

Before you begin

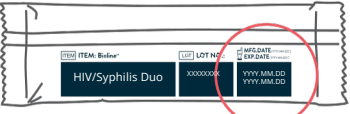
- Please read the instructions for use in its entirety, prior to use.
- Cover your work space with a clean, disposable absorbent workspace cover.
- All components must be brought to room temperature (between 15-30 °C) prior to testing.

Preparation

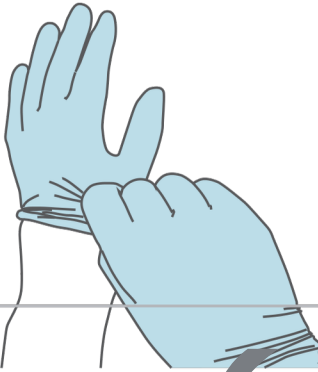
- Test pouch (test device)
- Alcohol swab (06FK35 only)
- Lancet (06FK35 only)
- Assay diluent
- Disposable capillary pipette (20µl) (06FK35 only)
- Timer (not provided)
- Disposable gloves (not provided)

For more detailed instructions please refer to Instructions for use.

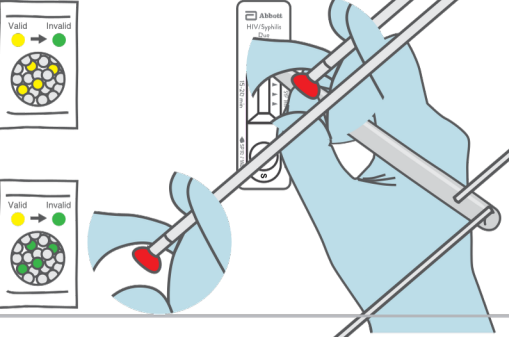
1 Check the expiration date. **If the device is expired, use another kit.**



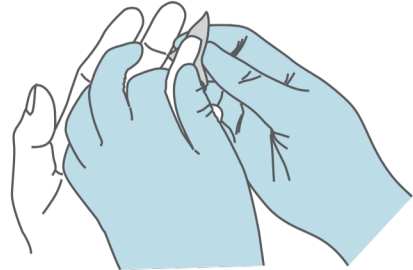
2 Put on disposable gloves. **Use new gloves for each patient.**



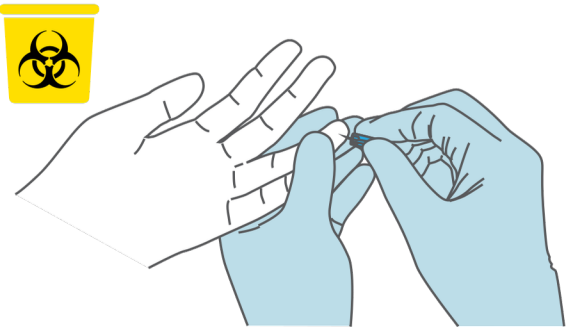
3 Open the test pouch and write the patient's name on the test device.



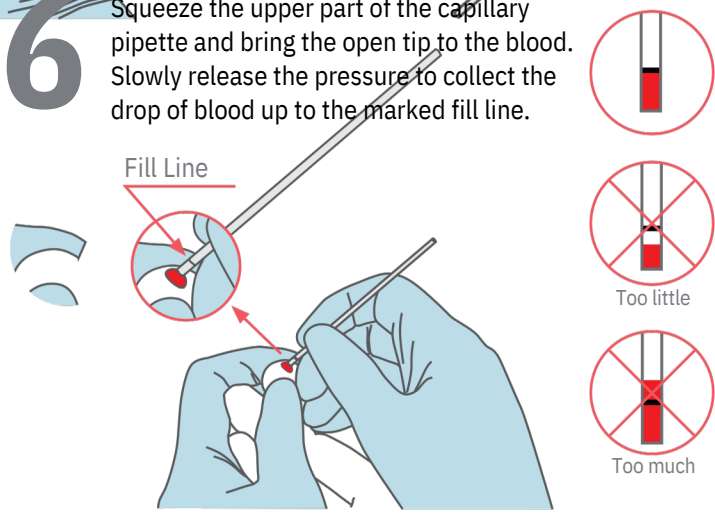
4 Open the alcohol swab and clean the patient's finger. **The alcohol must be dried before pricking, or the test may NOT work.**



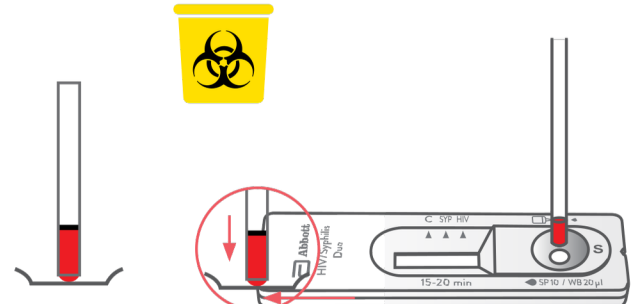
5 Prick the patient's finger with the lancet. **Discard the used lancet in the biohazard box immediately after pricking the finger.**



