One step rapid test for the detection of antibodies to HIV-1/-2

BIOLINE HIV 1/2 3.0 kit is intended for professional use, only for an initial screening test and reactive samples should be confirmed by a supplemental assay such as ELISA or Western Blot test.

Materials provided/ Active ingredients of main components

- Blood specimen (whole blood, plasma or serum)
- 1 strip
- 1 lancet
- 1 lancet handle
- 1 albumen solution
- 1 control solution
- 1 sample diluent
- 1 box
- 1 dry cloth
- 1 package
- 1 pipette
- 1 desiccant
- 1 outer packaging

Materials required but not provided

- Specimen collection, storage and precaution
- General precautions:
  - Avoid splashing or aerosol formations.
  - Do not eat or smoke while handling specimens.
  - Do not touch specimen containers by hand.
  - Avoid contamination of the end of bottle when dropping of assay diluents into sample well.
  - For hepatitis B, wash hands with water and soap immediately after contact.
  - Use by: Exp

- Specimen collection, storage and precaution
  - Serum or plasma specimens may be stored for 2 weeks at 2-8°C before testing.
  - Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
  - If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.

- Specimen storage, collection, and precaution
  - Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
  - Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
  - Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified before assaying.

- Procedure of the test (to refer to figure)
  - Remove the test device from the package, place it on a clean, flat surface.
  - Bring specimen to room temperature.
  - Add 10µl of plasma or serum specimen (20µl of blood specimen) into the sample well(s).
  - In the event of an inadequate reacts, mix gently for 30 seconds and repeat the process for 3 minutes.
  - Do not apply too much pressure to the sample well(s) or diluent well(s).
  - Do not let the test device dry out.
  - Do not use expired lancet. The use of an expired lancet may cause any infection at the punctured site.

- Interpretation of the test (Refer to figure)
  - A positive test result will appear within 10 minutes. A negative test result will appear within 10 minutes.

- Performance characteristics
  - Sensitivity: 99.7%
  - Specificity: 99.7%
  - Positive Predictive Value: 99.7%
  - Negative Predictive Value: 99.7%

- Materials required but not provided

- Specimen collection, storage and precaution
  - Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified before assaying.

- Procedure
  - Use by: Exp
  - Avoid contact with infectious body substances.
  - These lines are not visible before applying the sample. The Control Line is used for procedural control. A visible Control Line confirms that the diluents has been applied successfully and that the active ingredients on the strip are intact.
  - The presence of three lines as control line (C), test line 1 (1) and test line 2 (2) within the result window indicates a positive result for HIV-1 and/or HIV-2.

- Performance characteristics
  - Sensitivity: 99.7%
  - Specificity: 99.7%
  - Positive Predictive Value: 99.7%
  - Negative Predictive Value: 99.7%

- Materials required but not provided

- Specimen collection, storage and precaution
  - General precautions:
    - Avoid splashing or aerosol formations.
    - Do not eat or smoke while handling specimens.
    - Do not touch specimen containers by hand.
    - Avoid contamination of the end of bottle when dropping of assay diluents into sample well.
    - For hepatitis B, wash hands with water and soap immediately after contact.
    - Use by: Exp

- Specimen collection, storage and precaution
  - Serum or plasma specimens may be stored for 2 weeks at 2-8°C before testing.
  - Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
  - If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.

- Specimen storage, collection, and precaution
  - Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
  - Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
  - Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified before assaying.

- Procedure of the test (to refer to figure)
  - Remove the test device from the package, place it on a clean, flat surface.
  - Bring specimen to room temperature.
  - Add 10µl of plasma or serum specimen (20µl of blood specimen) into the sample well(s).
  - In the event of an inadequate reacts, mix gently for 30 seconds and repeat the process for 3 minutes.
  - Do not apply too much pressure to the sample well(s) or diluent well(s).
  - Do not let the test device dry out.
  - Do not use expired lancet. The use of an expired lancet may cause any infection at the punctured site.

- Interpretation of the test (Refer to figure)
  - A positive test result will appear within 10 minutes. A negative test result will appear within 10 minutes.

- Performance characteristics
  - Sensitivity: 99.7%
  - Specificity: 99.7%
  - Positive Predictive Value: 99.7%
  - Negative Predictive Value: 99.7%

- Materials required but not provided

- Specimen collection, storage and precaution
  - General precautions:
    - Avoid splashing or aerosol formations.
    - Do not eat or smoke while handling specimens.
    - Do not touch specimen containers by hand.
    - Avoid contamination of the end of bottle when dropping of assay diluents into sample well.
    - For hepatitis B, wash hands with water and soap immediately after contact.
    - Use by: Exp

- Specimen collection, storage and precaution
  - Serum or plasma specimens may be stored for 2 weeks at 2-8°C before testing.
  - Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
  - If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.

