

Hema•Strip® HIV-1/2

FOR *IN VITRO* DIAGNOSTIC USE

A rapid test for the detection of antibodies to
Human Immunodeficiency Virus
(HIV-1 and HIV-2) in whole blood, serum or plasma

STORAGE: Store at 20 to 33 °C

For Export Use Only – Not to be sold or distributed in the United States
For *in-vitro* diagnostic use only
For professional use only

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NAME AND INTENDED USE

The Hema•Strip HIV 1/2 is a single use rapid screening test for the detection of antibodies to HIV 1/2 in human whole blood, serum or plasma. Positive results are supportive evidence of exposure to HIV 1/2 and can be used to support a clinical diagnosis of HIV 1/2. Negative results should not be used to exclude infection. The Hema•Strip HIV 1/2 test is intended for use by medical professionals and must be used in accordance with the directions provided.

SUMMARY AND EXPLANATION OF THE TEST

The Human Immunodeficiency Virus (HIV) is a retrovirus, identified in 1983 as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS) [1]. AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune defense system. In the infected individual the virus causes a depletion of subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, contamination by blood or blood products and mother-to-newborn transmission [2-4].

Medical experts working for the United Nations (UN) have reported that almost 16,000 new infections are occurring a day. The UN has reported that worldwide, about 11.7 million people of all ages have died from AIDS in the 70's and 80's [3,4]. As of July 1996, an estimated 22 million people worldwide were living with HIV infection and HIV epidemics are rapidly increasing [5].

The HIV virus consists of a genomic RNA molecule protected by a capsid and an envelope. The HIV envelope is the major target for humoral antibody response. The presence of the virus in patients causes the immune system to elicit the production of anti-HIV antibodies. The detection of these antibodies can be used as a diagnostic tool.

ELISA, Western blots, PCR-based assays and various other test systems are currently available for HIV1/2 detection [6-10]. The Hema-Strip HIV 1/2 is a rapid immunochromatographic test, which is simple and easy to use. The Hema•Strip HIV 1/2 assay system utilizes immobilized antigens for the detection of antibodies to HIV1/2 in blood with high degree of sensitivity and specificity.

PRINCIPLES OF THE PROCEDURE

The Hema•Strip HIV 1/2 assay employs a unique combination of a specific antibody binding protein, which is conjugated on colloidal gold dye particles and antigens to HIV 1/2, which are bound to the solid phase membrane. Sample is applied to the device. The specimen, venous or capillary (fingerstick) whole blood, serum or plasma, is applied to the capillary tip of the test device. The sampler is inserted into the buffer, which is provided in a sealed vial. The buffer facilitates the lateral flow of the released products, promoting the binding of the antibodies and antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting a conjugate. If present, the antibodies bind to the gold conjugated antibody binding protein. In a positive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST area producing a pink/purple line. In the absence of HIV1/2 antibodies, there is no pink/purple line

in the TEST area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL area, demonstrating that the reagents are functioning properly. If the control line does not appear, the assay is invalid, and the test should be repeated.

HEMA•STRIP HIV 1/2 KIT COMPONENTS

- 25 Pouches
- 1 Product insert
- 1 Rack for holding buffer vials upright

Each pouch contains all components necessary to perform one test. A desiccant pack is included in each pouch; discard after opening pouch:

- 1 Sampler with a test strip inside
- 1 Buffer vial attached to the sampler
- 1 Lancet
- 1 Bandage
- 1 Desiccant

MATERIALS REQUIRED BUT NOT PROVIDED

- 1 Clock, watch, or other timing device

STORAGE & STABILITY

The Hema•Strip HIV1/2 should be stored in an unopened pouch at 20 to 33 °C and should not be used beyond the indicated expiration date. When stored as indicated, test strips are stable until the expiration date marked on the pouch. If the test is stored below 20° C, the test should be allowed to come to ambient temperature prior to use.