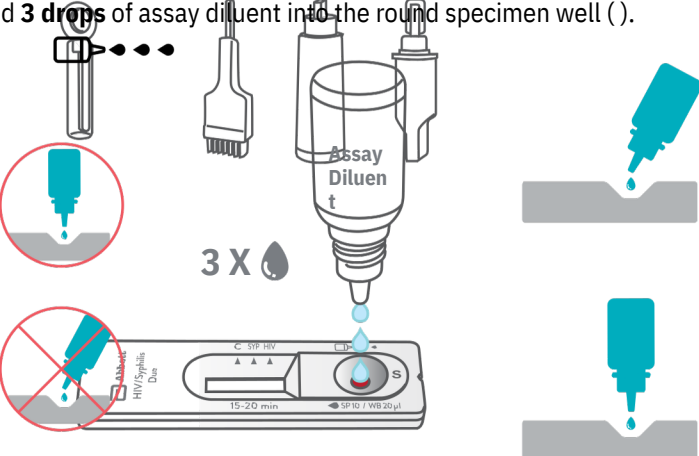
6 Squeeze the upper part of the capillary pipette and bring the open tip to the blood. Slowly release the pressure to collect the drop of blood up to the marked fill line.



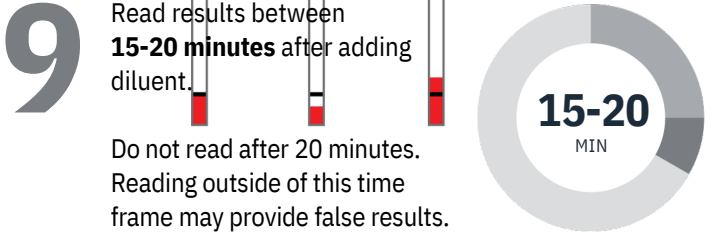
7 Add drawn specimen of blood into the round specimen well (S). **Discard the pipette in the biohazard box after use.**



8 Add **3 drops** of assay diluent into the round specimen well (S).



9 Read results between **15-20 minutes** after adding diluent. Do not read after 20 minutes. Reading outside of this time frame may provide false results.



LINE	POSITIVE		NEGATIVE	INVALID	
	HIV	Syphilis	HIV & Syphilis		
Control	✓	✓	✓	✗	✗
SYP	✗	✓	✗	✗	✗
HIV	✓	✗	✗	✗	✗

Caution: Visible test lines should be considered positive, even if faint.

The control line should appear for all results. If it does not appear, the result is considered invalid and the specimen should be retested using a new test kit.

FOR TECHNICAL SUPPORT PLEASE VISIT ABBOTT.COM/POCT

INFECTIOUS DISEASES

Bioline™ HIV/SYPHILIS DUO

SIMULTANEOUS DETECTION OF HIV-1/2 AND SYPHILIS ANTIBODIES TEST

Bioline™ HIV/Syphilis Duo test is a solid phase immunochromatographic assay for the qualitative detection of antibodies to all isotypes (IgG, IgM, and IgA) specific to HIV-1/2 and/or *Treponema pallidum* (TP) simultaneously in human serum, plasma or whole blood.

- Optimal screening test for HIV and syphilis during antenatal care
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance:
 - HIV: Sensitivity 99.91 %, Specificity 99.67 %
 - Syphilis: Sensitivity 99.67 %, Specificity 99.72 %



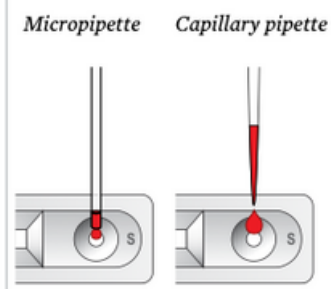
MATERIALS PROVIDED

- Test device
- Assay diluent
- Option : Lancet, alcohol swab, capillary pipette

SIMPLE PROCEDURE

- Dispense plasma, serum (10 µl) or whole blood (20 µl) into the specimen well "S".

1 Add Specimen



2 Add Assay Diluent

Dispense 3 drops of the assay diluent.



Wait 15-20mins.

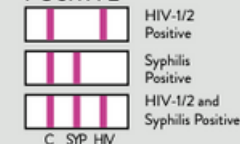


RESULTS INTERPRETATION

NEGATIVE



POSITIVE



INVALID



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
HIV/Syphilis Duo	06FK30	Device	Serum/Plasma/Whole blood	25T/Kit
HIV/Syphilis Duo*	06FK35	Device	Serum/Plasma/Whole blood	25T/Kit
HIV/Syphilis Duo	06FK30CE	Device	Serum/Plasma/Whole blood	25T/Kit
HIV/Syphilis Duo*	06FK35CE	Device	Serum/Plasma/Whole blood	25T/Kit

(*) Lancet, Capillary pipette, Alcohol swab included.