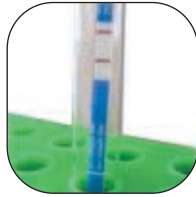
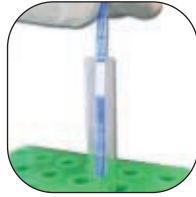
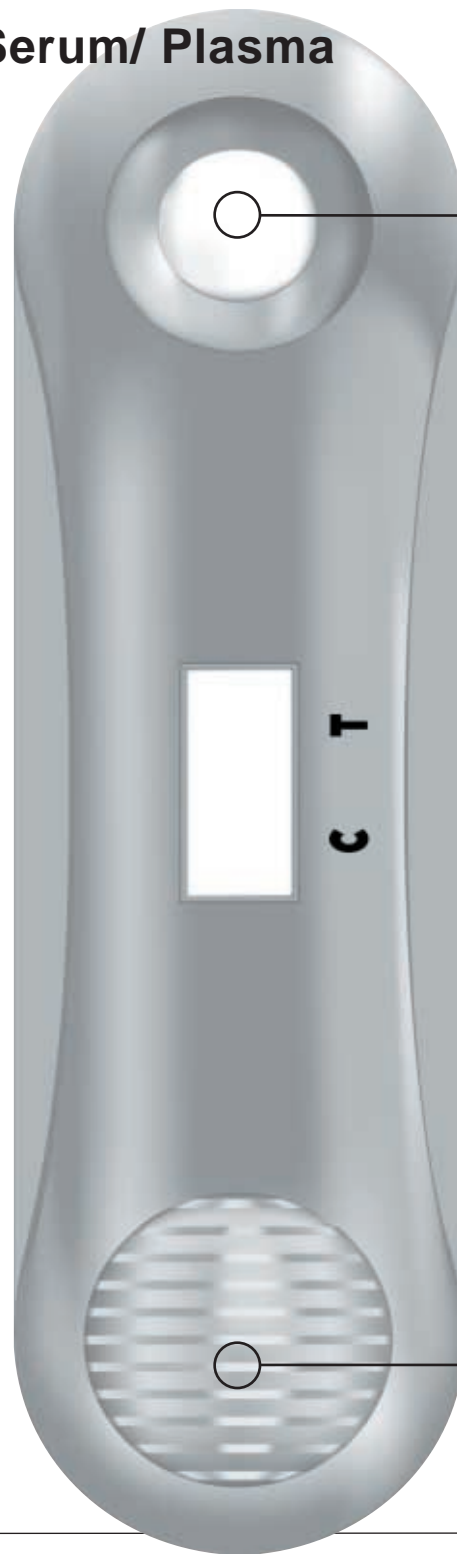
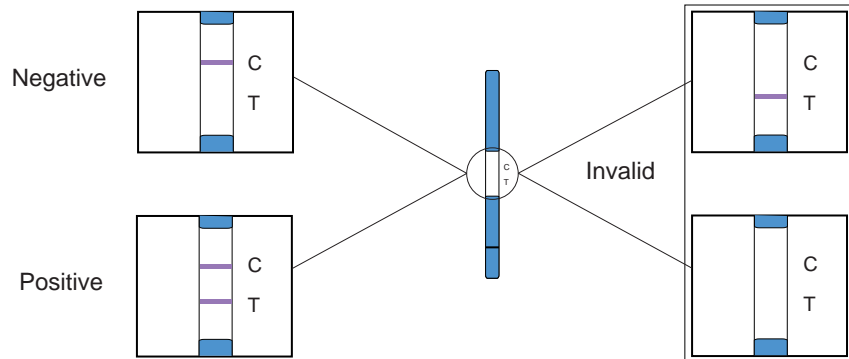


