**INTRODUCTION**

The MP Diagnostics HIV BLOT 2.2 is intended for use as a specific test for the in vitro detection of antibodies against HIV-1 and HIV-2. The antigen strips can be used to aid in the identification of patients who may be at risk for HIV infection. After reacting with the antigen strips, some samples cause dark patches on the spot of the strip. These samples are positive for HIV antibodies. The antigen strips can be used to detect antibodies to HIV-1 and/or HIV-2, the etiologic agents of the Acquired Immunodeficiency Syndrome (AIDS).

**COMPONENTS**

NITROCELLULOSE STRIPS

- Each strip contains HIV-1 antigenic proteins from partially purified inactivated HIV-1 (p55 GAG Precursor protein Discreet band; p66 POL Reverse Discreet band; gp120 ENV Outermembrane Diffuse glycoprotein; p24 and/or p17. The bands seen as p42 and p55 are not a common finding and should be interpreted as gp41 band. Many non-HIV infected samples give a strong gp41 band response. The bands seen as p31, p51, and p66 are seen as a polypeptide pattern (WHO), 1990 or POL (ASTPHLD /CDC), 1989 USA.

- Additionally, the buffer for the assay has been used and contaminated materials at 12°C (35°F) at 15 p.c. for 30 minutes before disposal. Alternatively, the assay can be stored in a refrigerator at 4°C (39°F) for 30 minutes before disposal in conformance with the storage and transportation requirements.

**MANUFACTURER**

Antigen strips with the use of a 20°C (68°F) water bath or laboratory equipment for the storage of reagents. Samples should be stored at 2°C (36°F) to 8°C (46°F) in a refrigerator or at 22°C (72°F) to 25°C (77°F) in a controlled environment.

The interpretation process involves the following:

1. Identify if the test was done in-house or by an outside laboratory.
2. Ensure all controls are HIV-negative.
3. Check the date of the test and the expiration date of the test kit.
4. Cross-reference the kit lot number with the lot number of the test kit.
5. Determine if the test was performed correctly.
6. Review the results and ensure they are interpreted correctly.

**STORAGE INSTRUCTIONS**

- Store HIV BLOT 2.2 at 2°C to 8°C (36°F to 46°F) and at room temperature (25°C to 30°C) for 30 days. Do not use after the expiration date.
- Store the specimen at 2°C (36°F) to 8°C (46°F) in a refrigerator or at 22°C (72°F) to 25°C (77°F) in a controlled environment.

**SPECIMEN COLLECTION, TRANSPORT AND STORAGE**

- Serum or plasma samples can be collected in EDTA, heparin or sodium citrate tubes. Specimen shall be stored at the ambient temperature until the aliquots from vials.
- The presence of HIV-1 or HIV-2 antibodies in a specimen indicates that the test is to be done with the reagents included in the kit.
- The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid

**DESCRIPTION OF SYMBOLS USED**

- The symbols used in this document are explained in detail in this section. The symbols are used to identify the important sections of the report.

**RECOMMENDATIONS**

- The recommendations for the interpretation of test results are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**PREPARATION OF REAGENTS**

- Dilute WASH BUFFER to be used for washing the strips.
- Add 2 ml of DILUTED WASH BUFFER to each well.
- Add 2 ml of working concentation of alkaline phosphatase conjugate or substrate.
- Include strips for Strong Reactive, Weak Reactive and background.

**PREPARATION OF SPECIMENS**

- Specimen tubes shall be capped for storage.
- The specimen should be stored at 2°C (36°F) to 8°C (46°F) in a refrigerator or at 22°C (72°F) to 25°C (77°F) in a controlled environment.

**SYMBOLS USED IN THE FIGURE**

- The symbols used in the figure are explained in detail in this section. The symbols are used to identify the important sections of the figure.

**TYPICAL CHARTS AND PATTERNS**

- The typical charts and patterns are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**INTERPRETATION OF RESULTS**

- The interpretation of the test results is as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**MATERIALS REQUIRED TO PERFORM TEST**

- The materials required to perform the test are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**GENERAL INFORMATION**

- The general information is as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**MATERIALS REQUIRED TO PERFORM TEST**

- The materials required to perform the test are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**REFERENCES**

- The references are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**NOTES**

- The notes are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**LOGICAL INTEGERS**

- The logical integrers are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**QUALITY CONTROL**

- The quality control tests are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**REPORT**

- The report is as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**INITIALS**

- The initials are as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**DIAGNOSIS**

- The diagnosis is as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.

