Positive Individuals and Routine Clinical Settings in HIV High-Risk Populations

Test Group	Total Samples	<i>Reveal</i> ™ Reactive	Licensed EIA Repeatedly Reactive	Western Blot Positive
Known HIV-1 Antibody Positive	483	483	483	483
High-Risk Population	2914	122	124*	123
Total	3397	605	607	606

* One specimen was Western blot indeterminate.

The overall sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test for the detection of anti-HIV-1 antibodies in serum specimens in these studies was calculated to be 605/606 = 99.8% (95% confidence interval; 99.2-100%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from the study of known HIV-1 antibody positive serum specimens with the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from the studies of high-risk populations.

Plasma Specimens

Sensitivity studies were performed using repository HIV-1 antibody positive plasma specimens from individuals known to be infected with HIV-1 and repository plasma specimens from clinically diagnosed AIDS patients. Plasma specimens were obtained from 397 individuals known to be infected with HIV-1, as well as 107 specimens from clinically diagnosed AIDS patients from one clinical site. All 397 plasma specimens were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA, 395 were Western blot positive (2 Western blot indeterminate) and 395 gave Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 107 specimens from clinically diagnosed AIDS patients, 107 were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA, 104 were positive by Western blot (3 Western blot indeterminate) and 103 were Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test. The results of these studies are shown in Table 3B.

Table 3B. Detection of Anti-HIV-1 Antibodies in Plasma Specimens Obtained From Known HIV-1 Antibody Positive Individuals and Clinically Diagnosed AIDS Patients in Routine Clinical Settings

Test Group	Total Samples	<i>Reveal</i> ™ Reactive	Licensed EIA Repeatedly Reactive	Western Blot Positive
Known HIV-1 Antibody Positive	397	395	397*	395
Clinically Diagnosed AIDS Patients	107	103	107**	104
Total	504	498	504	499

* Two specimens were Western blot indeterminate, ** Three specimens were Western blot indeterminate.

The overall sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test for the detection of anti-HIV-1 antibodies in plasma specimens in these studies was calculated to be 498/499 = 99.8% (95% confidence interval; 99.0-100%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from the study of known HIV-1 antibody positive plasma specimens with the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from clinically diagnosed AIDS patients.

SPECIFICITY

Serum Specimens

Specificity studies were performed using repository serum specimens obtained from 850 previously screened HIV-1 antibody negative individuals from a high-risk population and 2914 freshly collected serum specimens from previously unscreened individuals from high-risk populations. Specimens were collected from three clinical sites. Of the 850 repository HIV-1 antibody negative serum specimens, 845 gave Non-Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 2914 freshly collected serum specimens, 2763 gave Non-Reactive results using the *Reveal*™ Rapid HIV-1 Antibody Test. Five of the specimens were found to be Western blot indeterminate. The results of these studies are shown in Table 4A.

Table 4A. Performance of the *Reveal*™ Rapid HIV-1 Antibody Test on Serum Specimens Presumed to be Negative for Antibodies to HIV-1

Test Group	Total Samples	<i>Reveal</i> ™ Non- Reactive	Licensed EIA Non-Reactive	True Negative*
Known HIV-1 Antibody Negative	850	845	850	850
High-Risk Population	2914	2763	2789	2789
Total	3764	3608	3639	3639

* True Negative status was based on negative or indeterminate test results using a licensed Western blot.

The overall specificity of the *Reveal*™ Rapid HIV-1 Antibody Test for serum specimens in these studies was calculated to be 3608/3639 = 99.1% (95% Confidence Interval; 98.8-99.4%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Non-Reactive results obtained from the study of previously screened HIV-1 antibody negative serum specimens with the number of *Reveal*™ Rapid HIV-1 Antibody Test Non-Reactive results obtained from the studies of high-risk populations.

Plasma Specimens

Specificity studies were performed using plasma specimens that had been frozen once, obtained from 1000 previously screened HIV-1 antibody negative individuals, and 2011 freshly collected plasma specimens from previously unscreened individuals from low risk-populations. All plasma specimens were collected from the same clinical site. Of the 1000 pre-screened HIV-1 antibody negative plasma specimens, 992 gave Non-Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 2011 freshly collected HIV-1 antibody negative plasma specimens, 1978 gave Non-Reactive results using the *Reveal*™ Rapid HIV-1 Antibody Test. Four of the specimens were found to be Immunofluorescence Assay (IFA) indeterminate. The results of these studies are shown in Table 4B.

Table 4B. Performance of the *Reveal*™ Rapid HIV-1 Antibody Test on Plasma Specimens Presumed to be Negative for Antibodies to HIV-1

Test Group	Total Samples	<i>Reveal</i> ™ Non-Reactive	Licensed EIA Non-Reactive	True Negative*
Known HIV-1 Antibody Negative	1000	992	1000	1000
Low-Risk Population	2011	1978	2011	2011
Total	3011	2970	3011	3011

* True Negative status was based on negative or indeterminate test results using a licensed Western blot or IFA.

The overall specificity of the *Reveal*™ Rapid HIV-1 Antibody Test for plasma specimens in these studies was calculated to be 2970/3011 = 98.6% (95% Confidence Interval; 98.4-98.8%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Non-Reactive results obtained from the study of previously screened HIV-1 antibody negative plasma specimens with the number of *Reveal*™ Non-Reactive results obtained from the studies of low-risk populations.

XII. Conclusions Drawn from the Studies

Risk/Benefit Analysis

Conventional laboratory tests for antibodies to HIV-1 generally utilize complex, multi-step tests requiring use by highly trained individuals with a turnaround time of several days to a few weeks. Additionally, the complexity and cost of complex testing and required equipment may prohibit the universal utilization of conventional testing in medical settings with limited resources and personnel. Less complex HIV tests, such as MedMira’s *Reveal*™ Rapid HIV-1 Antibody Test, will improve the delivery of medical care and HIV prevention services with substantial time and cost savings. Realizing the utility of rapid tests, the World Health Organization (WHO) recommends the use of alternative testing strategies using rapid and simpler HIV tests. The United States Centers for Disease Control and Prevention (CDC) accompanied these recommendations with studies concluding that large numbers of patients tested for HIV using conventional methods did not return to the medical facility to obtain test results. From a public health perspective, this high non-return rate has great implications for the health and welfare of that individual and his/her contacts. The MedMira *Reveal*™ Rapid HIV-1 Antibody Test is a rapid, flow-through diagnostic immunoassay developed to utilize the performance characteristics of conventional diagnostic immunoassays while simplifying the testing procedure to eliminate the requirement for expensive equipment and highly trained personnel, thereby decreasing turnaround time.

Safety

No adverse reactions were observed during any of the HIV studies conducted. All operators conducted testing in accordance with the training provided.