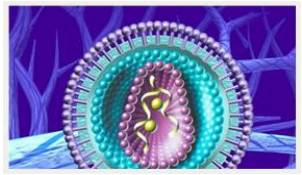
CATÁLOGO CORE PRUEBAS RÁPIDAS 2013, AKRALAB

Pulsar Aquí

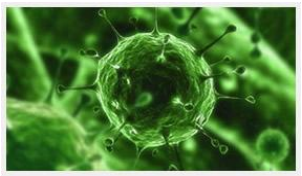
1.- VIH

- CORE HIV 1 & 2
- INMUNOFLOW VIH - VIH2 (WB)
- INMUNOFLOW VIH HIV2 (BM)
- CORE COMBO VIH HBsAs VHC



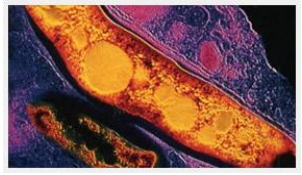
2.- HEPATITIS

- INMUNOFLOW VHC
- CORE DEL VHC
- CORE HBsAg
- CORE COMBO VIH HBsAg VHC



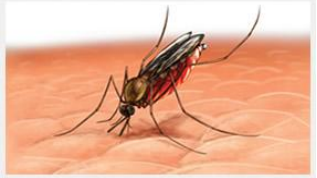
3.- TUBERCULOSIS

- CORE TUBERCULOSIS



4.- MALARIA, DENGUE Y CHAGAS

- CORE Pf MALARIA
- CORE Pan MALARIA / Pf
- CORE MALARIA Pf / Pv
- CORE MALARIA Pan / Pv / Pf
- CORE DENGUE IgG - IgM
- CORE CHAGAS



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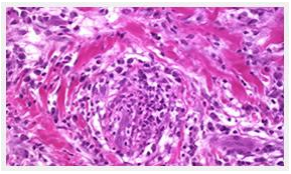
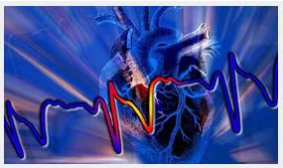
- 5.- SIFILIS

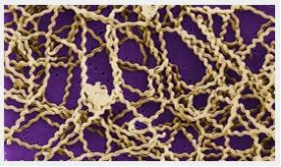


- CORE SIFILIS
- 6.- TIFOIDEA

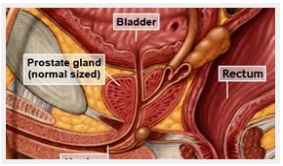
- CORE TIFOIDEA SALMONELLA
- 7.- TROPONINA



- CORE TROPONINA I
- 8.- LEPTOSPIROSIS



- CORE LEPTOSPIROSIS
- 9.- PSA - ANTÍGENO PROSTÁTICO ESPECÍFICO



- CORE PSA
- 10.- PRUEBA DE EMBARAZO

- BETA HCG CLEAR

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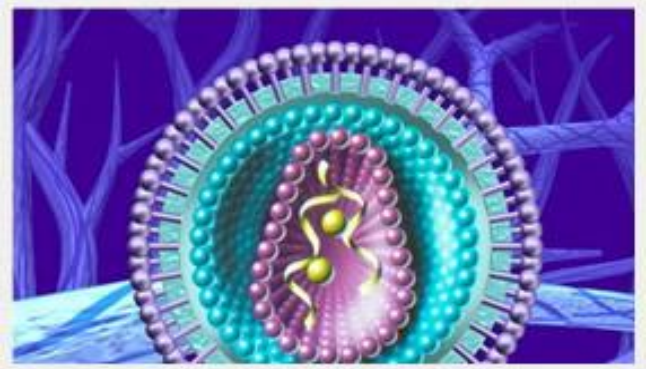
VIH

1.- CORE HIV 1 & 2

2.- INMUNOFLOW VIH - VIH 2 (WB)

3.- INMUNOFLOW VIH HIV2 (BM)

4.- CORE COMBO VIH HBsAg VHC



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Core™ HIV 1&2

Rapid test for the detection of Antibodies to Human Immunodeficiency Virus (HIV) in Serum, Plasma and Whole Blood

INTRODUCTION

Core™ HIV 1&2 is an *in vitro*, rapid, qualitative two site sandwich immunoassay used for the detection of antibodies to HIV 1/2 virus in human serum, plasma and whole blood. For Professional use.

SUMMARY

Core™ HIV 1&2 is using an immunochromatography method for the detection of antibodies to HIV 1/2 virus in human serum, plasma and whole blood. Highly purified antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide representing HIV-1 and gp 36 representing HIV-2 are used in this test to detect antibodies to HIV 1&2.

