**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 Revetest™ 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**

<table>
<thead>
<tr>
<th>Specimen flexibility</th>
<th>Whole Blood (finger-prick and venipuncture), Serum or Plasma</th>
<th>Plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to result</td>
<td>3 minutes, Hours to Days</td>
<td></td>
</tr>
<tr>
<td>Product storage</td>
<td>Room Temperature, Refrigeration</td>
<td></td>
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<tr>
<td>Interpretation</td>
<td>Visual</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Simple steps, no equipment required, Complex procedural step</td>
<td></td>
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<tr>
<td>Test location</td>
<td>Flexible, Laboratory</td>
<td></td>
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</table>

**Purpose**

The 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 clinic sites 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 HIV-1 and HIV-2 kits and Western blot confirmation of positive specimens (Figure 2).

The overall performance of the Miracare™ Rapid HIV Test using the three types of analyses (finger-prick whole blood, venipuncture whole blood, and plasma) was compared to the results obtained with the standard testing methods, HIV-1 and Western blot.

**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 analyzers 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.

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

A. Alcohol swab  
B. Dilute 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)

**Figure 2** Study Algorithm

205 Patients  
(From 3 STD/HIV Clinics)

Finger-prick Whole Blood Samples (n=205)  
Venipuncture Whole Blood Samples (n=205)

Prepare Plasma

Send to Public Health Laboratory

Test Plasma using Miracare Rapid HIV Test  
Test Plasma using Miracare Rapid HIV Test  
Confirm Reactive Results using Western Blot

**Figure 3** Interpretation of Test Results

Non-Reactive  
Reactive

**Conclusion**

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 bodies 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 a simple, easy to carry out, and truly rapid.