Abbott

FOR EXTERNAL USE

SD BIOLINE HIV/SYPHILIS DUO

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1. What do SD BIOLINE HIV/Syphilis Duo kits offer?

SD BIOLINE HIV/Syphilis Duo has 5 SKUs (Cat No. 06FK30, 06FK35, 06FK37, 06FK30CE, 06FK35CE).

06FK30	06FK35	06FK37	06FK30CE	06FK35CE
25 tests	25 tests	25 tests	25 tests	25 tests
1 assay diluent	1 assay diluent	25 tests	1 assay diluent	1 assay diluent
1 IFU	1 IFU	1 IFU	1 IFU	1 IFU
	25 alcohol swabs	25 alcohol swabs		25 alcohol swabs
	25 sterile lancets	25 safety lancets		25 sterile lancets
	25 capillary tubes	25 capillary tubes		25 capillary tubes

= CE marked

2. What does the SD BIOLINE HIV/Syphilis Duo test detect?

SD BIOLINE HIV/Syphilis Duo test is a rapid, qualitative test for the detection of antibodies to all isotypes(IgG, IgM, IgA) specific to HIV-1 including subtype-O, HIV-2 and Syphilis (Treponema pallidum) in human serum, plasma or whole blood. The SD BIOLINE HIV/Syphilis Duo is intended only for professional use, for an initial screening test and for in vitro diagnostic use. Reactive specimens should be confirmed by a supplemental assay such as ELISA or Western Blot for antibodies to HIV-1/HIV-2 and the treponemal test (e.g. TPPA, TPHA) and non-treponemal test (e.g. RPR and VDRL) for antibodies to T. pallidum.

Each test has a window where 3 lines coated: a control line area (labeled “C”), HIV line area (labeled ”HIV”) and syphilis line area (labeled “SYP”).

3. What are the storage conditions for the test?

The test should be stored between 1° to 30°C. Do not use kit contents beyond labelled expiration date. Do not freeze the kit or its components. Assay diluent cap should be kept firmly sealed between each use.

4. What are the recommended conditions for running the test?

It is recommended to run the test at room temperature and to perform the test immediately after removing the test device from the foil pouch.

5. What documents come in the kits?

Each kit has the instruction for use in English, French, Spanish and Portuguese for non-CE and in English, French, Spanish, Portuguese, German and Italian for CE.

6. What is the shelf life of the kit?

The shelf life is 24 months from the date of manufacturing for the SD BIOLINE HIV/Syphilis Duo kits. The expiry date of the kits is clearly indicated on the SD BIOLINE HIV/Syphilis Duo kit boxes and pouches. Don’t use the products past their expiration date.

7. Are there any controls available?

No.

8. Can the external controls from other manufacturers be used?

No. Use of Kit Control reagents manufactured by another source may not produce the required and anticipated results.

9. What clinical samples can be used?

SD BIOLINE HIV/Syphilis Duo must ONLY be used with fingerstick or venous (venipuncture) whole blood, serum or plasma samples. Other body fluids or pooled specimens may not give accurate results and should not be used. Blood samples stored using anticoagulants including heparin, EDTA and sodium citrate can be used. Use of other anticoagulants has not been validated and may not yield accurate results.

10. What are the storage conditions of the clinical samples?

- Serum and plasma specimens should be stored at 2-8°C if the test is to be run within 14 days of collection. If testing is delayed more than 14 days, the specimen should be frozen (-20°C or colder).
- Serum and plasma specimens containing a precipitate may yield inconsistent test results, hence must be clarified prior to assaying.
- Avoid repeated freeze/thaw cycles.
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 3 days of collection. **Do not use a whole blood specimen stored for more than 3 days.**
- Mix specimen well by gentle inversion of the tube immediately before testing.
- Whole blood collected by fingerstick should be tested immediately.
- Bring all types of blood specimens to room temperature prior to use.

11. How long can a frozen plasma/serum sample be stored?

The frozen plasma/serum can be stored for 12 months or more, if freeze and thaw cycle is not repeated.

12. Can a clinical sample go through freeze/thaw cycles?

Avoid repeated freeze/thaw cycles for plasma/serum and DO NOT freeze whole blood. Specimens showing particulate matter or turbidity should be centrifuged at 10,000g for 5 min at room temperature.

13. Does the capillary tube contain or is it coated with an anticoagulant / preservative?

No. It does not contain anticoagulant or preservative.

14. Is it possible to store the blood sample inside the capillary tube for later testing?

No. The blood should be transferred immediately to the sample pad of the SD BIOLINE HIV/Syphilis Duo. Whole blood collected by fingerstick should be tested immediately.

