



**Potential cross-reacting**

Sample Profile	Total Sample Size	Performance of MP Diagnostics MULTISURE® HIV Rapid Test
Rheumatoid Factor (RF)	10	90.00% (09/10)
Syphilis	11	100.00% (11/11)
Hepatitis A	10	100.00% (10/10)
HBsAg	10	100.00% (10/10)
Hepatitis C	10	100.00% (10/10)
Epstein-Barr virus (EBV)	10	100.00% (10/10)
Human T-lymphotropic Virus Type I (HTLV-I)	11	100.00% (11/11)
Human T-lymphotropic Virus Type II (HTLV-II)	8	100.00% (08/08)
Cytomegalovirus (CMV)	10	100.00% (10/10)
Hepatitis E	10	100.00% (10/10)
<b>Total</b>	<b>100</b>	<b>99.00% (99/100)</b>

**Potential Interferences**

Sample Profile	Total Sample Size	Performance of MP Diagnostics MULTISURE® HIV Rapid Test
Icteric (= 1-10mg/DL)	10	100.00% (10/10)
Hemolyzed (= 25-100mg/DL)	10	100.00% (10/10)
Triglyceride (1100 – 2593mg/dL)	12	100.00% (12/12)
Lipemic (= 60-150mg/DL)	10	100.00% (10/10)
Total Protein (9.1-9.6 g/dL)	8	100.00% (08/08)
Total bilirubin (5.5 – 42.9 g/dL)	10	100.00% (10/10)
Anti-streptolysin O (ASO) (200-400IU/ml)	10	100.00% (10/10)
Antinuclear Antibody (ANA)	10	100.00% (10/10)
Autoimmune Disease	11	100.00% (11/11)
Diabetes	4	100.00% (04/04)
Intravenous Drug User	8	100.00% (08/08)
<b>Total</b>	<b>103</b>	<b>100.00% (103/103)</b>

**Differentiation of HIV-1 and HIV-2**

Serotype	Total Sample Size	Accuracy of differentiation by MP Diagnostics MULTISURE® HIV Rapid Test
HIV-1	530	97.55% (517/530)
HIV-2	132	93.94% (124/132)

**Detection of HIV-1 and HIV-2 subtypes**

Serotype^	Total Sample Size	Performance of MP Diagnostics MULTISURE® HIV Rapid Test
HIV-1	89*	100% (89/89)
HIV-2	4	100% (4/4)

\* Including Group M (Subtype A, B, C, D, E, F, G, H, J, K, BC, C/E, CRF01\_AE, CRF02\_AG, CRF02\_AB, E/F, G/CRF02, H/A1, K/CRF09, CRF01/CRF15) & Group O

^ Source of panels:

- HIV worldwide Performance Panel WWRB301, Sera Care Life Sciences
- HIV worldwide Performance Panel WWRB304, Sera Care Life Sciences
- HIV worldwide Performance Panel WWRB305, Sera Care Life Sciences
- WHO International Standard-NIBSC Code 02/210, NIBSC
- National Reference for Confirmation Reagent of HIV Antibody, China

**Sero-conversion panels**

A total of 30 sero-conversion panels purchased from SeraCare Life science, Boston Biomedica, Inc and Zeptomatrix Corporation were tested on MP Diagnostics MULTISURE® HIV Rapid Test. The reactivity and average days of detection from 1<sup>st</sup> bleed of MP Diagnostics MULTISURE® HIV Rapid Test was found to be better or comparable with the commercially available Rapid Test kits and Western Blot kits.

**Analytical Sensitivity**

With the titration of one anti HIV-1 positive and one anti HIV-2 positive specimens, the reactivity end point for MP Diagnostics MULTISURE® HIV Rapid Test were found to be at 1:2560 dilution (HIV-1) and 1:10240 dilution (HIV-2) respectively. The results are comparable with commercially available Rapid Test kit.

**Precision**

The inter-assay (between-run) and intra-assay (within-run, within-day and day-to-day) reproducibility of MP Diagnostics MULTISURE® HIV Rapid Test have been evaluated using a set of control panel members. All results obtained consistently fall within the acceptance criteria, indicating the MP Diagnostics MULTISURE® HIV Rapid Test is robust, reproducible and consistent in three lots studied.

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**LIMITED EXPRESSED WARRANTY DISCLAIMER**

The manufacturer makes no express warranty other than that the test kit will function as an *in vitro* diagnostic assay within the specifications and limitations described in the product Instruction Manual when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damage, injury or economic loss howsoever caused by the product in the use or in the application thereof.

**TECHNICAL PROBLEMS / COMPLAINTS**

Should there be a technical problem / complaint, please do the following:

- Note the kit lot number and the expiry date.
- Retain the kits and the results that were obtained.
- Contact the nearest MP Biomedicals office or your local distributor.



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