

Human Immunodeficiency Virus Type 1

SUDS HIV-1 Test

See package insert for more information

Reagent and Material Preparation:

1. Allow all reagents to reach the recommended temperature of 20-25°C before use.
2. The Latex-Antigen Suspension should be resuspended before use by shaking vigorously or by vortex mixing the capped vial several times.

Specimen Collection and Preparation:

1. The SUDS HIV-1 Test may be performed on fresh serum or plasma.
2. If the specimens are not tested on the day of collection, the serum or plasma may be stored refrigerated for up to 24 hours. If longer storage is required, the serum or plasma should be stored frozen.
3. Centrifuge frozen specimens before testing according to what is listed in the Sample Centrifugation section.
4. No dilution of specimens is required before testing.

Sample Centrifugation (For preparation of proficiency survey samples, frozen specimens, and in samples that do not drain within the time listed in the Assay Procedure):

1. Transfer an aliquot (0.5-1 mL) of the specimen into a small capped test tube.
2. Centrifuge the tube containing the specimen at 15,000rpm for at least 5 minutes.
3. Using a disposable micropipet, add two drops of centrifuged specimen to a disposable sample cup. Avoid disturbing sediment in the specimen.
4. Continue at Step 4 of the Assay procedure on page 5.

Assay Procedure:

1. Label the required number of SUDS Test Cartridges with the appropriate identification numbers. One Positive Control and One Negative Control should be assayed **each time** the tests are performed.
2. Place a SUDS sample cup into the funnel of each SUDS Test Cartridge.
3. Using a disposable micropipet, add two drops of test sample or control reagent to the SUDS sample cup. Make certain that the test sample or control reagent drop does not cling to the wall of the sample cup.
4. Using a Calibrated Dropper, add 0.5mL of Diluent to each SUDS sample cup.
5. Resuspend **the Latex-Antigen Suspension (A)** by shaking the bottle vigorously and add 1 drop of the thoroughly mixed Latex-Antigen Suspension (A) to the contents in each SUDS sample cup.
6. Gently swirl contents of each SUDS sample cup to mix the added reagents.
7. Using a timer, incubate the reaction mixture in the SUDS sample cup for 3 minutes at a room temperature of 20-25°C.
8. Pour the contents of each SUDS sample cup into its respective SUDS Test Cartridge. Discard the SUDS sample cups in a biohazard waste container. Allow the liquid to drain completely into the SUDS test cartridge before adding the next reagent. If this step takes longer than one minute, process the sample as described in the Sample Centrifugation section and repeat the test.

9. Using the Calibrated Dropper, add to each SUDS Test Cartridge 0.5mL of **Wash Reagent**. Allow to drain completely before adding the next reagent.
10. Add 1 drop of **Enzyme-antibody Conjugate (B)** to each SUDS Test Cartridge and incubate for 3 minutes at a room temperature of 20-25°C.
11. Using the Calibrated Dropper, add to each SUDS Test Cartridge 0.5mL of **Wash Reagent**. Allow to drain completely before adding the next reagent.
12. Add 1 drop of **Substrate (C)** to each SUDS test cartridge and incubate for 2 minutes at a room temperature of 20-25°C.
13. Add 4 drops of **Stop Solution (D)** to each SUDS test cartridge. Allow liquid to drain completely.
14. Turn SUDS Test Cartridge over and observe each Test Cartridge for the presence of any blue color in the center circle. Record the presence or absence of blue color for each specimen tested using the Color Key. This observation must be made **within 5 minutes** after adding **Stop Solution (D)**.

Interpretation of Results:

A Color Key is provided to assist in the determination of color. Use the color key provided with each kit. Whether or not a blue color is produced in the center circle, the outer circles should remain white and serve as control zones to indicate that the washing steps were properly performed. If one or both of the outer circles develops blue color, regardless of the presence of blue color in the center circle, the test result is inconclusive and the specimen should be retested.

Specimens which do not produce a blue color are considered non-reactive by the SUDS HIV-1 Test and may be considered negative for HIV-1 antibodies. Further testing is not required.

The presence of any blue color in the center circle, as viewed from the bottom of the SUDS test cartridge, indicates that the specimen is initially reactive in the SUDS HIV-1 Test. Any specimen producing a blue color on initial testing should be retested in duplicate. If on repeat testing a blue color is observed in one or both of the test cartridges, the specimen is repeatedly reactive and should be retested using an additional, more specific test. See package insert for more detailed instructions.