

Diagnostic Product Catalog 2010



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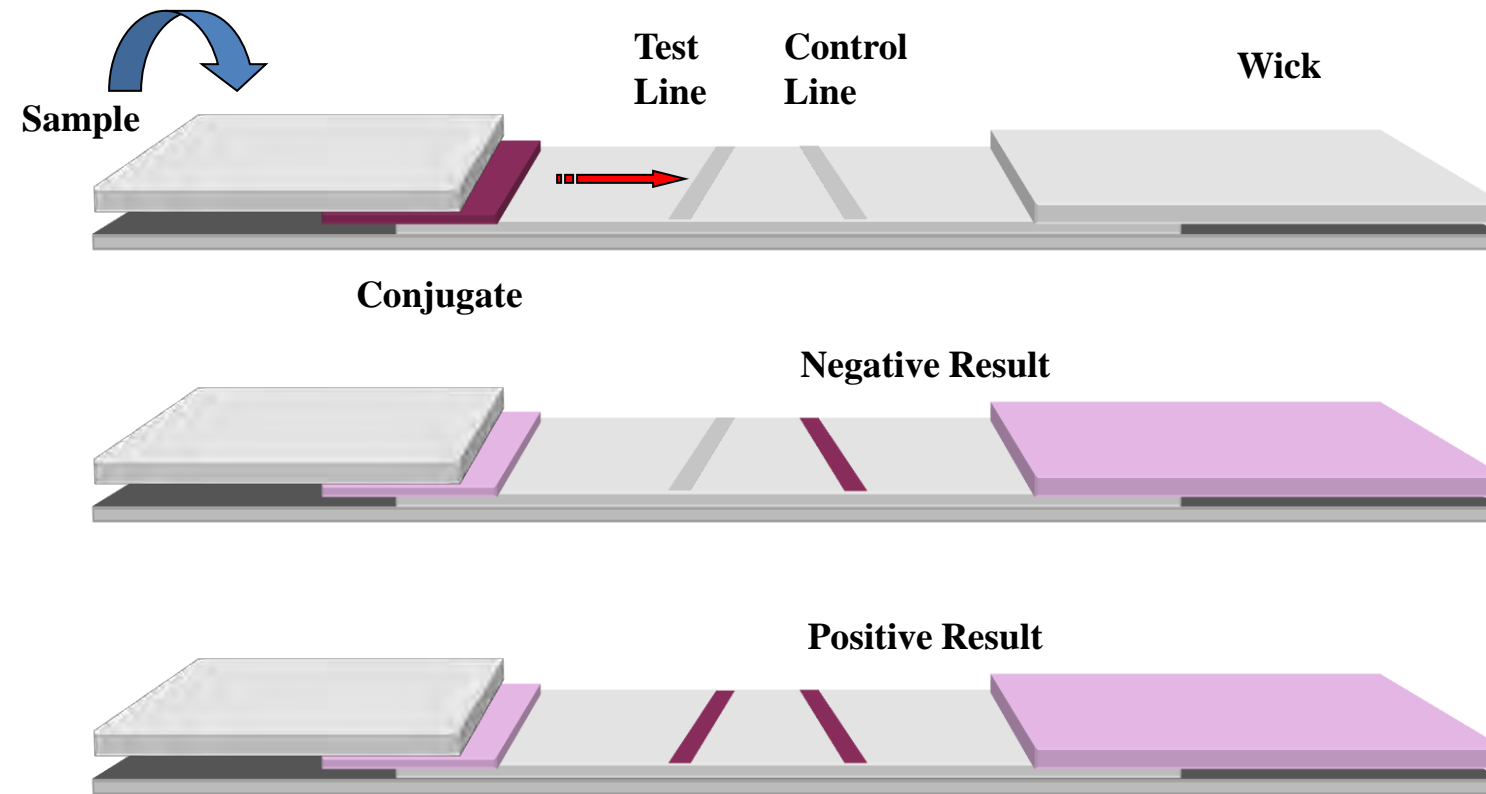
Diagnostic Products

- **Infectious Diseases**
 - HIV-1 and HIV-2
 - Tuberculosis (TB)
 - Hepatitis C (HCV)
 - Malaria
- **Pregnancy Detection (HCG)**
 - Urine Samples



JN-QC-Product)

Lateral Flow Technology – 2 minutes detection of \ HIV / TB / Malaria for screening 1 million people per month



