MULTISURE HIV Rapid Test

Instructions For Use

FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTICS PROCEDURES

REVISION DATE: 2016-01
MDY0012-ENG-0

REF 43032-020 (20 tests)

TRADE NAME AND INTENDED USE

The **MP Diagnostics MULTISURE HIV Rapid Test** is a qualitative immunochromatographic assay for the rapid *in vitro* detection and differentiation of antibodies to HIV-1 and HIV-2 in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants.

This kit is supplied for research purposes only. It is not intended for use in the diagnosis or prognosis of disease.

INTRODUCTION

Human Immunodeficiency Viruses (HIVs) are pathogenic retroviruses that cause HIV infection and the acquired immunodeficiency syndrome (AIDS) [1], which remains one of the most important global public health threats. It was estimated that 35 million people worldwide are living with HIV, with 2.1 million newly infected; and 1.5 million of AIDS-related deaths (UNAIDS, 2013) [2]. HIV infection causes gradual failure of the immune system in human, leading to an increased susceptibility of the body to life-threatening opportunistic infections and cancers.

HIV was first discovered in two separate research groups independently in 1983 [3, 4]. Two types of HIV have been identified and characterized: HIV-1 and HIV-2. Both types are transmitted by sexual contact, through contaminated blood, body fluids and from mother to child during pregnancy or breastfeeding. HIV-1 is the major cause of HIV infection and AIDS in the world [5]. HIV-2 is less common and less infective [6]. Studies of the geographic distribution of HIV infections reveal that HIV-1 is the predominant type worldwide, HIV-2 is largely concentrated in West Africa [6, 7].

Prevention and treatment of AIDS depends on the accurate laboratory diagnosis of HIV infections, which is essential to identify HIV infected persons who could benefit from treatment and to reduce HIV transmission [8]. HIV infections elicit immune responses and induce HIV specific antibodies in human [9]. The serological methods, such as Enzyme-linked Immunosorbent Assay (ELISA), Colloidal Gold Immunochromatographic Rapid Test, and Western Blot (WB) are widely used in the laboratory diagnosis of HIV-1 and HIV-2 infection [10,11].

The **MP Diagnostics MULTISURE HIV Rapid Test** is intended as a rapid screening test, developed to detect antibodies specific to HIV-1 gp120, HIV-1 gp41, HIV-1 p24 (also react with HIV-2) and HIV-2 gp36 antigens in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The **MP Diagnostic MULTISURE HIV Rapid Test kit** is an indirect solid-phase immunochromatographic assay, based on MP Biomedicals' proprietary Reverse Flow technology (US Patent No.: 6,316,205) for simultaneous and differential detection of antibodies to HIV-1 and HIV-2 in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants.

Highly purified recombinant antigens gp120 and gp41 representing HIV-1, gp36 representing HIV-2 and p24 (reactive for both HIV-1 and HIV-2) are striped on the membrane as 4 separate test lines.

The antibodies in the test sample (serum, plasma, finger pricked whole blood or whole blood with anti-coagulants) form antibody-antigen complexes with HIV specific recombinant antigens immobilized on nitrocellulose membrane in the test viewing window as the test sample migrates upward from the sample well.

The bound antibody-antigen complexes are subsequently detected by goat anti-human IgG gold conjugate carried by chase buffer that flows downward giving a pink-purplish color. The control line containing protein A captures human IgG from patient's sample, subsequently binds with the anti-human IgG gold conjugate. The appearance of control line serves to validate the proper addition and migration of sample and chase buffer, as well as the resolubilised anti-human IgG gold conjugate.

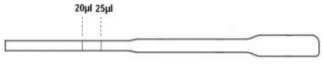
DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on MP Diagnostics' products and packaging. These symbols are the most common ones appearing on medical devices and their packaging.