PRINCIPLE

Core™ HIV 1&2 utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane.

A mixture of highly purified recombinant antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide, representing HIV-1 and recombinant gp36 representing HIV-2 are coated on the membrane in the test region and anti-rabbit antiserum in the control region.

As the test sample flows through the membrane assembly within the test device, the colored HIV 1/2 specific recombinant antigen-colloidal gold conjugate complexes with HIV antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the HIV 1/2 specific recombinant antigens coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Core™ HIV 1&2 kit has the following components.

A. Individually pouched devices comprising of:

1. Test Device: Comprising of HIV 1/ 2 specific recombinant antigen-colloidal gold conjugate, Rabbit IgG- colloidal gold conjugate, membrane assembly predispensed, with HIV 1/2 specific recombinant antigen and goat anti-rabbit antiserum coated at the test region and the control region respectively.
2. Disposable Plastic Dropper.
3. Desiccant Pouch.

B. Sample Running Buffer: 0.1 M Tris buffer with 1.5% Tween 20 and 0.1% Sodium azide.

Cat. No./ Component	HIV-110001	HIV-110010	HIV-110021	HIV-110050	HIV-110100
Test Device	1	10	25	50	100
Sample Running Buffer	1 ml X 1 bottle	5 ml X 1 bottle	10 ml X 1 bottle	10 ml X 2 bottles	10 ml X 4 bottles

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial.

After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C.

Do not freeze the kit or components.

NOTES

1. For *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.
7. If the color of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. No prior preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Anticoagulated whole blood can also be used as specimen. Whole blood or plasma specimens containing anticoagulants other than EDTA, Trisodium citrate or Heparin may give incorrect results. Serum / plasma may be stored at 2-8°C upto 24 hours in case of delay in testing. For long-term storage, freeze the specimen at -20°C. Whole blood should be used immediately and should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided. Maximum of 2 freeze/thaw cycles are allowed.
4. Do not use haemolysed, clotted, contaminated, viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not heat inactivate the sample before use.
7. Frozen samples for retrospective studies must be centrifuged at 3000 rpm for 15 minutes and the clear supernatant must be used for tests.

Precautions under the HIV regulations:

1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HIV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Let the sealed pouches attain room temperature (20-30°C).
2. Tighten the cap of sample running buffer bottle clockwise to pierce the dropper bottle nozzle. The pin situated inside the buffer bottle cap will break through the plastic membrane which seals the opening of the dropper vial.
3. Tear open the sealed pouches and retrieve the appropriate number of test device as required. Label the test device appropriately. Once opened, the devices must be used immediately.
4. The addition of the specimen and buffer must be done at the center of the sample/reagent addition ports holding the sample dropper / dropper bottles in a vertical position. Ensure the drops are free falling. Use a new sample dropper for each specimen to avoid cross contamination.
5. Dispense two drops (50 µl) of serum / plasma OR whole blood using the sample dropper provided into the sample port "A".
6. Dispense five drops of sample running buffer into reagent port "B".
7. Between 15-30 minutes after addition of buffer, read the results as follows:

Positive
If HIV-1 and/or HIV-2 antibodies are present, two colored bands appear at Test (T), and Control (C) region.

Negative
If HIV-1 and/or HIV-2 antibodies are not present, only one colored band at Control (C) would appear.

Invalid
The test is invalid if the Control band is not visible at 30 minutes. Verify the test procedure and repeat the test with a new **CORE HIV 1&2** device.

Invalid
The test is also invalid if only the Test band and no Control band is visible at 30 minutes. Verify the test procedure and repeat the test with a new **CORE HIV 1&2** device.

8. Negative results must be confirmed only at the end of 30 minutes although, depending on the concentration of antibodies to HIV in the specimen, positive results may start appearing as early as 2 minutes.

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REMARK:
To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. **Diagnostic specificity:**
A total of 1204 samples were tested with **Core™ HIV 1&2** at two European Blood Transfusion Centres. 3 samples were found repeatedly positive. The diagnostic specificity is determined as 99.75%.

Centre	Number of samples tested	Core™ HIV 1 & 2	
		Negative	Positive
A	1009	1006	3
B	195	195	0
Total	1204	1201 (**99.75%**)	3

2. **Diagnostic sensitivity:**
500 HIV positive samples were tested with **Core™ HIV 1&2,** all of them were found positive. The diagnostic sensitivity is determined as 100%.