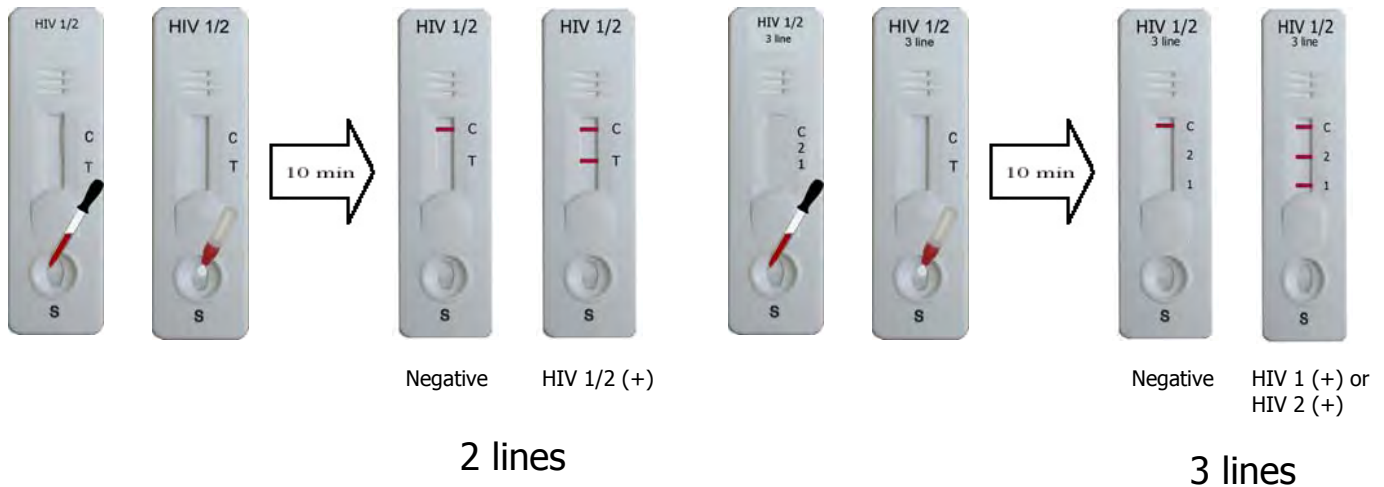
JN-QC-Spot HIV-1 & 2™

Quality Approved

- Accurate: Sensitivity over 99%, Specificity 99.5%
- Simple: Two step process
- Easy: Anyone & Everyone
- Stable: Room temperature storage
- Fast: Results in 10 minutes

Test Procedure

- Step 1 Add 10 μ l of serum, plasma, or 20 μ l of whole blood.
 Step 2 Then add 1 drop or 40 μ l of developer solution.
 Step 3 Read test results in 10 minutes



Purchasing Information

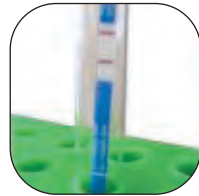
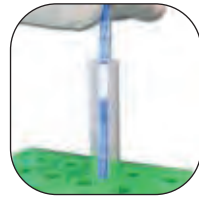
Cat. No.	Description	Type	Pack Size
D0111	HIV - ½ 2 lines	Device	30 Test/Kit, 100 Test/Kit
D0112	HIV - ½ 3 lines	Device	30 Test/Kit, 100 Test/Kit
D0121	HIV - ½ 2 lines	Strip	30 Test/Kit, 100 Test/Kit
D0122	HIV - ½ 3 lines	Strip	30 Test/Kit, 100 Test/Kit

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

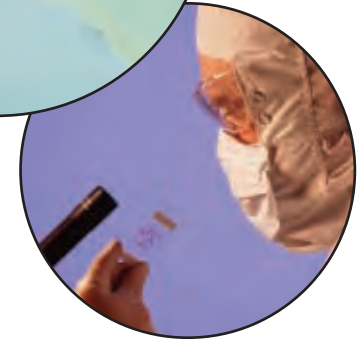
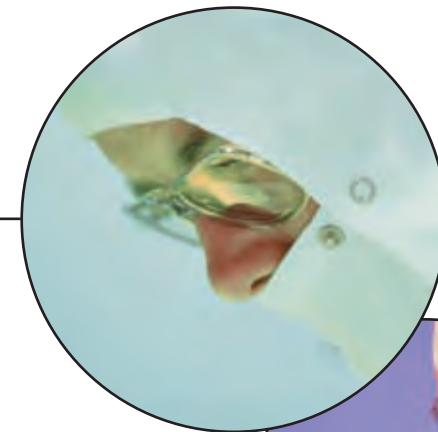
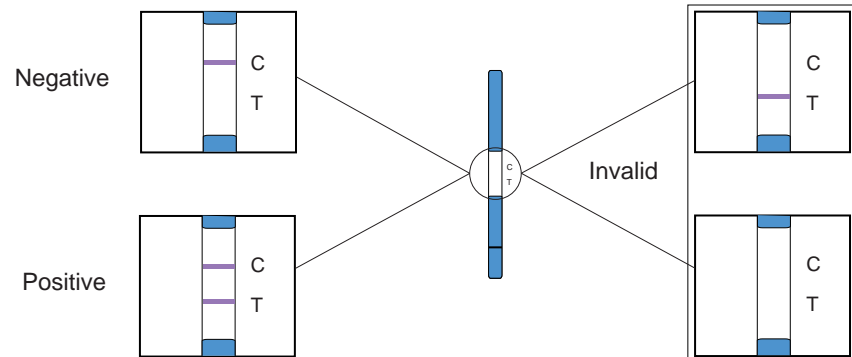
ASSAY

INNOVATION

JN-QC™ Rapid HIV-1/2 Test



INTERPRETATION OF TEST



ISO 9001

ISO 13485

EN 46001

GMP

QSR

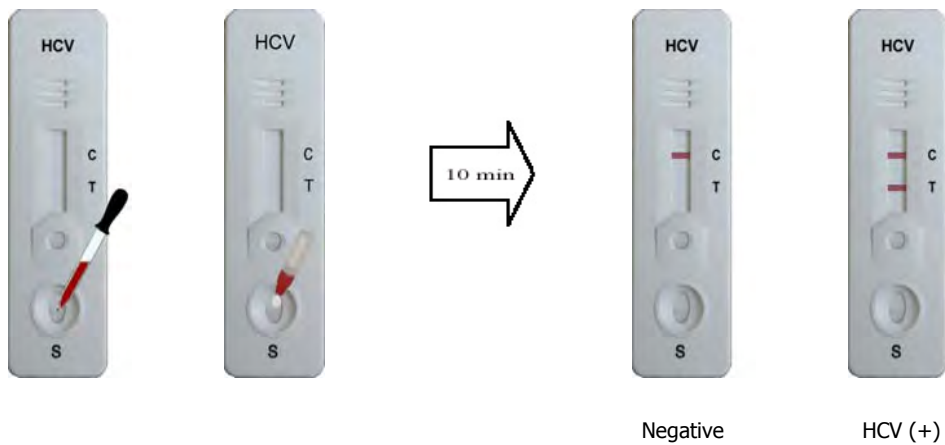
JN-QC-Spot HCV

Quality Approved

- Accurate: Sensitivity over 97%, Specificity 97%
- Simple: Two step process
- Easy: Anyone & everyone
- Stable: Room temperature storage
- Fast: Results in 10 minutes