	Use by	IVD	*In vitro* diagnostic medical device
LOT	Batch Code *Synonyms for this are:* *Lot Number* *Batch Number*	REF	Catalogue Number *Synonyms for this are:* *Reference Number* *Reorder Number*
	Temperature Limitation		Caution
	Manufacturer		Consult Instructions for Use
Σ	Contains sufficient for <n> tests		Do not reuse

KIT COMPONENTS

DEVICE	MP Diagnostics MULTISURE HIV Rapid Test Device Incorporated with recombinant HIV proteins. Packed in individually sealed pouch with a desiccant. Store at 2°C - 28°C	20 devices
APPLICATOR	SAMPLE APPLICATOR With marking of 20µl and 25µl.	20 pieces
BUFFER	CHASE BUFFER Contains sodium azide as preservative.	1 bottle (5ml)



Store at 2°C - 28°C

INSTRUCTIONS FOR USE 1 copy

HEALTH AND SAFETY INFORMATION

1. In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.
3. Wipe any spills of sera, plasma or blood promptly with 0.5% sodium hypochlorite solution.
4. Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 0.5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste-bags.

Pursuant to EC regulation 1272/2008 (CLP), hazardous components are classified and labelled as follows:

Component:	Chase Buffer
Signal Word:	Warning
Pictogram:	
Hazard Statements:	H319 Causes serious eye irritation.
Precautionary Statements:	P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/ face protection.
Supplemental Statements:	EUH 210 Safety Data Sheet is available on request
Contains:	1% Triton X-100

ANALYTICAL PRECAUTIONS:

1. The sample applicator is for single use only. DO NOT re-use the sample applicator.
2. Each sealed test device is for single use only. DO NOT re-use the test device.
3. For *in vitro* diagnostic use only.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
6. Optimal assay performance requires **STRICT ADHERENCE** to the assay procedure described in this Instruction For Use. Deviations from the procedure may lead to aberrant results.
7. Do not interchange reagents between kit lots.
8. Do not use kit components beyond the expiry date printed on the kit box.
9. The chase buffer reagent contains sodium azide as a preservative. Handle reagent carefully to avoid spills on work surface. Clean up spills with absorbent paper and water.
10. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
11. For best results, allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.
12. Humidity and temperature can adversely affect results.
13. DO NOT use the test device if the seal of the pouch is broken.
14. Conduct the test as soon as possible within 1 hour after removing the test device from the pouch.
15. Ensure lighting is adequate for the interpretation of results. The test should be read from a comfortable distance without manipulating the test device. As a rule of thumb, lighting is sufficient if text printed on the test device can be read without difficulty.

STORAGE

1. Store the kit and its components at 2°C - 28°C.
2. Do not freeze the kit and its components.
3. The test device must remain in the sealed pouch until use.
4. Do not use after the expiry date printed on the pouch.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Timer
2. Lancet
3. Alcohol swabs

SPECIMEN COLLECTION

Whole blood can be collected in anti-coagulant containing tubes and used as outlined in the assay procedure immediately or stored at 2°C to 8°C for not more than 72 hours before use.

The presence of 6 anti-coagulants, Acid Citrate Dextrose (ACD), Citrate-phosphate-dextrose (CPD), Ethylenediaminetetraacetic acid (EDTA), Potassium Oxalate (K-Oxalate), Lithium Heparin (Li Hep) and Sodium Citrate (Na Citrate) were found to have no effects on the performance of MP Diagnostics MULTISURE HIV Rapid Test.

Serum / plasma samples should be stored at 2°C to 8°C if the test is to be run within 7 days of collection or frozen at -20°C or colder if the test is to be delayed for more than 7 days. Clear, non-hemolyzed samples are preferred. Lipemic, icteric or contaminated (particulate or bacterial) samples should be filtered (0.45µm) or centrifuged before testing.

Repeated freeze-thawing of the sample is not recommended. Do not use specimens (serum & plasma) with more than five (5) freeze-thaw cycles.

ASSAY PROCEDURE

IMPORTANT: Strict adherence to the assay procedure will ensure optimal performance. Deviations from the procedure may lead to aberrant results.

Note:

- Allow the kit to warm to room temperature (25°C ± 3°C) before running the assay.
- For best results, conduct the assay at room temperature (25°C ± 3°C).

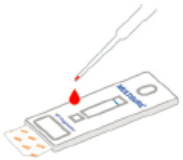
1. Open the pouch by tearing at the tear notch on the right side of the pouch.
2. Label the test device with the sample name.
3. Proceed with the assay procedures as shown in the diagrams below.

Assay Procedures for MULTISURE HIV Rapid Test

1

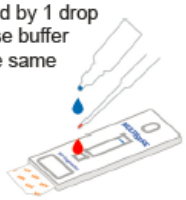
For Serum/Plasma Samples

Add **25µl** serum/plasma sample into square well.