WARNINGS & PRECAUTIONS

1. The test is FOR *IN VITRO* DIAGNOSTIC USE only. For PROFESSIONAL USE only. Use the test only in accordance with instructions supplied with the kit.
2. Handle all specimens as recommended for any potentially infectious human serum or blood specimen in the CDC-NIH manual, Biosafety in Microbiological and Biomedical Laboratories, 1993.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient specimens.
4. Do not eat, drink or smoke in the area where the specimens and kit reagents are handled. Avoid any contact between hands, eyes or mouth during specimen collection and testing.
5. Do not mix reagents from different lots of test kits.
6. After the completion of assay, dispose of all specimens and test devices in accordance with guidelines for handling biohazardous waste.
7. Do not use kits beyond expiration date, which appears on the label.

KIT COMPONENT PREPARATION

All components for the Hema•Strip HIV-1/2 test are ready to use as supplied. Instructions for use are given in the Hema•Strip HIV-1/2 test procedure. Follow directions as indicated.

LIMITATIONS OF THE PROCEDURE

The Hema•Strip HIV1/2 must be used with either capillary (fingerstick) or venous whole blood, serum or plasma.

Venous whole blood must be collected with an anticoagulant (heparin or EDTA).

Do not open the sealed foil pouch until just prior to use.

If stored refrigerated (2-8°C), let pouch come to ambient temperature before opening it.

Do not use kit contents beyond their labeled expiration date.

To obtain accurate results, follow the test procedure exactly as described in this insert.

Ensure finger is completely dry before performing finger stick.

Read results in a well-lit area.

The Hema•Strip HIV 1/2 procedure and the interpretation of the results must be followed closely. The Hema•Strip HIV 1/2 is a screening test designed for detecting antibodies against HIV1/2 in human whole blood, serum or plasma. Any result from the testing of other body fluids should not be used.

For positive results, testing must be confirmed with EIA, Western blot or IFA according to CDC recommendations, and the clinical evaluation of the patient's situation should be performed before a final diagnosis is made. Rapid testing alone should not be used to diagnose HIV infection even if antibodies to HIV1/2 are present. A negative result at any time does not preclude the possibility of infection with HIV1/2.

SPECIMEN COLLECTION

The Hema•Strip HIV 1/2 assay may be performed on finger stick or venous whole blood, serum or plasma.

Fingerstick Whole Blood: For fingerstick blood, following laboratory procedure, prick the finger and wipe away the first drop. Collect the sample from the second drop touching the sampler tip of the device to the drop of blood until the sampler tip is full. Follow test procedure instructions.

Venous Whole Blood: Draw blood following laboratory procedure for obtaining venous blood. Collect sample in a tube containing an anticoagulant – Heparin or EDTA.

Serum or Plasma: Collect serum or plasma in a clean container following standard laboratory procedures. Turn the sampling tip of the sampler to face upwards and carefully pipette 2.5 µL of serum or plasma into the narrow opening. Follow test procedure instructions.

CONFIRMATION OF TEST PERFORMANCE

When the test is complete, you will see a pink/purple colored line in the CONTROL area of the test device on negative as well as positive samples. The control line serves as an internal control and gives confirmation of proper test performance.

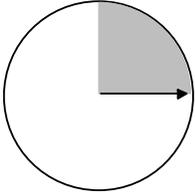
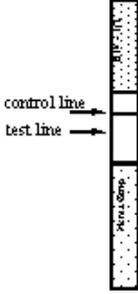
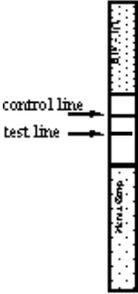
If a pink/purple colored line is seen in the TEST area of the device. The test is positive.