Test Procedure

- Step 1 Add 10 μ l of serum, plasma, or 20 μ l of whole blood.
Step 2 Then add 1 drop or 40 μ l of developer solution.
Step 3 Read test results in 10 minutes



Purchasing Information

Cat. No.	Description	Type	Pack Size
D0511	HCV	Serum, Plasma, or Whole Blood	30 Test/Kit, 100 Test/Kit

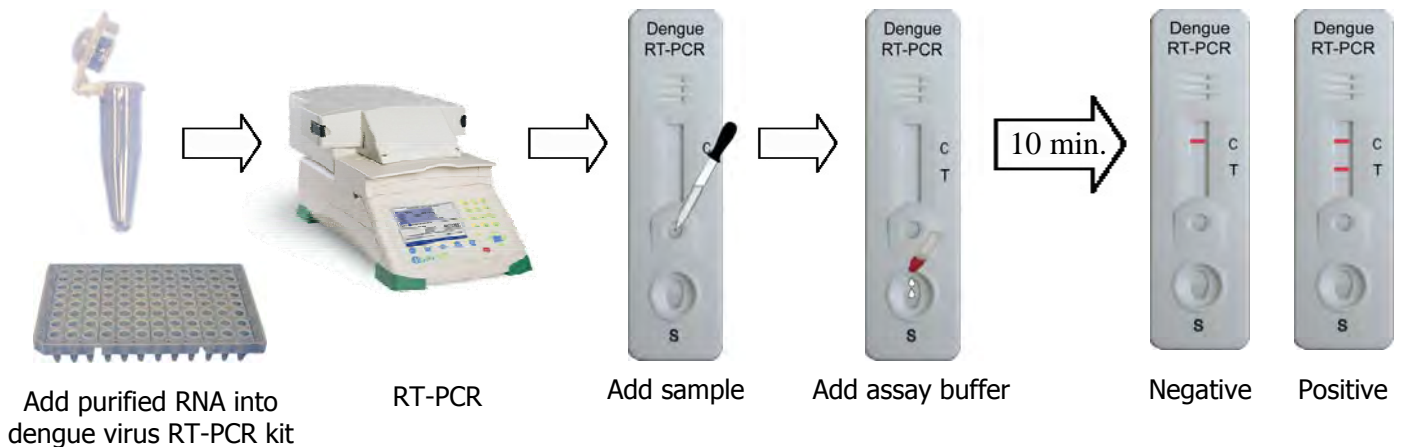
Dengue RT-PCR

Quality Approved

- Accurate: Sensitivity over 99%, Specificity over 99%
- Easy: Simple steps for anyone & everyone
- Stable: Room temperature storage
- Fast: Results in 10 minutes

Test Procedure

- Step 1 Purification of viral RNA from serum or plasma
- Step 2 Add purified viral RNA into the PCR tube or 96-well ready-to-use dengue virus RT-PCR Kit
- Step 3 Run thermal cycler
- Step 4 Add 5 μ l of PCR resultant into the sample well
- Step 5 Then add 2 drops or 60 μ l of assay buffer into buffer well
- Step 6 Read test results in 10 minutes



Ordering Information

Cat. No.	Description	Type	Pack Size
H0111	Dengue virus detection kit	PCR resultant	30 Test/Kit, 100 Test/Kit

Cardiac Markers

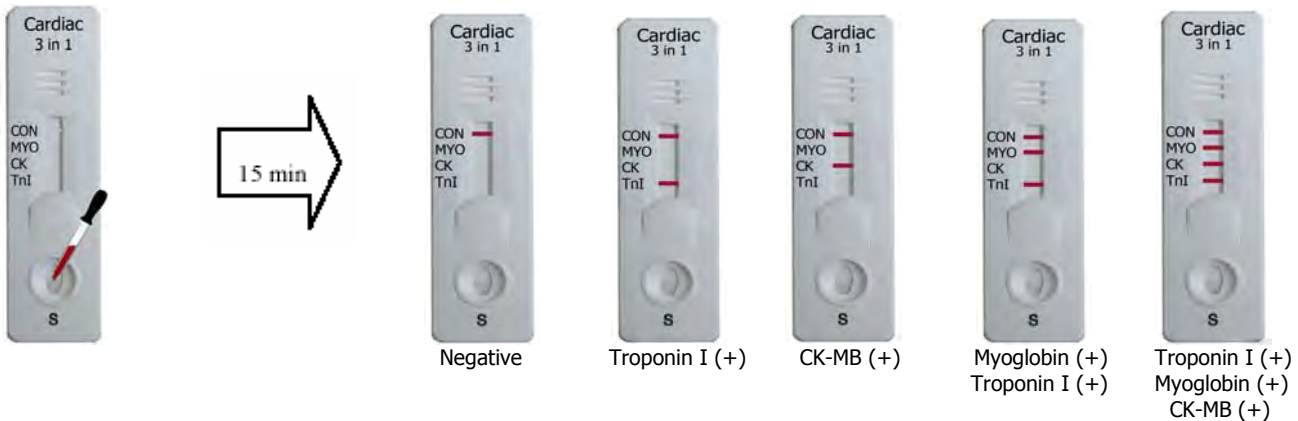
Troponin I, CK-MB, Myoglobin

Quality Approved

- **Accurate:** Troponin I - Sensitivity 96.9%, Specificity 98.9%
CK-MB - Sensitivity 96.1%, Specificity 97.2%
Myoglobin – Sensitivity over 99%, Specificity 97.5%
- **Simple:** One step process
- **Easy:** Anyone & Everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 15 minutes

Test Procedure

- Step 1 Add 80 μ l of whole blood, 60 μ l of serum/plasma.
Step 2 Read test results in 15 minutes.



