multiplo
rapid HBc/HIV/HCV antibody test

Multiplo Rapid HBc/HIV/HCV Antibody Test (Multiplo HBc/HIV/HCV) is a qualitative rapid vertical flow test to detect the presence of antibodies to human immunodeficiency virus (HIV) type 1 and 2 (HIV-1/2), hepatitis B virus core antigen (HBc), and hepatitis C virus (HCV) in human serum, plasma or whole blood specimens.

INTENDED USE

Multiplo HBc/HIV/HCV is a single use, qualitative immunoassay to detect antibodies to hepatitis B virus core antigen (anti-HBc), human immunodeficiency virus (HIV) Type 1 and Type 2, and hepatitis C virus (HCV) in human serum, plasma, or whole blood. Multiplo HBc/HIV/HCV is intended for use by healthcare professionals as an aid in the diagnosis of infection with HBV, HIV-1 and/or HIV-2, and HCV.

MATERIALS PROVIDED

Product Format	Content
Multiplo HBc/HIV/HCV (POC) **815311004551** *(for Fingerstick Whole Blood)*	20 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 1 auto-fill pipette 1 sample tube 1 vial Universal Buffer 1 lancet (sterile) 1 alcohol swab 1 package insert
Multiplo HBc/HIV/HCV (LAB+) **815311004575** *(for Venipuncture Whole Blood/Serum/ Plasma)*	50 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 2 bottles Universal Buffer 50 transfer pipettes 50 sample tubes 1 package insert
Multiplo HBc/HIV/HCV (LAB S/P) **815311004582** *(for Serum/Plasma)*	50 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 2 bottles Universal Buffer 50 transfer pipettes 1 package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Laboratory coat
- Eye protection
- Permanent marking pen
- Disinfectant
- Biohazard waste container(s)

WARNINGS AND SAFETY RECOMMENDATIONS

1. **The test is intended for *in vitro* diagnostic use in healthcare settings. This product is not to be used for self-testing.**
2. **Read this package insert completely and carefully prior to use of this test. If the directions are not followed exactly, inaccurate test results may occur.**
3. Handle specimens and all materials contacting specimens as if capable of transmitting infectious agents. It is recommended that all specimens and test reagents be handled according to Universal Precautions.[1-4]
4. Do not smoke, eat, or drink in areas where specimens or test reagents are handled. Do not pipette by mouth.
5. Wear disposable gloves, laboratory coat and eye protection throughout the test procedure.
6. Wipe spills promptly with a 1:10 sodium hypochlorite solution or other appropriate disinfectant.[5]
7. Dispose of all test specimens and materials used in the test in a biohazard waste container. Follow local guidelines for the disposal of solid and liquid biohazardous waste.

HANDLING AND STORAGE PRECAUTIONS

1. Use test components only once, excluding bottles of Universal Buffer in LAB+ and LAB S/P products, and dispose of properly.
2. Do not touch the immunoreactive test membrane. Touching the membrane may compromise test results.
3. Exercise care in handling test components to prevent contamination.
4. Adequate lighting is required to read the test result.
5. Store in a dry place at 2 - 30°C.
6. Keep pouches sealed until immediately prior to use. Ensure that the pouch is intact and that the expiration date printed on the outside of the pouch is valid. If the pouch is not intact or is expired, discard and obtain a new pouch.
7. Perform Multiplo HBc/HIV/HCV on a flat work surface to ensure that reagents and specimens uniformly flow through the device.
8. Do not interchange reagents or devices from different lots.