- Specimen storage, collection, and precaution
  - Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
  - Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
  - Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified before assaying.

- Procedure of the test (to refer to figure)
  - Remove the test device from the package, place it on a clean, flat surface.
  - Bring specimen to room temperature.
  - Add 10µl of plasma or serum specimen (20µl of blood specimen) into the sample well(s).
  - In the event of an inadequate reacts, mix gently for 30 seconds and repeat the process for 3 minutes.
  - Do not apply too much pressure to the sample well(s) or diluent well(s).
  - Do not let the test device dry out.
  - Do not use expired lancet. The use of an expired lancet may cause any infection at the punctured site.

- Interpretation of the test (Refer to figure)
  - A positive test result will appear within 10 minutes. A negative test result will appear within 10 minutes.

- Performance characteristics
  - Sensitivity: 99.7%
  - Specificity: 99.7%
  - Positive Predictive Value: 99.7%
  - Negative Predictive Value: 99.7%

- Materials required but not provided

- Specimen collection, storage and precaution
  - General precautions:
    - Avoid splashing or aerosol formations.
    - Do not eat or smoke while handling specimens.
    - Do not touch specimen containers by hand.
    - Avoid contamination of the end of bottle when dropping of assay diluents into sample well.
    - For hepatitis B, wash hands with water and soap immediately after contact.
    - Use by: Exp

- Specimen collection, storage and precaution
  - Serum or plasma specimens may be stored for 2 weeks at 2-8°C before testing.
  - Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
  - If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.

- Specimen storage, collection, and precaution
  - Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
  - Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
  - Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified before assaying.

- Procedure of the test (to refer to figure)
  - Remove the test device from the package, place it on a clean, flat surface.
  - Bring specimen to room temperature.
  - Add 10µl of plasma or serum specimen (20µl of blood specimen) into the sample well(s).
  - In the event of an inadequate reacts, mix gently for 30 seconds and repeat the process for 3 minutes.
  - Do not apply too much pressure to the sample well(s) or diluent well(s).
  - Do not let the test device dry out.
  - Do not use expired lancet. The use of an expired lancet may cause any infection at the punctured site.
Open the foil pouch and look for the following.

1. Test devices individually foil pouched with a desiccant
2. Assay diluents
3. Instructions for use

For in vitro diagnostic use only.
Store at 1~30°C sealed.

ONE STEP Anti-HIV 1/2 TEST 1 Test
HIV-1/2 3.0
03FK10CE-P-1
1°C
30°C

Now, open the package and look for the following:

1. Test devices individually foil pouched with a desiccant
2. Assay diluents
3. Instructions for use

For in vitro diagnostic use only.
Store at 1~30°C sealed.

ONE STEP Anti-HIV 1/2 TEST 1 Test
HIV-1/2 3.0
03FK10CE-P-1
1°C
30°C

Option

1. 20μl capillary Pipettes
2. Lancets

Add 10μl of plasma or serum (20μl of blood) into the sample well(s) using a micropipette.

Dispense 20μl of plasma or serum

Black Line
Blood

Dispense 4 drops of assay diluents into the sample well(s).

4 drops

1. Blood specimen (with a lancet)

II. Blood (by venipuncture), Plasma or Serum specimen

Add 20μl of drawn blood into the sample well(s).

Add 4 drops of assay diluents into the sample well(s).

Exactly, 4 drops should be added.

Interpretation

Time to result is 10 to 20 minutes. After adding the diluent, read the result after 10 minutes but not more than 20 minutes. If the test result is not legible after 10 minutes due to high background color, read again last but within 20 minutes of adding the diluent. Do not read after 20 minutes.

How to interpret test results

Negative

HIV-1 Positive

When 3 lines appear
“C”, “1” and faint “2” Line

Strong
Medium
Weak

If line “1” is darker than line “2”, it should be interpreted as HIV-1 positive only.

HIV-2 Positive

When 3 lines appear
“C”, “2” and faint “1” Line

Strong
Medium
Weak

If line “2” is darker than line “1”, it should be interpreted as HIV-2 positive only.

Remark

Both HIV 1 and HIV 2 Positive

If the band thickness between line 1 and line 2 is so similar to each other, even very rare, it can be both positive for HIV-1 and HIV-2. In this case, confirm test using Western Blot is recommended to know exact virus type.

Invalid

No “C” line