Purchasing Information

Cat. No.	Description	Type	Pack Size
C0111	Troponin I	Device	30 Test/Kit, 100 Test/Kit
C0121	Myoglobin, Troponin I	Device	30 Test/Kit, 100 Test/Kit
C0131	Troponin I, CK-MB, Myoglobin	Device	30 Test/Kit, 100 Test/Kit
C0141	Cardiac CRP	Device	30 Test/Kit, 100 Test/Kit
C0151	Cardiac Myoglobin	Device	30 Test/Kit, 100 Test/Kit
C0161	CK-MB	Device	30 Test/Kit, 100 Test/Kit

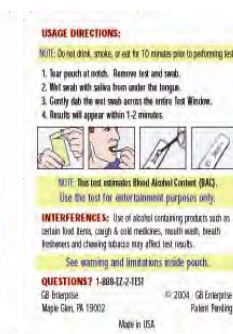
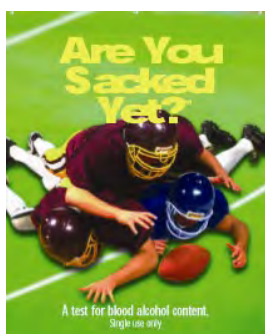
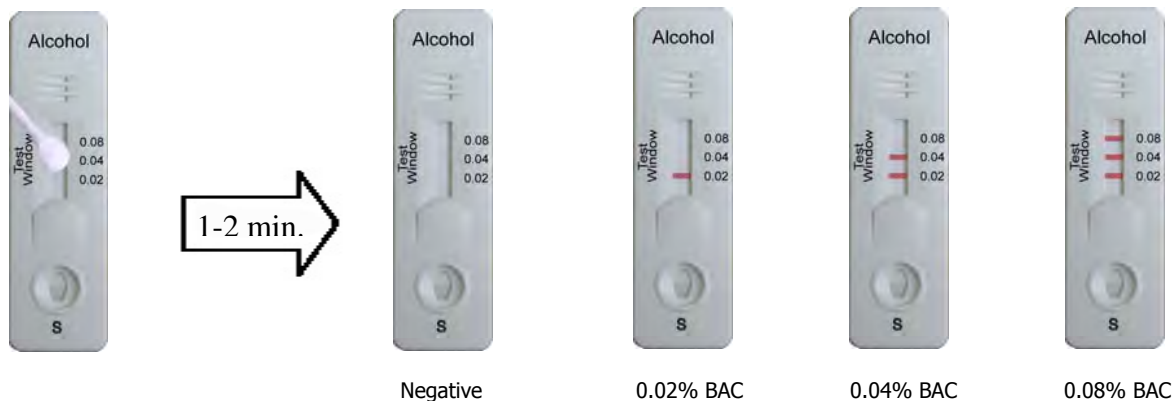
Alcohol

Quality Approved

- **Simple:** One step process
- **Easy:** Anyone & everyone
- **Stable:** Room temperature storage
- **Fast:** Blood Alcohol Concentration (BAC) Results in 2 minutes

Test Procedure

- Step 1 Wet swab with saliva from under tongue.
- Step 2 Gently dab the wet swab across entire test window.
- Step 3 Read test results within 1-2 minutes.



Purchasing Information

Cat. No.	Description	Type	Pack Size
E0111	Alcohol	Saliva	30 test/box, 100 test/box

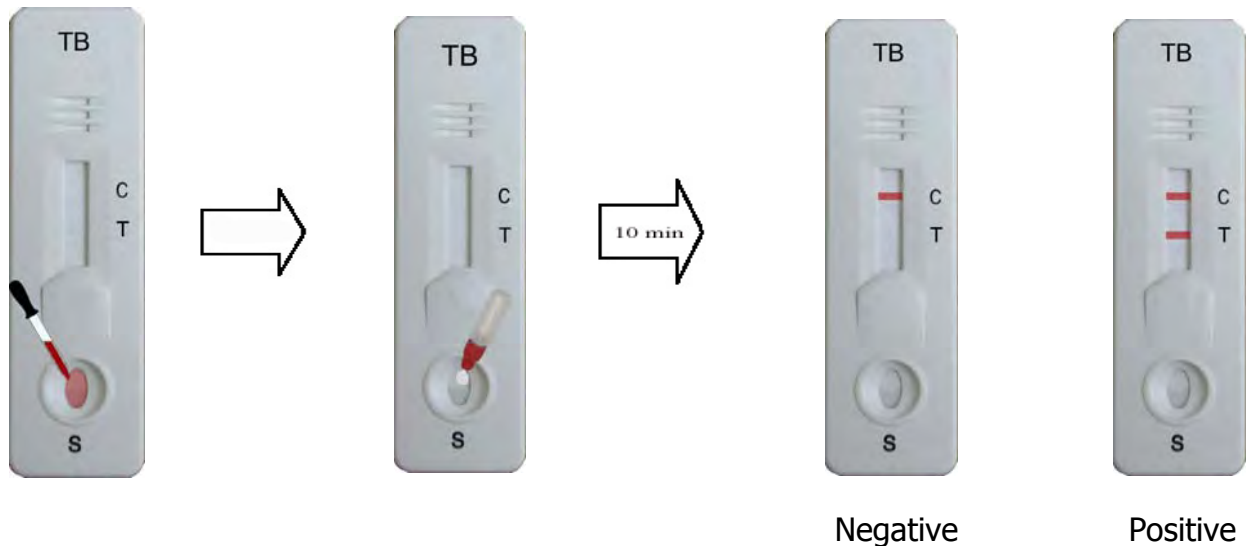
TUBERCULOSIS (TB)