SPECIMEN HANDLING & COLLECTION

Serum/Plasma Collection (Cat#815311004575 & 815311004582)

1. Fresh serum and plasma specimens may be tested immediately upon receipt or stored at 2 - 8°C for up to 5 days prior to testing. If storage is necessary for over 5 days, serum or plasma specimens should be stored at -20°C or below.
2. Particulate matter can block the test membrane or cause high background making the results difficult to interpret. Cloudy, viscous, or highly hemolyzed specimens should not be used for testing.
3. For serum or plasma that has been previously frozen:
   a. Thaw completely at room temperature (15 - 27°C) and mix thoroughly by gently tapping the capped tube.
   b. Centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15 - 27°C) at 3361 g (radius of rotor 8.35 cm = 6000 rpm) for at least 5 minutes and use only the clear supernatant for testing.
4. Avoid multiple freeze-thaw cycles. A specimen should not be frozen and thawed more than twice prior to use with this test.
5. Proceed to TEST PROCEDURE.

Venipuncture Whole Blood Collection and Use (Cat#815311004575)

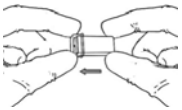
1. Use standard venous phlebotomy procedures to collect a whole blood sample. If specimens are not tested at the time of collection, they may be stored at 2 - 8°C for up to 5 days prior to testing. If storage is necessary for over 5 days, plasma should be separated from the whole blood specimen and stored at -20°C or below.
2. Place the sample tube in a secured rack on a flat surface. Add 5 drops from the bottle of Universal Buffer to the sample tube.
3. Using the transfer pipette provided, collect whole blood from the specimen tube. Add 1 drop of whole blood to the sample tube prepared in Step 2.
4. Hold the sample tube and gently tap the side of the tube near the bottom until the mixture becomes a clear reddish colour.
5. Proceed to TEST PROCEDURE.

Fingerstick Whole Blood Collection and Use (Cat#815311004551)

1. Place the sample tube in a secured rack on a flat surface.

2. Add 5 drops from the vial of Universal Buffer to the sample tube.

3. Using an alcohol swab, clean the index finger. Allow the finger to dry thoroughly.



4. Remove the protective cap from the sterile lancet provided with the test. Do not use lancet if damaged.

5. Firmly press the lancet against the puncture site to activate the device and puncture the skin.

6. Apply gentle pressure and massage the lanced fingertip beside the point of puncture to form a drop of blood.

7. Use the auto-fill pipette provided to collect a drop of blood from the fingerstick site. To do this, touch the tip of the pipette to the blood sample in a horizontal position. The blood sample will be automatically drawn to the black fill line and stop. **Do not** squeeze the pipette bulb during filling.

8. Place the tip of the auto-fill pipette into the Universal Buffer in the sample tube (prepared in Step 2). Squeeze the bulb to empty the blood sample into the tube. Discard the auto-fill pipette.

9. Hold the sample tube and gently tap the side of the tube near the bottom until the mixture becomes a clear reddish colour.

10. Proceed to TEST PROCEDURE.

TEST PROCEDURE

Important Notes:

- Check the Multiplo HBc/HIV/HCV catalogue number and select corresponding procedure.
- All solutions must be completely absorbed into the test membrane before proceeding to the next step in the test procedure.
- Once the test has been started, all subsequent steps should be completed without interruption.
- Perform the test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.
- Read the test results immediately.

Whole Blood Procedure
Multiplo HBc/HIV/HCV (Cat # 815311004551 OR 815311004575)

❶

Pour the entire contents of the sample tube into the center of the test cartridge. Allow the specimen to absorb completely.

❷

Place the InstantGold cap on the test cartridge. Select the catalogue number that corresponds to the test format being used and proceed to the next step.

❸

Cat. # 815311004551

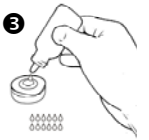
Dispense the remaining buffer from the vial of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely.

Remove the InstantGold cap and wait for the solution to absorb completely.

Read test results immediately.

OR

❸



Cat. # 815311004575

Dispense 12 drops of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely.

Remove the InstantGold cap, wait for the solution to absorb completely. Add 3 drops of Universal Buffer to clarify results.

Read test results immediately.

