MIRACARE Rapid HIV TEST FOR DETECTION OF HIV ANTIBODIES IN WHOLE BLOOD: REPORT OF A PILOT STUDY

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Introduction

Rapid HIV testing at point of care (POC) can improve patient care and HIV prevention services. The MiraCare™ Rapid HIV Antibody Test is a new POC test developed by MedMira Laboratories based on the same principle as the FDA-approved Reveal™ G2 Rapid HIV-1 Antibody Test for Serum/Plasma (MedMira Laboratories Inc., Halifax). The MiraCare™ Rapid HIV Antibody Test utilizes an easy four-step procedure to detect HIV-1 antibodies in whole blood (finger-prick and venipuncture), serum or plasma within three minutes. Some competitive advantages of the MiraCare™ Rapid HIV are highlighted in Table 1.

Table 1. Competitive Advantages of the MiraCare™ Rapid HIV Test

	MiraCare™ Rapid HIV Test	EIA	Western Blot
Specimen flexibility	Whole Blood (finger - prick and venipuncture), Serum, and Plasma	Serum or Plasma	Plasma
Time to result	3 minutes	Hours	Hours to days
Product storage	Room Temperature	Refrigeration	Refrigeration
Interpretation	Visual	Requires equipment and computation	Visual
Procedure	Simple steps, no equipment required	Complex, requiring specialized equipment	Complex procedural step
Test location	Flexible	Laboratory	Laboratory

Purpose

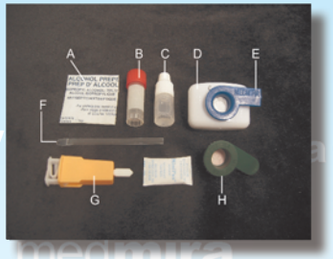
This study was a pilot study to determine the performance and ease of use of the MiraCare™ Rapid HIV Antibody Test POC test (Figure 1) using finger-prick whole blood samples obtained in STD/HIV clinics. Rapid test results obtained on site at STD/HIV clinics using finger-prick specimens were compared to those obtained independently at the Public Health Laboratory (PHL) using venipuncture whole blood and plasma specimens from the same subjects.

Study Description

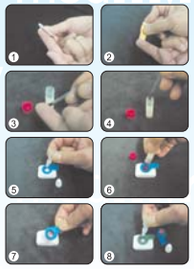
A total of 205 patients were enrolled in the study through 3 STD/HIV clinics and included confirmed HIV positive cases being cared for at one of the STD/HIV clinics. Finger-prick whole blood samples were tested on-site using the MiraCare™ Rapid HIV Antibody Test. Venipuncture whole blood samples were also obtained from the same subjects and sent to the PHL for standard HIV testing. At the PHL the MiraCare™ Rapid HIV test was used independently to test each venipuncture whole blood specimen and plasma prepared from it. Standard HIV testing was done at the PHL using plasma with Abbott Axsym EIA HIV screen and Western blot confirmation of EIA positive specimens (Figure 2).

The overall performance of the MiraCare™ Rapid HIV Test using the three types of analytes (finger-prick whole blood, venipuncture whole blood, and plasma) was compared to the results obtained with the standard testing methods, EIA and Western blot.

Figure 1 **MiraCare™ Rapid HIV Antibody Test**



A. Alcohol swab
B. Diluent Buffer Solution (Red colour Cap)
C. Universal Buffer dropper bottle (White colour Cap)
D. Test cartridge
E. Blue colour Specimen Filtration Unit
F. Disposable pipette
G. lancet
H. Instant Gold™ Cap (Green colour)



SPECIMEN COLLECTION

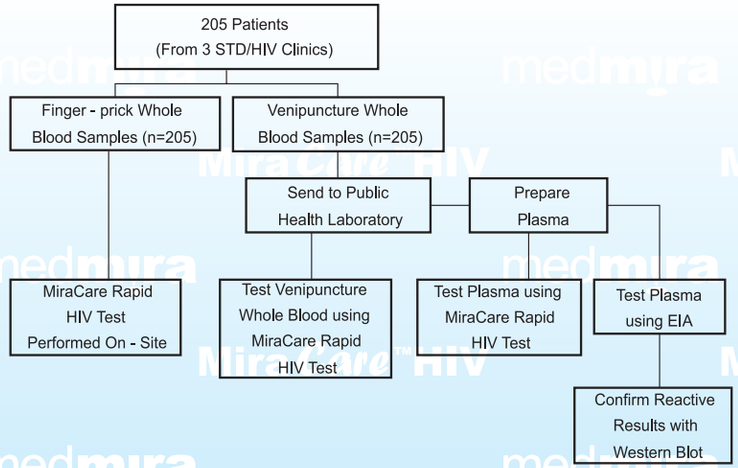
1. Using the alcohol swab provided, clean your Index finger. Allow the finger to dry thoroughly.
2. Pull the white plastic tip of the lancet and place it against your clean site of your Index finger. Puncture the skin by pressing the handle all the way. Hold the finger downward and apply gentle pressure beside the point of puncture.
3. Squeeze the outside of the disposable pipette and place it in the center of the blood drop. Slowly release the pressure to draw the blood into the channel of the pipette.
4. Apply **one (1)** drop of blood into the uncapped Diluent Buffer vial (Red colour cap). Gently mix by tapping the bottom of the vial. Immediately begin the **TESTING PROCEDURE.**