Quality Approved

- **Accurate:** Sensitivity over 95%, Specificity over 82%
- **Simple:** Two step process
- **Easy:** Anyone & Everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 10 minutes

Test Procedure

- Step 1 Add 10 μ l of serum, plasma, or 20 μ l of whole blood.
Step 2 Then add 1 drop or 40 μ l of developer solution.
Step 3 Read test results in 10 minutes



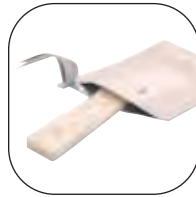
Purchasing Information

Cat. No.	Description	Type	Pack Size
D0611	Tuberculosis	Serum, Plasma, or Whole Blood	30 Test/Kit, 100 Test/Kit

JN-QC- Rapid TB Test Device

Whole Blood, Plasma or Serum

TEST INSTRUCTIONS



1. Remove the test device from the foil pouch, and place it on a flat, dry surface.



2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end.



3. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. Make sure that you do not use more than 5ul of sample. If using whole blood, allow sample to absorb for 1-2 minutes before adding the diluent.



4. Slowly add 5 drops of TB sample diluent to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window.
NOTE: full absorption of each drop is necessary to allow the sample to flow through the special filter in the sample well.



5. Start the timer.



6. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.

7. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpreting time should be properly increased.

INTERPRETATION OF THE TEST

Positive		Invalid	
C	T	C	T
Negative		Invalid	
C	T	C	T



ASSAY INNOVATION

JN-QC Rapid TB Test Device

[Comp Immunol Microbiol Infect Dis](#). 2002 Jan;25(1):21-7.

An immunochromatographic serological assay for the diagnosis of *Mycobacterium tuberculosis*.

[Reddy JR](#), [Kwang J](#), [Lechtenberg KF](#), [Khan NC](#), [Prasad RB](#), [Chengappa MM](#).

JN-International, Inc., Oakland, NE 68045, USA. jninternational@msn.com

A rapid serological test for tuberculosis (TB) infection was designed using antigens specific to *Mycobacterium tuberculosis*. Tuberculosis infection, TB vaccination and exposure to environmental *Mycobacteria* cannot be distinguished using skin tests based on tuberculin protein derivatives. The standard diagnostic techniques such as skin tests, X-rays and DNA techniques are time consuming, expensive, and not practical for screening large populations. We used the 38, 63, 64, 14, 59-kDa antigens of *M. tuberculosis* to develop a rapid immunochromatographic test kit. This study evaluates the diagnostic potential of the rapid test kit using TB positive and TB negative serum samples from various hospitals in India. The samples were obtained from patients infected with or exposed to bacteria and viral pathogens. The results demonstrated that the combination of antigens improved the diagnostic specificity and sensitivity. The specificity of the test was 99.42% with sensitivity of 98.52% (n = 241). In case of multiple infections, the specificity was 93.15% with a low sensitivity of 73.52% (n = 141). The test kit may offer an improved alternative to purified protein derivative (PPD). This rapid TB test kit may be a useful tool for first-line testing of suspected cases, epidemiological studies and in designing a quality health system to reduce health hazards in resource-poor countries.

ISO 9001

ISO 13485

EN 46001

GMP

QSR

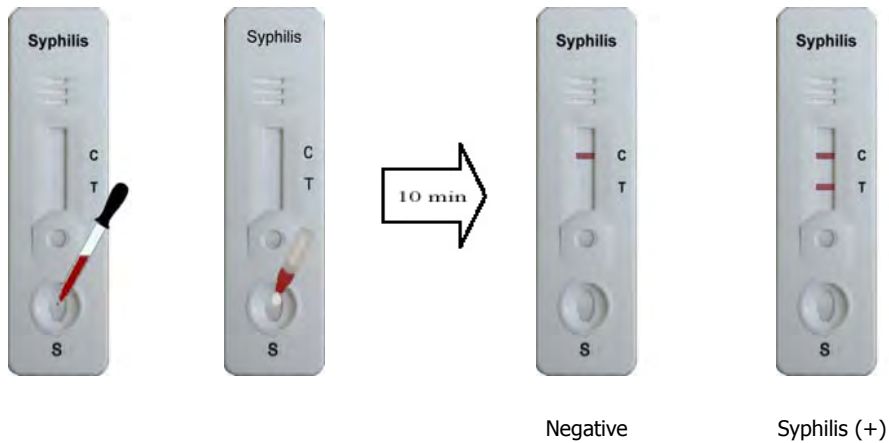
Syphilis

Quality Approved

- **Accurate:** Sensitivity over 97%, Specificity 97%
- **Simple:** Two step process
- **Easy:** Anyone & everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 10 minutes

Test Procedure

- Step 1 Add 10 μ l of serum, plasma, or 20 μ l of whole blood.
Step 2 Then add 1 drop or 40 μ l of developer solution.
Step 3 Read test results in 10 minutes



Purchasing Information

Cat. No.	Description	Type	Pack Size
D0411	Syphilis	Serum, Plasma, or Whole Blood	30 Test/Kit, 100 Test/Kit

