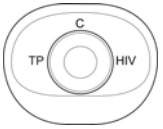
FOR RESEARCH USE ONLY. Not for use in diagnostic procedures.

miriad
rapid TP/HIV antibody test

Miriad Rapid TP/HIV Antibody Test (Miriad TP/HIV) is a qualitative rapid vertical flow test to detect the presence of antibodies to *Treponema pallidum* bacteria (TP), the causative agent of syphilis and human immunodeficiency virus (HIV) type 1 and 2 (HIV-1/2) in human serum, plasma or whole blood specimens.

PRODUCT COMPONENTS

	**Test Cartridge** - a unitized, leak-proof plastic test cartridge encasing the reaction membrane coated with a combination of synthetic peptides and recombinant antigens which function to capture anti-TP and anti-HIV-1/2 antibodies which may be present in human serum, plasma, or whole blood
	**Universal Buffer** - solution composed of Tris-buffered saline, lysing agents, synthetic polymers and anti-microbial agents (Preservative: 0.05% ProClin 950)
	**InstantGold cap** - plastic cap housing a filter medium impregnated with a gold label which produces a colorimetric reaction that can be easily visualized and interpreted in the test zone and control zone

PRODUCT FORMATS & CONTENTS

Product	Contents
Miriad TP/HIV (LAB+) **Cat. No. 815311005961**	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

ACCESSORIES

Test Controls (Cat. No. 815311006074)

OTHER MATERIALS YOU MAY REQUIRE

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

SPECIMEN HANDLING

Serum/Plasma

1. Plasma obtained using EDTA, heparin, or sodium citrate as anticoagulants is suitable for testing.
2. Fresh serum and plasma specimens may be tested immediately upon receipt or stored at 2 - 8°C (35 - 45°F) for up to five (5) days prior to testing. If storage is necessary for over five (5) days, serum and plasma specimens should be stored at -20°C (-4°F) or below.
3. 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.
4. For serum or plasma that has been previously frozen:
   a. Thaw completely at room temperature (15 - 27°C, 60 - 80°F) 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, 60 - 80°F) at 3361 g (radius of rotor 8.35 cm = 6000 rpm) for at least five (5) minutes and use only the clear supernatant for testing.
5. Avoid multiple freeze-thaw cycles. A specimen should not be frozen and thawed more than twice prior to use with this test.

Venipuncture Whole Blood

1. If specimens are not tested at the time of collection, they may be stored at 2 - 8°C (35 - 45°F) for up to 24 hours prior to testing. If storage is necessary for over 24 hours, plasma should be separated from the whole blood specimen and stored at -20°C (-4°F) or below.

SUGGESTED PROCEDURES

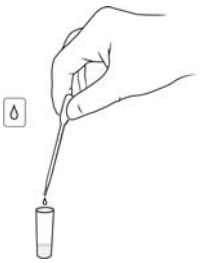
These procedures have been optimized during internal testing. Different results may occur if the procedures are altered.

- 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.

SAMPLE PREPARATION

1. Allow all test components and specimens to equilibrate to room temperature (15 - 27°C, 60 - 80°F) for 30 - 60 minutes prior to opening the container or Mylar pouch.
2. Remove test components from Mylar pouch using the notched corners to tear open the Mylar pouch.
3. Ensure that a silica gel packet is present in the pouch containing the test cartridge and InstantGold cap. If a silica gel packet is not present, discard the Mylar pouch and its components and open a new pouch.
4. Align the test cartridge in front of the specimen to be tested. Label the test cartridge on the white plastic casing with a permanent marking pen. **Do not label or make marks on the reaction membrane.**
5. Place a MedMira supplied sample tube in a secured rack on a flat surface. Add seven (7) drops from the bottle of Universal Buffer to the sample tube.

6. Using the transfer pipette provided, collect specimen from the specimen collection tube. Add one (1) drop of specimen to the sample tube prepared in Step 5.

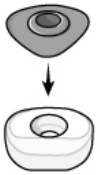


7. Hold the sample tube and gently tap the side of the tube near the bottom until the mixture becomes translucent. This can take 15-30 seconds of gentle tapping to mix properly.

TEST PROCEDURE

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

2. Place the InstantGold cap on the test cartridge.

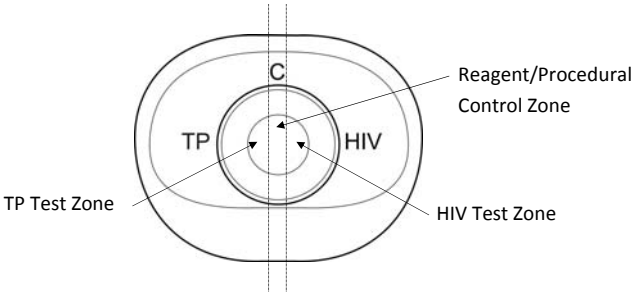


3. Dispense twelve (12) drops of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely.

Remove the InstantGold cap, wait for the solution to absorb completely. Add three (3) drops of Universal Buffer to clarify results. Wait for the solution to absorb completely. Read test results immediately.