Serum/Plasma Procedure
Multiplo HBc/HIV/HCV (Cat # 815311004575 OR 815311004582)

❶

Apply 3 drops of Universal Buffer to the center of the test cartridge. Allow the buffer to absorb completely.

❷

Apply 1 drop of serum or plasma specimen to the center of the test cartridge. Allow the specimen to absorb completely.

If the serum or plasma specimen is not absorbed within 30 seconds, centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15 - 27°C) at 3361 g (radius of rotor 8.35 cm = 6000 rpm) for at least 5 minutes. Test the clear supernatant using a new test cartridge. If slow absorption persists after centrifugation, the specimen may not be suitable for use.

❸

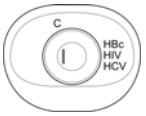
Place the InstantGold cap on the test cartridge. Dispense 12 drops of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely.

Remove the InstantGold cap, wait for the solution to absorb completely. Add 3 drops of Universal Buffer to clarify results.

Read test results immediately.

TEST RESULTS

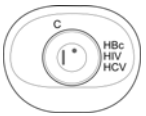
Non-Reactive Test Result



Probable Non-Exposure to HBV, HIV-1/2 and HCV

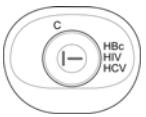
The presence of a vertical red line under the **C** and the absence of a horizontal red line beside **HIV** and absence of a red dot beside **HBc** and a red dot beside **HCV** on the test means that the individual has probably not been exposed to HIV-1/2, hepatitis B virus (HBV) or HCV.

Reactive Test Results



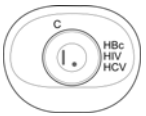
Probable Exposure to HBV

The presence of a vertical red line under the **C** and a red dot beside the **HBc** on the test indicates the individual might have been exposed to HBV. It means that HBV core antibodies are probably present in the individual's blood. Further testing is required to determine HBV infection status.



Probable Exposure to HIV-1 and/or HIV-2

The presence of a vertical red line under the **C** and a horizontal red line beside **HIV** on the test indicates the individual may have been exposed to HIV-1 and/or HIV-2. It means that HIV-1 and/or HIV-2 antibodies are probably present in the individual's blood.



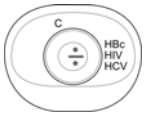
Probable Exposure to HCV

The presence of a vertical red line under the **C** and a red dot beside **HCV** on the test indicates the individual might have been exposed to HCV. It means that HCV antibodies are probably present in the individual's blood.

Probable Exposure to Multiple Viruses

The presence of a vertical red line under the **C** with a red line beside **HIV** and/or a red dot beside **HBc** and/or **HCV** on the test means the individual might have been exposed to more than one of HIV-1/2, HBV or HCV.

Invalid Test Results



The result is Invalid if no red line appears under the **C** or if the red line under the **C** appears broken, even if a line appears beside **HIV** or a dot beside **HBc** and/or **HCV** on the test. The absence of the red line under the **C** or the presence of a broken line under the **C** indicates that there has been a problem, with the test or the specimen, during the Test Procedure.

If an invalid test result occurs, the test procedure should be repeated with a new Multiplo HBc/HIV/HCV test. If the problem persists, contact MedMira Customer Support.

QUALITY CONTROL

It is the responsibility of the user to establish an adequate quality assurance program to ensure the proper performance of this rapid test under its conditions of use.

Built-in Control Features

This rapid test includes a built-in procedural and reagent Control Line that demonstrates the validity of the testing procedure and reagent function. A vertical red line under the "**C**" (Control Zone) on the test cartridge indicates that specimen has been added to the test cartridge, and that the test reagents are functioning properly. The Control Line will appear on all valid tests, regardless of whether the test result is Reactive or Non-Reactive (see **Test Results** section).

External Test Controls

Test Controls are available as an accessory to this test. Test controls validate the storage and ability of the test to detect the analytes.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

1) HIV—Sensitivity was evaluated in a multi-center clinical trial in various North American and African cities. Results indicated 99.8% sensitivity when 1967 HIV positive specimens were tested.