**PROCEDURE**

- The procedure is as follows:

- **Positive:** The test results should be interpreted using the control bands visible and without misinterpretation. Developed strips must be completely dry to avoid.
**INTERPRETATION OF RESULTS FOR INDETERMINATE BLOT**

INDETERMINATE results should not be used as the basis for diagnosis of HIV-1 infection. Based on the fact that most INDETERMINATE results should not be used as the basis for definitively identifying a sample as positive or negative, a BLOT result should be considered INDETERMINATE if it shows a pattern of antibody bands typical of HIV-1 but also shows bands typical of a different virus or antigen.

**LIMITATION OF THE METHOD**

Detection of antibodies to HIV-1 does not constitute a diagnosis of Acquired Immunodeficiency Syndrome (AIDS). A negative test result indicates that the test specimen is negative for HIV-1 antibodies; a positive result indicates the presence of HIV-1 antibodies. A positive result must be confirmed by an independent test to be considered positive. A negative result is not necessarily indicative of the absence of HIV-1 infection. False-negative results may occur in cases of recent infection, when the test was performed too soon after the initial infection. False-positive results may occur due to cross-reactivity with other viruses, such as hepatitis B or C, or due to nonspecific staining of the immunochemical reagent.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The performance of the MP HDV SPEC BLOT 2.2 for the detection of antibodies to HIV-1 and HIV-2 was evaluated in clinical studies.

**Theoretical basis of results:**

Table 1: Summary study of HIV-1 and/or antibody reactivity to HIV-1 in a seropositive sample. (Number of samples = 179)

<table>
<thead>
<tr>
<th>HIV-1 seropositive samples</th>
<th>HIV-2 seropositive samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>151 (89.3%)</td>
<td>90 (51.0%)</td>
</tr>
<tr>
<td>28 (16.0%)</td>
<td>39 (21.4%)</td>
</tr>
<tr>
<td>1 (0.6%)</td>
<td>1 (0.6%)</td>
</tr>
</tbody>
</table>

Table 2: Specificity study of HIV-1 viral antigen reactivity with normal donor samples and sera with various viral infections.

**Non-specific bands develop and do not inhibit antigen reactivity**

A total of 17 commercial HIV-1 seroconversion panels were tested with the MP HDV SPEC BLOT 2.2 and results that showed no inhibition of antigen reactivity were considered to indicate a false-positive result in the same sample in all panels.

**LIMITED EXPRESS WRITTEN WARRANTY DISCLAIMER**

The manufacturer makes no expressed warranty other than that the test will function as an in vitro diagnostic assay within the specific conditions described in the directions for use. The manufacturer disclaims any warranty, expressed or implied, as to the performance or implied warranty with respect to merchantability, fitness for use or implied purpose. The manufacturer is limited to either the replacement of the product or refund of the purchase price (except for the cost of the test). The manufacturer shall not be liable to the purchaser or third parties for any injury or economic loss caused by the product in the course of or as a result of the application thereof.

**BIBLIOGRAPHY**


3. J. Schubach, M. Popovic, B. V. Gelder, M. A. Gonda, G. M. Sansigurahen and R. C. Gallo. 1986. Serological analysis of defects in human immunodeficiency virus type 1 infection. J Virol. 56:608-610.

4. F. Clavel, D. Guetard., F. Brun-Vezinet, et al. 1986 Isolation of a second human immunodeficiency virus (HTLV-III) associated with AIDS. Science 224, 503-505.


11. World Health Organization. 1988. Guidelines for HIV Diagnosis and monitoring of antiretroviral therapy. Regional Office for South-East Asia, New Delhi, India.

**TROUBLE SHOOTING CHART**

1. Dark spots on developed strip.
   - Solution: Check test positive control. Read test strip again.

2. White patches on developed strip.
   - Solution: Check control positive. Read test strip again.

3. Absence of Serum Control Band on strips.
   - Solution: Use new plates.

4. Strips are defective.
   - Solution: Use new plates.

5. Watery marks on developed strips.
   - Solution: Use new plates.

6. Bands other than the Serum Control band develop on negative control.
   - Solution: Use new plates.

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3. J. Schubach, M. Popovic, B. V. Gelder, M. A. Gonda, G. M. Sansigurahen and R. C. Gallo. 1986. Serological analysis of defects in human immunodeficiency virus type 1 infection. J Virol. 56:608-610.

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