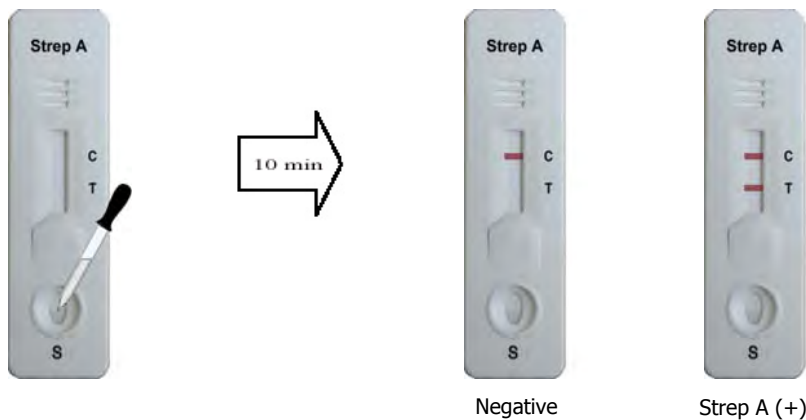
Strep A

Quality Approved

- **Accurate:** Sensitivity over 97%, Specificity over 97%
- **Simple:** Two step process
- **Easy:** Anyone & Everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 7 minutes

Test Procedure

- Step 1 Add 4 drops of Reagent A to test tube
- Step 2 Then add 4 drops of Reagent B and swab. Wait 2 minutes.
- Step 3 Remove swab after squeezing liquid out.
- Step 4 Using pipette, add 2 drops of extracted solution to the sample well.
- Step 5 Read the results in 5-10 minutes.



Purchasing Information

Cat. No.	Description	Type	Pack Size
D0311	Group A Streptococcus	Throat Swab	30 Test/Kit, 100 Test/Kit

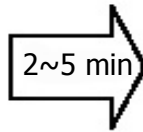
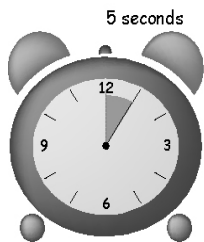
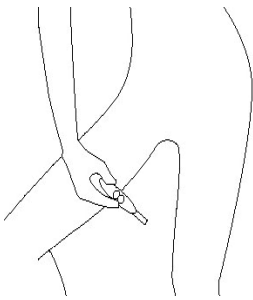
Ovulation Test (OTC)

• Quality Approved

- **Simple:** One step process
- **Easy:** Anyone & everyone
- **Fast:** Results in 2~5 minutes

• Test Procedure

- Step 1 Place the absorbent tip in your urine stream for 5 seconds.
Step 2 Read the results in 2~5 minutes.



Negative (No LH Surge)

Positive (LH Surge)

• Purchasing Information

Cat. No.	Description	Type	Pack Size
F0211	LH Ovulation Test (OTC) Mid-stream	Device	5 test/box 7 test/box
F0221	LH Ovulation Test	Device	5 test/box 7 test/box

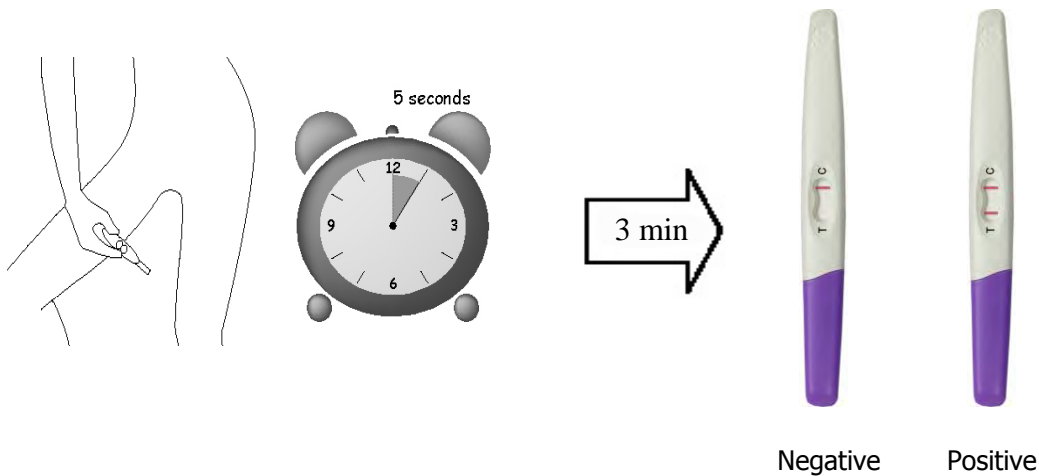
Pregnancy Test (OTC)

Quality Approved

- **Accurate:** Sensitivity over 99%
- **Simple:** One step process
- **Easy:** Anyone & Everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 3 minutes

Test Procedure

- Step 1 Place the absorbent tip in your urine stream for 5 seconds.
 Step 2 Read test results after 3 minutes but within 10 minutes.



Purchasing Information

Cat. No.	Description	Type	Pack Size
F0111	hCG Pregnancy Test (OTC) Mid-stream	Device	1 test/box 2 test/box
F0121	hCG Pregnancy Test Combo (CLIA Waived)	Device	1 test/box 30 test/box
F0131	hCG Pregnancy Test Combo	Device	1 test/box 30 test/box
F0211	LH Ovulation Test (OTC) Mid-stream	Device	5 test/box 7 test/box
F0221	LH Ovulation Test	Device	5 test/box 7 test/box

Ovulation

Quality Approved

- **Simple:** One step process
- **Easy:** Anyone & everyone
- **Fast:** Results in 2~5 minutes

Test Procedure

- Step 1 Place the absorbent tip in your urine stream for 5 seconds.
Step 2 Read the results in 2~5 minutes.