# JN-QC Rapid HIV-1/2 Test Whole Blood / Serum/ Plasma

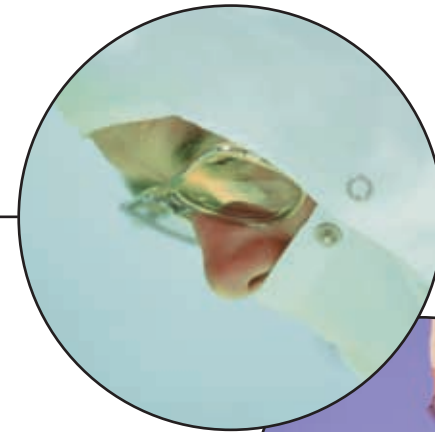


## INTERPRETATION OF TEST



# ASSAY INNOVATION

JN-QC™ Rapid HIV-1/2 Test



**JN-International, Inc.**  
P.O. Box 35, Oakland, NE 68045, USA  
TEL: 1-877-864-4558; Fax: 402-614-4437  
E-mail: [jninternational@msn.com](mailto:jninternational@msn.com)  
Website: <http://www.jnii-usa-bharat.com>  
Not for sale in the United States.

ISO 9001

ISO 13485

EN 46001

GMP

QSR

# JN-QC Rapid HIV-1/2 Test

## EXPLANATION OF THE TEST

**HIV-1** has been isolated from patients with AIDS and AIDS related complex, and from healthy persons with high potential risk of developing AIDS (1). Patients with **HIV-2** are found primarily in parts of West Africa (2). HIV-1 and HIV-2 are similar in their morphology, cell tropism, host interaction and generic structure. Serological studies have determined that HIV-1 and HIV-2 have multiple common epitopes in core antigens but much less so in the envelope antigens.

JN-QC™ HIV-1/2 test strip has a soluble dye used as a quality control feature indicating the location of the “Test Line” and “Control Line” in the Result Window. The “Control Line” is used for procedural control. The Control Line should always appear if the test procedure is performed properly and the test reagents of the Control Line are working. A purple “Test Line” will be visible in the Result Window if the test is working properly. If antibodies against HIV-1 or HIV-2 are not present or are present at very low levels in the sample, then no color appears in the “Test Line”.

The **JN-QC™** HIV-1/-2 test strip is a solid phase immunochromatographic assay for the qualitative detection of antibodies against HIV-1 and HIV-2. This test is intended for professional use as an aid on the diagnosis of HIV-1 or HIV-2.

## MATERIALS PROVIDED

- 1-JN-QC™ HIV-1/2 test strip
- 1-Instruction sheet
- 1-HIV-1/2 Diluent
- 1-5 microliter pipette or 5 microliter loop

## MATERIALS NEEDED BUT NOT PROVIDED

- 1-Test tube or 96 well polypropylene EIA plate
- 1-Clock or timer

## PRECAUTIONS/WARNINGS

The **JN-QC™** HIV-1/2 test strips should be stored at room temperature. The test strip is sensitive to humidity, as well as to heat. Perform the test immediately after removing the test device from the foil pouch. **Do not use it beyond the expiration date.**

1. For professional *in vitro* diagnostic use only.
2. Avoid cross contamination of clinical samples by using a new test tube or sample well for each sera sample tested.

3. Sera/blood specimens are potentially infectious. Proper handling and disposal of clinical samples should be established according to good laboratory practices. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards. Avoid splashing or aerosol formation. Clean up spills thoroughly using an appropriate disinfectant. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
4. Do not eat or smoke while handling specimen in the laboratory.
5. The JN-QC™ HIV-1/2 strip should remain in its sealed pouch until ready for use.
6. Do not use the test if the pouch is damaged or the seal is broken.
7. **Do not use the test kit after the expiration date.**

## SPECIMEN COLLECTION AND STORAGE

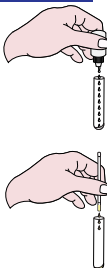
**Whole Blood specimen collection:** Collect an anticoagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested immediately or stored at 2-8 degrees C.