TESTING PROCEDURE

Cautions
All solutions must be completely absorbed into the test membrane before proceeding to the next step in the testing procedure.
Once the assay has been started, all subsequent steps hould be completed without interruption.
Perform the test on a flat work surface.
Read the test results immediately. Failure to do so may result in inaccurate test results.

5. Apply **six (6)** drops from the MedMira Universal Buffer vial (White colour cap) to the center of the Blue Specimen Filtration Unit. Allow the buffer to absorb completely.
6. Pour the entire contents of the Diluent Buffer vial (Red colour cap) into the center of the blue Specimen Filtration Unit. Ensure that the solution has completely absorbed into the blue Specimen Filtration Unit before proceeding to the next step.
7. Remove the blue Specimen Filtration Unit by gently twisting the handle in a circular and upwards motion.
8. Place the Instant Gold™ Cap (Green colour) loosely into the well of the test cartridge. Apply **twelve (12)** drops of MedMira Universal Buffer to the center of the Instant Gold™ Cap. Allow the buffer to absorb completely. Remove the Instant Gold™ Cap and **Read Result.**

Figure 2 **Study Algorithm**



Methods

Manufacturers' instructions were followed for all test methods utilized.The MiraCare™ Rapid HIV Test procedure and interpretation of test results is shown in Figures 1 and 3 respectively.

Results:

Test results obtained independently at each of the three STD/HIV clinics, and the PHL using MiraCare™ Rapid HIV Test and standard test methods were recorded and subsequently analyzed. The results of the three analytes with the MiraCare™ Rapid HIV Test showed 100% correlation with 100% agreement of the MiraCare™ Rapid HIV Test results performed at the STD/HIV clinic and at the PHL when compared to the standard testing methodology (Table 2 and 3). No false positive or false negative results of the MiraCare test were found during the study.

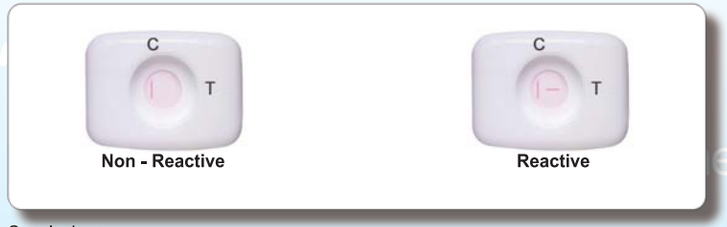
TABLE 2.
Comparison of the MiraCare™ Rapid HIV test performed at the STD/HIV clinic to standard testing at the Public Health Laboratory.

		MiraCare™ Rapid HIV Antibody Test (Finger - prick Whole Blood)		Agreement
		+	-	
Abbott EIA Screen and Western blot HIV Positive	74	74	0	100%
Abbott EIA Screen HIV Negative	131	0	131	100%

TABLE 3.
Comparison of the MiraCare™ Rapid HIV test performed at the Public Health Laboratory to standard testing at the Public Health Laboratory.

		MiraCare™ Rapid HIV Antibody Test				Agreement
		Venipuncture Whole Blood		Plasma		
		+	-	+	-	
Abbott EIA Screen and Western blot HIV Positive	74	74	0	74	0	100%
Abbott EIA Screen HIV Negative	131	0	131	0	131	100%

Figure 3 **Interpretation of Test Results**



Conclusions

The MiraCare™ Rapid HIV Test showed 100% agreement with the reference method with both POC finger-prick and venipuncture whole blood samples. This data provides evidence that the MiraCare™ Rapid HIV Test can be used for POC screening using finger-prick whole blood samples. Also of significance is the fact that the MiraCare™ test did not have a single false positive result. This attests to its very high specificity, and bodes extremely well for its application in mass screening programs where the potential for false positive results are of a major concern especially in low prevalence settings. The MiraCare™ Rapid HIV Test is simple, easy to carry out, and truly rapid.