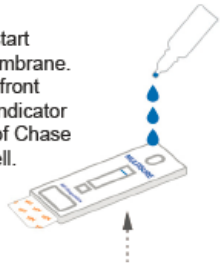
For Whole Blood Samples

Add **20µl** whole blood sample into square well, followed by 1 drop of chase buffer into the same well.



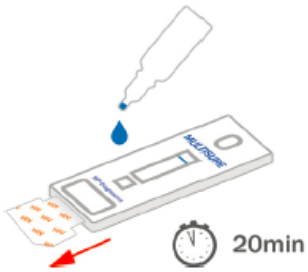
2

Sample front will start wicking up the membrane. When the sample front reaches the blue indicator line, add 3 drops of Chase Buffer into oval well.



(Caution: Do not allow sample front to flow out of Test Viewing Window.)

3



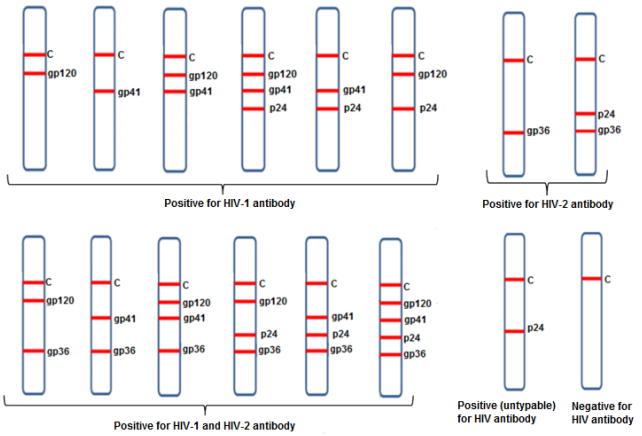
- Pull out the "HIV" Pull Tab until resistance is felt.
- Add **1 drop** of Chase Buffer into square well.
- Start timing, read results at **20 minutes**.
- Do not read the results after 25 minutes.

Example of test device with all visible test lines

QUALITY CONTROL

The control line is an internal procedure control. Absence of control line indicates insufficient/improper sample volume, incorrect assay technique used or faulty device. The assay procedure should be reviewed before repeating with a new device.

INTERPRETATION OF RESULTS



1. Positive for HIV-1 antibody

A test is HIV-1 positive if it meets any of the following criteria:

(i) Control Line (C) appears with visible gp120 test line (with or without visible gp41 and/or p24 test lines)

(ii) Control Line (C) appears with visible gp41 test line (with or without visible gp120 and/or p24 test lines)

(iii) Control Line (C) appears with visible gp120 & gp41 test lines (with or without visible p24 test line)

2. Positive for HIV-2 antibody

A test is HIV-2 positive if Control Line (C) appears with visible gp36 test line (with or without visible p24 test line)

3. Positive for HIV-1 and HIV-2 antibody

A test is HIV-1 and HIV-2 positive if it meets any of the following criteria:

(i) Control Line (C) appears with visible gp120 & gp36 test lines (with or without visible gp41 and/or p24 test lines)

(ii) Control Line (C) appears with visible gp41 & gp36 test lines (with or without visible gp120 and/or p24 test lines)

(iii) Control Line (C) appears with visible gp120 & gp41 & gp36 test lines (with or without visible p24 test line)

4. Positive (untypable) for HIV antibody

A test is HIV positive (untypable) if Control Line (C) appears with visible p24 test line only.

5. Negative for HIV antibody

A test is negative if Control line (C) appears and Test line(s) are not visible.

6. Invalid

A test is invalid if Control line (C) is absent. The assay should be repeated using a new device.

LIMITATIONS OF THE PROCEDURE

The **MP Diagnostics MULTISURE HIV Rapid Test** is for research use and for the detection and differentiation of HIV antibodies in serum, plasma, finger-pricked whole blood or whole blood with anti-coagulants. This test is not for determining the quantitative value or the rate of increase in HIV antibodies.

Optimal assay performance requires the strict adherence to the assay procedure described. Deviation from the procedure may lead to aberrant results.

REFERENCES

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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:

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

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