15. Can you just transfer blood directly from the finger to the test provided you have a large enough drop?

No. 20µL (0.02mL) of whole blood is required for proper operation of the test. A seemingly "large" drop may contain less or more than the specified volume. Use the capillary tube provided and follow the instruction for use to obtain the specified volume of blood from the finger and transfer it to the SD BIOLINE HIV/Syphilis Duo test.

16. Would it adversely affect the test if I put more than one drop of assay diluent on the test?

Yes. Only 3 drops of assay diluent are required for proper running of the test. In case of accidental application of more or less than 3 drops, discard the test strip and commence the test with an unused SD BIOLINE HIV/Syphilis Duo test.

17. Can the test be moved after the sample and assay diluent is applied?

Once started, the test strip should not be moved as to avoid contamination and exposure to potentially hazardous samples.

18. How long can the Test be left outside of the foil pouch?

The Test should be used immediately after removing from the foil pouch. It is recommended to open the test pouch just prior to use. Does the desiccant in the packaging of this test have an indicator?

19. Does the desiccant in the packaging of this test have an indicator?

The desiccant has a window where you can check the color of the beads contained in it. Do not use the test device if the desiccant is green.

20. Is it possible to test infants with SD BIOLINE HIV/Syphilis Duo?

SD BIOLINE HIV/Syphilis Duo is not intended for infants up to around eighteen months.

Testing infants for HIV is difficult and problematic. Diagnosis of an HIV infection in infants born to HIV-infected mothers cannot be established using conventional anti-HIV antibody tests. Infants born to HIV-infected mothers may carry maternal antibodies and will test antibody positive until eighteen months of age, which may not necessarily indicate the true infection status of the new born.

Also, the diagnosis of congenital syphilis can be difficult, as maternal nontreponemal and treponemal IgG antibodies can be transferred through the placenta to the fetus, complicating the interpretation of reactive serologic tests for syphilis in neonates.

21. Can I read the results before or after the 15-20 minute window?

A device should NOT be read until the 15-20 minute reading time frame. If no lines appear within the time frame and the control line is present, the test is considered non-reactive. The sample flow rate in the strip might differ from specimen to specimen because of different factors. The device should NOT be read after 20 minutes. If a device is only read after 20 minutes, the testing should be repeated.

22. How do I interpret the test results?

- HIV Reactive (Two lines – Control and HIV line)
- Purple lines appear in both the control line area (labeled "C") and in the HIV line area (labeled "HIV") of the test. Any visible purple line in the test line area should be interpreted as reactive.
- Syphilis (SYP) Reactive (Two lines – Control and SYP line)
- Purple lines appear in both the control line area (labeled "C") and in the Syphilis line area (labeled "SYP") of the test. Any visible purple line in the test line area should be interpreted as reactive.
- HIV Reactive and syphilis Reactive (Three lines – Control, HIV and SYP lines)
- Purple lines appear in the control line area (labeled "C") and in the test line area for both HIV and syphilis (labeled "HIV" and "SYP") of the test. Any visible purple line in the test line area should be interpreted as reactive.
- Non-reactive (One line – Control line)
- One purple line appears in the control line area of the test (labeled "C"), and no purple line appears in the test line area of the test (labeled "HIV" and "SYP").
- Invalid (No Control line)
- If there is no purple line in the control line area of the test, and even if a purple line appears in the test line area of the test, the result is invalid and should be repeated.

23. Does the color intensity/density of the Control line have a meaning? For example, should the intensity of test lines be equal or stronger than the Control line for the test result to be considered "reactive"?

No. The intensity of the Control line has no meaning and its intensity may be different for different samples. The presence of a line in the control window regardless of intensity is considered a valid test.

24. Does the color intensity/density of the HIV line and SYP line have a meaning?

The intensity of the HIV and SYP lines does not correlate to the titer of antibody in specimens. Any line in either the test window of the test regardless of intensity is considered a reactive and should be followed by confirmatory testing. There can be variability in line intensity between the control and test lines and also between samples.

25. The Control line does not appear even after 20 minutes from application of the sample and the assay diluent. How should I interpret the results, even if a reactive signal is formed on one or two of the test lines?

The test result is invalid and the sample should be retested.

If the serum or plasma sample does not flow or shows abnormal flow, such as stopping in the middle of the window, the specimen should be centrifuged and the test repeated.

In case of repeat failure, the sample may not be compatible with the structure of the SD BIOLINE HIV/Syphilis Duo test. Please contact local Technical Support for further advice. It is recommended to consider testing the sample with another diagnostic device.