Purchasing Information

Cat. No.	Description	Type	Pack Size
F0211	LH Ovulation Test (OTC) Mid-stream	Device	5 test/box 7 test/box
F0221	LH Ovulation Test	Device	30 test/box, 100 test/box

Pregnancy Test

Quality Approved

- **Accurate:** Sensitivity over 99%
- **Simple:** One step process
- **Easy:** Anyone & Everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 3 minutes

Test Procedure

- Step 1 Place the absorbent tip in your urine stream for 5 seconds.
Step 2 Read test results after 3 minutes but within 10 minutes.



Purchasing Information

Cat. No.	Description	Type	Pack Size
F0111	hCG Pregnancy Test (OTC) Mid-stream	Device	1 test/box 2 test/box
F0121	hCG Pregnancy Test (CLIA Waived)	Device	1 test/box 30 test/box
F0131	hCG Pregnancy Test Combo	Device	1 test/box 30 test/box

MALARIA

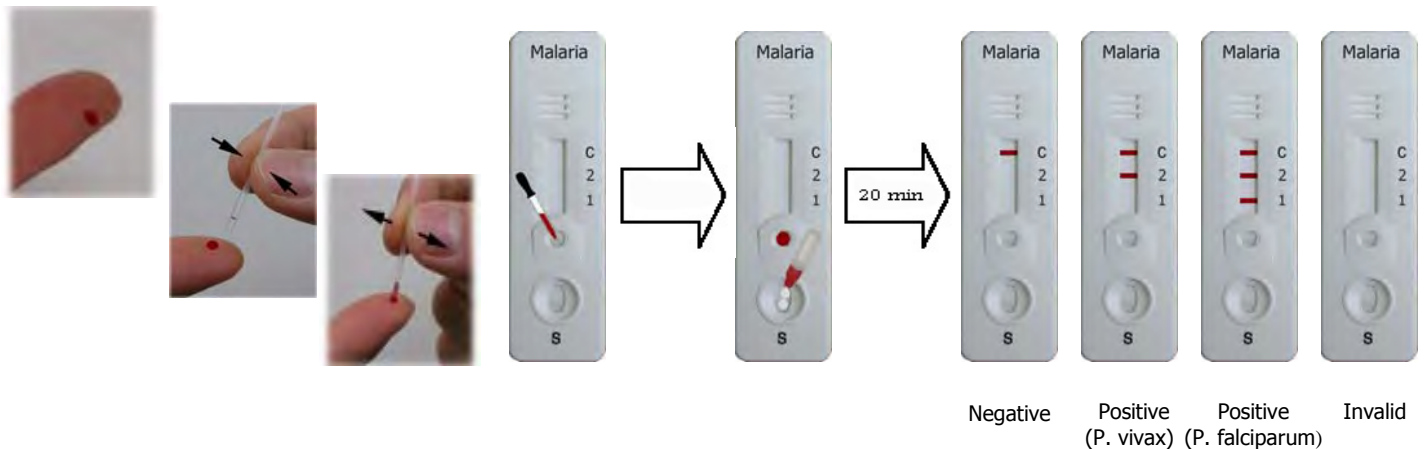
Quality Approved

- **Accurate:** Sensitivity over 90%, Specificity 99.5%
- **Simple:** Two step process
- **Easy:** Anyone & everyone
- **Stable:** Room temperature storage
- **Fast:** Results in 20 minutes



Test Procedure

- Step 1 Add 5 μ l of whole blood into sample well.
- Step 2 Then add 2 drops or 60 μ l of assay buffer into developer well.
- Step 3 Read test results in 20 minutes.



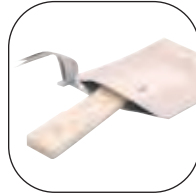
Purchasing Information

Cat. No.	Description	Type	Pack Size
G0111	Malaria Device (2 line, PAN specific-pLDH)	Whole Blood	30 Test/Box
G0112	Malaria Strip (2 line, PAN specific-pLDH)	Whole Blood	50 Test/Box
G0121	Malaria Device (3 line, P.f/P.v Ag Test-pLDH)	Whole Blood	30 Test/Box
G0122	Malaria Strip (3 line, P.f/P.v Ag Test-pLDH)	Whole Blood	50 Test/Box
G0131	Malaria Device (3 line, PAN-pLDH, P.f.-HRP2)	Whole Blood	30 test/box
G0132	Malaria Strip (3 line, PAN-pLDH, P.f.-HRP2)	Whole Blood	50 Test/Box
G0141	Malaria Device (2 line, P.f.-HRP2 Test)	Whole Blood	30 test/box
G0142	Malaria Strip (2 line, P.f.-HRP2 Test)	Whole Blood	50 Test/Box

EctgUwt vJ TR4'O cmrk Test

Whole Blood, Plasma or Serum

TEST INSTRUCTIONS



1. Remove the test device from the foil pouch, and place it on a flat, dry surface.



2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end.



3. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. Make sure that you do not use more than 5ul of sample. If using whole blood, allow sample to absorb for 1-2 minutes before adding the diluent.



4. Slowly add 5 drops of TB sample diluent to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window.
NOTE: full absorption of each drop is necessary to allow the sample to flow through the special filter in the sample well.