2) HCV—Sensitivity was evaluated at four different testing sites in North America and Europe using previously characterized specimens. Results indicated 99.1% sensitivity when 349 HCV positive specimens were tested.

3) HBc—Sensitivity was evaluated at one testing site in North America using previously characterized specimens. Results indicated 96.2% sensitivity when 53 HBc positive specimens were tested.

4) HBc/HIV/HCV—Sensitivity was evaluated at one testing site in North America with 176 previously characterized specimens. The sensitivity values for each seromarker were as follows: HBc 51/53 = 96.2%, HIV 56/56 = 100%, and HCV 67/67 = 100%

The data from all clinical trials conducted was combined to calculate the total sensitivity of each disease marker (Table 1).

Table 1 : Combined Sensitivity for the detection of HBc, HIV and HCV

Analyte	MedMira Reactive Samples	Confirmed Reactive Samples	Sensitivity
HBc	51	53	96.2%
HIV	1963	1967	99.8%
HCV	346	349	99.1%

SPECIFICITY

The overall specificity of the rapid test was 100% when 459 HBV, HIV, and HCV negative specimens were tested (117 HBV, 169 HCV, and 173 HIV).

The data from all clinical trials conducted was combined to calculate the total specificity of each disease marker (Table 2).

Table 2 : Combined Specificity for the detection of HBc, HIV and HCV

Analyte	MedMira Non-Reactive Samples	Confirmed Non-Reactive Samples	Specificity
HBc	117	117	100%
HIV	11630	11669	99.7%
HCV	587	589	99.7%

LIMITATIONS OF THE TEST

1. The test must be used in accordance with this package insert to ensure accurate results.
2. The test is for use only with serum, plasma, or whole blood specimens. Use of other types of specimens may yield inaccurate results.
3. Test results are to be read and interpreted immediately upon completion of the test procedure. A delay in reading test results may yield inaccurate results.
4. A Reactive test result suggests the presence of HIV, and/or HBc, and/or HCV antibodies in the specimen. Multiplo HBc/HIV/HCV is intended to be used as an aid in the diagnosis of infection with HIV, HBV and/or HCV.
5. The intensity of the red line and/or dot (Reactive Test Result) does not necessarily correlate with the antibody titre of the specimen.
6. A Non-Reactive test result indicates the absence of detectable antibodies to HBc, HIV and/or HCV in the specimen but does not exclude the possibility of exposure to, or infection with HIV, HBV and/or HCV. Following a recent exposure, it may take several weeks to months for the antibody response to reach detectable levels.
7. All Reactive test results should be confirmed and evaluated with respect to an overall clinical evaluation before a diagnosis is made.

REFERENCE DOCUMENTS

1. CDC. Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings. MMWR Recommendations and Reports. 1988. 37(24):377-388.
2. Laboratory Biosafety Guidelines: 3rd Edition, Population and Public Health Branch, Health Canada. 2004.
3. Biosafety in Microbiological and Biomedical Laboratories: 5th Edition, US Department of Health and Human Services, 2009.
4. Laboratory Biosafety Manual: Third Edition, World Health Organization, 2004. Geneva.
5. CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. *Healthcare Infection Control Practices Advisory Committee.*

PRODUCT WARRANTY

MedMira Laboratories Inc. guarantees the quality of this product if stored and used as instructed. Any component of the test found to be defective shall be replaced free of charge upon return of the defective product. MedMira Laboratories Inc. disclaims any implied warranty of merchantability or fitness for a particular purpose, and in no event shall MedMira Laboratories Inc. be liable for consequent damage.

Explanation of Symbols

	Storage conditions		Do not reuse
	Manufacturer		Use by date
REF	Catalogue number	IVD	For *In Vitro* Diagnostic Use
LOT	Lot number		Consult instructions for use

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