26. Why would the Control line not develop?

In some cases such as specimens showing particulate matter or turbidity the Control line may not appear, because the sample flow stops in the middle of the test. Specimens showing particulate matter or turbidity should be centrifuged at 10,000g for 5 min at room temperature.

In case of repeat failure, the sample may not be compatible with the structure of the SD BIOLINE HIV/Syphilis Duo test. It is recommended to consider testing the sample with another diagnostic device.

27. The sample migration is very slow - I did not see a control line when evaluating the SD BIOLINE HIV/Syphilis Duo kit until much later. What went wrong?

If the Control line did not appear by 20 minutes following application of the sample the test result is considered invalid. The test should be repeated with an unused strip. If the problem repeats, centrifugation of the sample (in case of serum or plasma) may alleviate the problem. Among others, reasons for delayed appearance of the Control line could be: (a) viscosity of the sample; (b) coagulation of the sample; (c) damaged test.

28. If I see a partial control line with SD BIOLINE HIV/Syphilis Duo, are the results of the test valid?

The test result would be considered invalid and should be repeated with a new test.

29. If the rapid test is non-reactive, does that ensure the person is negative for HIV?

A non-reactive result for both antibodies to HIV and syphilis does not preclude the possibility of exposure to HIV or infection with HIV-1 or HIV-2 viruses and with syphilis. No test provides absolute assurance that a specimen does not contain low levels of antibodies to HIV-1 and HIV-2 viruses and antibodies to syphilis. If a test result is non-reactive and clinical symptoms persists, additional testing using other clinical methods is recommended.

30. If the rapid test is reactive, does that ensure the person is positive for HIV?

Reactive results alone are insufficient for diagnosis of the infections and should be confirmed using another method. They should be evaluated in light of the overall clinical information before diagnosis is made.

31. What are the performance characteristics of the SD BIOLINE HIV/Syphilis Duo?

A summary of clinical performance is included in the instruction for use.

SENSITIVITY

- Diagnostic sensitivity

  HIV: 400 anti-HIV-1 positive samples, among which 40 non-B subtype and 100 anti-HIV-2 positive samples were tested in the Institute of Tropical Medicine, Belgium. The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 500 positive samples, is 99.8%.

  Syphilis: 150 anti-Treponema pallidum positive samples, among which 100 anti-HIV-1 positive and 50 anti-HIV-1 negative samples were tested in the Institute of Tropical Medicine, Belgium. The Diagnostic Sensitivity for anti-Treponema pallidum antibody detection, calculated on 150 confirmed positive samples is 90.0 %.

SPECIFICITY

- Diagnostic specificity - In total 1,000 EDTA plasma and 500 whole blood samples from blood donors were tested. The samples originated from 2 collection sites in Germany, Frankfurt and Kassel.

  HIV: 100 % (99.7 - 100%)

  Syphilis: 99.9 % (99.6 - 100 %)

32. How early can you detect HIV infection with the SD BIOLINE HIV/Syphilis Duo tests?

30 commercially available HIV seroconversion panels were tested showing how early detection can be obtained with the SD BIOLINE HIV/Syphilis Duo test by the Institute of Tropical Medicine (20 panels) and by Paul-Ehrlich-Institut (10 panels). And Early HIV seroconversion samples selected in the seroconversion panel were tested as well. The performance of the SD BIOLINE HIV/Syphilis Duo test on seroconversion panels is comparable to other CE marked Anti-HIV-1/2 screening and rapid tests.

33. What is the minimum level of detection for HIV?

The term “minimum level of detection” cannot be applied for HIV antibody. The more applicable term is the first detectable sample in a seroconversion panel. Specific antibodies to HIV are produced shortly after infection, but the exact time of their detectability depends on several factors (both host and virus influences this time).

34. What subtypes of HIV-1 Ab does the test detect?

Subtype A, B, C, D, F, G, H, J, K, O, CRF01-AE were tested and detected with SD BIOLINE HIV/Syphilis Duo.

35. What if the rapid test is reactive but the Western Blot and 3rd Generation EIA’s are negative?

Various analytes and pathological conditions can cause cross-reactivity, hence false reactive is probable.

If the same results are repeated using the new tests, the sample may not be compatible with the structure of the SD BIOLINE HIV/Syphilis Duo test. Please contact local Technical Support for further advice.

36. How confident can you be in the performance of SD BIOLINE HIV/Syphilis Duo?

SD BIOLINE HIV/Syphilis Duo is a professional use only test manufactured to the highest quality standards at Abbott. A reactive result with SD BIOLINE HIV/Syphilis Duo should always be confirmed in line with standard clinical operating procedures. Additionally a non-reactive result does not exclude HIV infection and results should be interpreted in line with clinical presentation at the time of testing.

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