## PLASMA/SERUM SPECIMEN COLLECTION:

1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8 degrees C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.
3. Specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

## TEST PROCEDURE

1. Place 10 drops of HIV-1/2 Diluent in a clean glass tube or into the unused well of a 96 well polypropylene EIA plate (avoid polystyrene plates or tubes).
2. Place 5 microliters of sera into the tube/well using a pipette or 5 microliter loop, stir together in the tube/well before inserting strips.



3. Remove the test strip from its foil pouch.
4. Holding the strip vertically, carefully dip it into the specimen with the arrows pointing downward into the solution. **Do not immerse the strip past the maximum line (Figure 1).**
5. Interpret test results at 7 minutes. **Do not interpret test results after 15 minutes.**



## INTERPRETATION OF THE TEST

1. As the test kit begins to work, a purple band will appear at the upper section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The lower section of the Result Window indicates the test results. If another purple band appears at the lower section of the Result Window, this band is the Test Band.

FIGURE 1

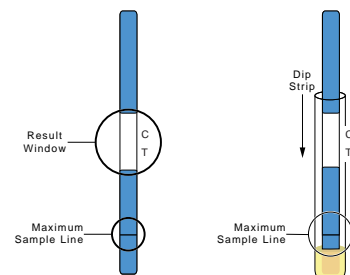
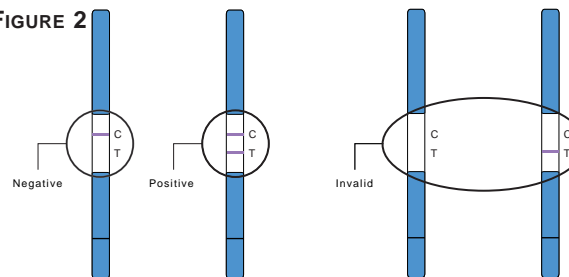


FIGURE 2



## POSITIVE: TWO PURPLE BANDS

The presence of two purple bands (“T” band and “C” band) within the Result Window, no matter which band appears first, indicates that antibodies against HIV-1 or HIV-2 are detected (**Figure 2**). **Note:** Generally, the higher the analyte level in the specimen, the stronger the “T” band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the “T” band will be very faint.

## NEGATIVE: ONE PURPLE BAND

The presence of only one purple control line within the Result Window indicates that antibodies against HIV-1 or HIV-2 are not detected (**Figure 2**).

## INVALID RESULT

If after performing the test and no control line is visible within the Result Window, the result is considered invalid (**Figure 2**). Some causes of invalid results are: not following the directions correctly or using the test beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

## LIMITATIONS OF THE TEST

Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers for Disease Control. For samples repeatedly tested positive, more specific supplemental tests must be performed. Immunochromatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 or HIV-2 are present in a patient specimen. A negative result at any time does not preclude the possibility of HIV-1 or HIV-2 infection.

## PERFORMANCE CHARACTERISTICS

No standards for performance have yet been established for HIV rapid assays. In a preliminary evaluation, OSG’s HIV-1/2 **STAT-Dx™** rapid assay was compared to another rapid assay marketed world-wide. Samples were from the National Aids Reference Lab (NARL), the World-Wide BBI Performance panel comprising of all seven serotypes of HIV-1 (A-G), HIV-O, and HIV-2, as well as other panels following the manufacturer’s protocol:

Test	Narl	BBI	Other	Neg	Spec%	Sen%
<b>JN-QC</b>	34/35	28/28	41/41	27/27	99%	100%
Vendor 1	30/35	ND	20/20	25/25	91%	100%

While the number of samples tested is limited, the OSG HIV-1/2 JN-QC™ rapid assay detected most samples used in these panels and performed better than the tests from another vendor.

## REFERENCES

1. Gallo, RC et al. Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS. Science 1984; 224:500-503.
2. Clavel, F. et al. HIV-2, the West African AIDS Virus. AIDS 1987; 1:135-140.