READING TEST RESULTS

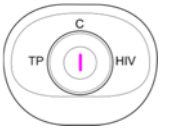
The reaction membrane is made up of THREE zones: reagent/procedural control zone, TP test zone and HIV test zone. The first step in reading test results is to look for a vertical line in the control zone. A solid line in the control zone validates the test. If no line is present repeat the test with a new Miriad TP/HIV test. If the control line is present, examine the TP and HIV test zones for the presence of a dot of any intensity.



Non-Reactive Test Result

Probable Absence of Antibodies to TP and HIV-1/2

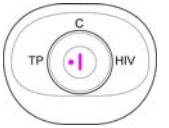
The presence of a vertical red line under the **C** and the absence of a red dot beside **TP** and a red dot beside **HIV** on the test means that the sample probably does not contain antibodies to TP or HIV-1/2.



Reactive Test Results

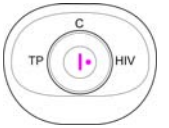
Probable Presence of Antibodies to TP

The presence of a vertical red line under the **C** and a red dot beside the **TP** on the test indicates that TP antibodies are probably present in the sample.



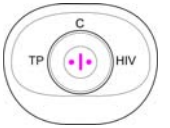
Probable Presence of Antibodies to HIV-1/2

The presence of a vertical red line under the **C** and a red dot beside **HIV** on the test indicates that HIV-1 and/or HIV-2 antibodies are probably present in the sample.



Probable Presence of Antibodies to TP and HIV-1/2

The presence of a vertical red line under the **C** with a red dot beside **TP** and a red dot beside **HIV** on the test means the sample probably contains antibodies to TP and HIV-1/2.

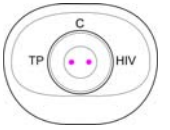


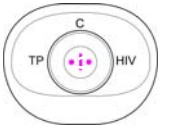
***Note: intensity of the line or dot can vary, examine the test closely before interpreting results.**

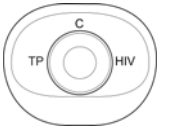
Invalid Test Results

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 dot appears beside **TP** and/or a dot beside **HIV** 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 either the test or the specimen, during the Test Procedure.

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







RECOMMENDATIONS AND LIMITATIONS

1. **The test is intended for RESEARCH USE ONLY. Not for use in diagnostic procedures.**
2. **Read this package insert completely and carefully prior to use of this test. If the directions are not followed, inaccurate or unexpected test results may occur.**
3. Suggested procedures have been provided for whole blood, serum, or plasma. Use of other sample types is possible but has not been experimented with at MedMira.
4. When adding the sample to the specimen preparation tube take care that the drop goes into the Universal Buffer at the bottom of the tube. If the drop of sample remains attached to the walls of the sample tube tap the tube on the bench to move the drop to the bottom.
5. Tapping of the sample tube to mix the specimen with Universal Buffer is critical to ensure quality results. It is recommended that tapping/mixing is performed for approximately 15-30 seconds.
6. Some specimens may yield results with higher background. If high background is observed centrifuge the specimen and retest.
7. If the specimen does not flow through the test membrane or particulate matter accumulates around the edges of the test membrane and does not pass through after 45 seconds, such specimens must be either (1) centrifuged and retested or (2) discarded.
8. 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.[1-5]
9. Wear disposable gloves, laboratory coat and eye protection throughout the test procedure.
10. 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. 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.
11. Wipe spills promptly with a 1:10 sodium hypochlorite solution or other appropriate disinfectant.
12. Do not smoke, eat, or drink in areas where specimens or test reagents are handled.

HANDLING AND STORAGE

1. Use test components only once, excluding bottles of Universal Buffer, and dispose of properly.
2. Do not touch the reaction 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 (35 - 85°F).
6. Keep Mylar pouches sealed until immediately prior to use. Ensure that the Mylar 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 Miriad TP/HIV 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.

Explanation of Symbols

	Temperature limit		Do not reuse
	Manufacturer		Use by
REF	Cat. No.		Consult instructions for use
LOT	Lot number		

QUALITY 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 **Reading Test Results** section).

REFERENCES

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. Canadian Biosafety Standard: 2nd Edition, Public Health Agency of Canada, 2015.
3. Canadian Biosafety Handbook: 2nd Edition, Public Health Agency of Canada, 2016
4. Biosafety in Microbiological and Biomedical Laboratories: 5th Edition, US Department of Health and Human Services, 2009.
5. Laboratory Biosafety Manual: Third Edition, World Health Organization, 2004. Geneva.

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 change 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 held liable for consequent damage.

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