5. Start the timer.



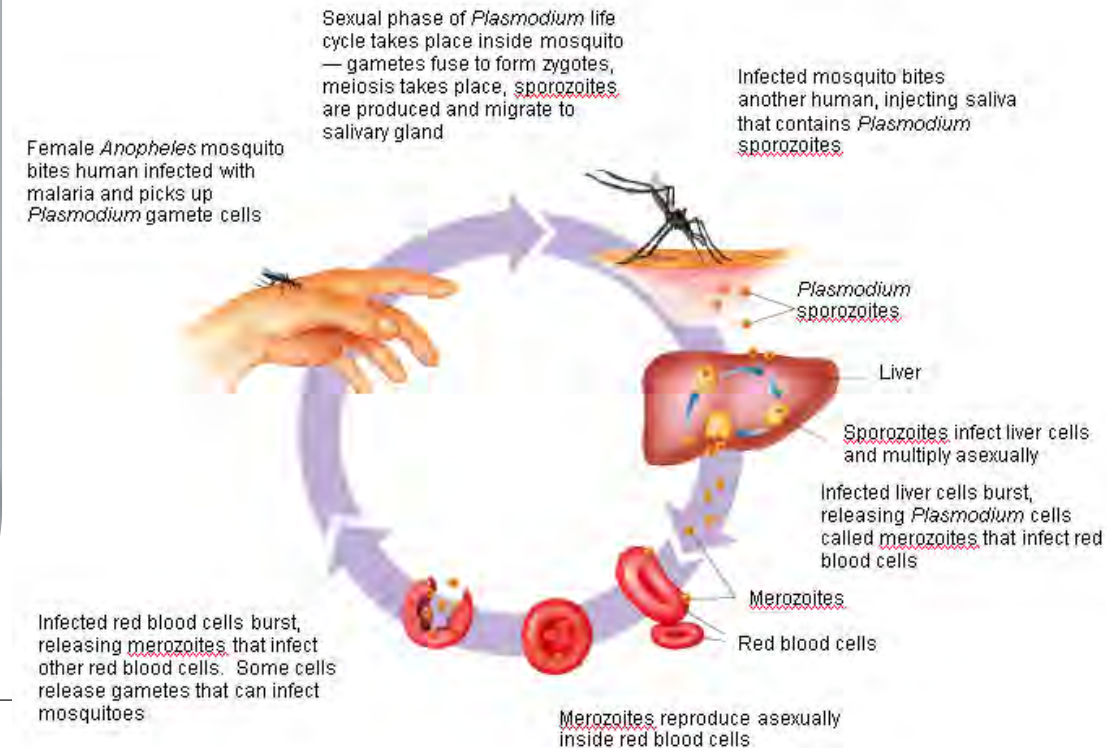
6. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.

7. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpreting time should be properly increased.

INTERPRETATION OF THE TEST

Positive	Invalid
C T	C T
Negative	Invalid
C T	C T



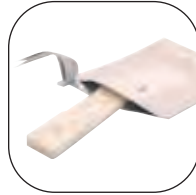
ASSAY
INNOVATION



CareStart pLDH Malaria Test

Whole Blood, Plasma or Serum

TEST INSTRUCTIONS



1. Remove the test device from the foil pouch, and place it on a flat, dry surface.



2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end.



3. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. Make sure that you do not use more than 5ul of sample. If using whole blood, allow sample to absorb for 1-2 minutes before adding the diluent.



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NOTE: full absorption of each drop is necessary to allow the sample to flow through the special filter in the sample well.



5. Start the timer.



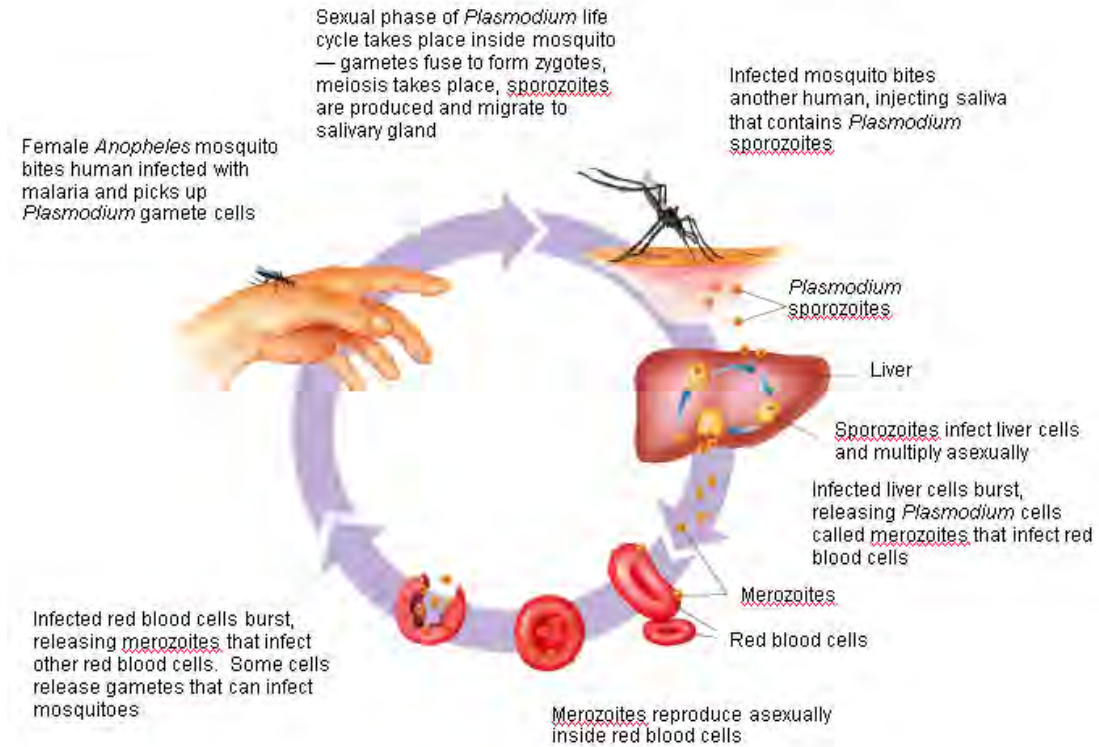
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INTERPRETATION OF THE TEST

Positive	Invalid
C T	C T
Negative	Invalid
C T	C T



ASSAY INNOVATION

ISO 9001

ISO 13485

EN 46001

GMP

QSR