TEST PROCEDURE

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| <p>1. Each sealed test package should include the following:</p> | <p>SAMPLER, WITH BUFFER VIAL</p> | <p>SAFETY LANCET</p>  <p>BANDAGE</p> | <p>DESICCANT PACK</p> <p>(discard after opening pouch)</p> |
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| <p>2. Fingerstick/Capillary Blood Obtain a blood drop by finger stick. Venous Whole Blood Obtain a venous blood sample in a tube containing an anticoagulant, either heparin or EDTA. Serum or Plasma Obtain a serum or plasma sample following standard laboratory procedure.</p> |
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| <p>3. Collect specimen - For blood, touch blood drop or surface of blood with sampler tip until tip is full. For serum or plasma, turn sampler upside down and pipet 2.5 µL of specimen into sample tip.</p> <p style="text-align: center;">Fingerstick example</p> | <p>4. Remove buffer vial - separate from top of sampler and place on flat surface.</p> |
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| <p>5. Start the test -</p> <ol style="list-style-type: none"> 1. Hold buffer vial and firmly press the sampler tip through foil cover. 2. Continue pushing to the bottom of the vial until sampler and buffer vial snap together tightly. <p>CAUTION: When inserting tip through foil cover, push gently to puncture foil, but do not jab at the foil cover.</p> <p>Continue pushing down firmly to the bottom of the vial. Sampler must snap firmly into buffer vial.</p> | <p>6. Start timing - wait for 15 minutes</p> <p>NOTE: the sampler/vial should be kept upright.</p>  |
| <p>7. Read results - Read the test at 15 minutes.</p> <p>NOTE: Positive results may be seen and read earlier than 15 minutes. To verify a negative test result, be certain to wait the full 15 minutes after starting the test.</p> | <p>8. Interpret results - refer to Interpretation of the Results section.</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p><u>Negative</u></p>  </div> <div style="text-align: center;"> <p><u>Positive</u></p>  </div> </div> |

INTERPRETATION OF THE RESULTS

When the Hema•Strip HIV-1/2 test is properly performed, one or two pink/purple indicator lines will become visible. These are:

1. The **Control line** - which appears closer to the top of the test strip, indicates the presence of specimen and proper hydration and migration of reagents. The control line will become visible within 15 minutes of starting the test regardless of the HIV antibody status of the specimen.
2. The **Test line** - which appears closer to the bottom of the test strip (below the control line) indicates the presence of HIV-specific antibodies. The test line will only become visible within 15 minutes of starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.

Negative: A non-reactive test line, with a reactive control line (only one indicator line visible) is interpreted as negative for the presence of HIV-specific antibodies.

Positive: A reactive test line, with a reactive control line (both test and control indicator lines visible) is interpreted as positive for the presence of HIV-specific antibodies.

Invalid Test: A non-reactive control line, regardless of any other reactivity on the test strip is interpreted as an invalid test, and must be repeated using a new device.

Caution:

- Intensity of the test and control lines may vary. A visible test line, regardless of intensity, is considered reactive (a positive result).

EXPECTED RESULTS

This is a qualitative test for the detection of antibodies to HIV1/2 in whole blood, serum or plasma. As described in the SPECIFIC PERFORMANCE CHARACTERISTICS section below, the sensitivity of the Hema•Strip HIV 1/2 test was found to be substantially equivalent to the EIA and Western blot test when tested on selected performance panels.

QUALITY CONTROL

A pink/purple colored line should always appear in the control area if the test has been performed correctly and the device is working properly. It serves as an internal procedural control. A clear background in the test area is an internal negative procedural control.

Good laboratory practice recommends the use of control materials along with the test samples to ensure proper performance of the test kit. Positive and negative serum or plasma based commercial controls should be used for this purpose. Use controls as per the TEST PROCEDURE instructions of this insert. Please note that certain commercial controls designed for ELISA may not perform properly with the Hema•Strip HIV 1/2. Serum or heparinized plasma based controls for example from BBI (Boston Biomedica Inc, USA) or NABI (Nabi Diagnostics, USA) can be used.

SPECIFIC PERFORMANCE CHARACTERISTICS

In-house studies demonstrate that the sensitivity of the Hema•Strip HIV 1/2 test is substantially equivalent to the EIA and Western blot tests when tested on BBI performance panels PRZ204 Anti-HIV 1/2 Combo Performance Panel, PRF202 Anti-HIV 2 Performance Panel and PRB203 Anti-HIV 1 Mixed Titer Performance Panel as well BBI Seroconversion panels PRB904 and PRB909.

In an external evaluation of the performance of the Hema•Strip HIV 1/2 test using 337 confirmed negative and positive serum, plasma and whole blood samples, sensitivity was 99.2% (121/122) and specificity, 100% (216/216). In this same study, excellent analytical sensitivity relative to EIA was demonstrated using BBI seroconverter panels PRB940 and PRB931.

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