HIV Type	Number of samples tested	Core™ HIV 1 & 2	
		Negative	Positive
HIV-1	360	0	360[a]
HIV-2	100	0	100
HIV-1 subtype non-B	40	0	40

[a]: among the positive results, 6 samples obtained a very faintly colored test band.

3. **Possible Interferences :**
The table below shows the results of **Core™ HIV 1&2** tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	Core™ HIV 1 & 2	
		Negative	Positive
Clinical specimens	200	200	0
Pregnant women	200	200	0
Related infections (*)	100	98	2
Rheumatoid Factor positive	7	7	0
Multipara	1	1	0
Anti-E coli positive	2	2	0

(*) The results were negative for samples containing HBsAg (15), anti-HCV (12), anti-HTLV (14), anti-HSV (16), anti-VZV (4) and anti-EBV (4). 1 of the 20 anti-CMV samples and 1 of the 15 anti-HAV samples were found false positive.

All the above mentioned data of test performance was carried out using serum samples.

4. **Comparison of Core™ HIV 1&2 performance in paired whole blood, serum and plasma samples**

Sample type	Number of samples tested	Positive by Core™ HIV 1 & 2		
		Serum	Plasma	Whole blood
HIV positive	100	100	100	100
HIV negative	1064	2	2	2

Sensitivity 100 % , Specificity 99.8 %.

5. **Seroconversion panels**
The sensitivity, evaluated on 30 commercially available seroconversion panels (plasma samples, Boston Biomedica Inc.), is comparable to HIV Antibody detection ELISA's registered in major European countries. Three panels (N, X and D) were converted to whole blood panels by mixing equal volumes of O Rh+ packed cells and each panel specimen. The results were similar to that of original panel specimen.

6. **Precision**
Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. The test detects the presence of antibodies to HIV in the specimen and hence should not be used as the sole criterion for the diagnosis of HIV infection.
2. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow-up testing using other clinical methods is recommended.
3. A negative result at any time does not preclude the possibility of exposure to or infection with HIV.
4. A positive test result, even a very faintly positive, must be verified with a confirmation test.

BIBLIOGRAPHY

1. Popovic, M., et.al. Detection Isolation and continuous production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and pre-AIDS. Science 1984; 224:497.
2. Carlson, J. R., et.al. AIDS serology testing in low and high risk groups. JAMA 1985; 253:3405.
3. Centers for Disease Control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982; 31:507.
4. Gallo, R. C., et. al. Frequent detection and isolation of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and a risk for AIDS. Science. 1984; 224:500.

SYMBOLS USED ON CORE™ HIV 1&2 LABELS

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
IVD	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient for <n> tests

Version : En4 - 04/2009

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LIMITATIONS OF THE TEST

ImmunoFlow HIV1-HIV2 kit alone cannot be used to diagnose infection with HIV even if the sample is repeatedly reactive or has high intensity of bands. Clinical diagnosis can only be established by a physician. A negative result does not preclude the possibility of exposure to or infection with HIV. Since HIV 1 and HIV 2 viruses are similar in genomic structure and morphology and antibodies to them have (30-70 %) cross reactivity, reactive test bands for HIV1 and HIV 2 do not necessarily imply mixed infection with HIV 1 and HIV 2.

BIBLIOGRAPHY

1- Popovic, M., et.al., Detection Isolation and continuous production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and pre-AIDS. Science 1984;224:497.
2- Carlson, J. R.,et.al., AIDS serology testing in low and high risk groups. JAMA 1985;253:3405
3- Centers for Disease Control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982;31:507
4- Gallo, R. C., et. al., Frequent detection and isolation of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and a risk for AIDS. Science. 1984; 224:500.

SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

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ImmunoFlow HIV 1- HIV 2

Rapid test for the detection and differentiation of Antibodies to Human Immunodeficiency Virus (HIV 1 and HIV 2) in Serum.
Cat N° HIV-110022

INTRODUCTION

ImmunoFlow HIV1-HIV2 is intended to be used for simultaneous and differential detection of antibodies to HIV 1 and HIV 2 virus in human serum.

SUMMARY

ImmunoFlow HIV1-HIV2 is a third generation immunochromatographic method for simultaneous and differential detection of antibodies to HIV 1 and 2 virus in human serum . Highly purified antigens gp 41-120 and 'O' fusion polypeptide representing HIV- 1 and synthetic peptide gp 36 representing HIV-2 are stripped on the membrane as two separate test bands. An assay control forms the third band. The same antigens are also coated on colloidal gold.

PRINCIPLE

The membrane of ImmunoFlow HIV1-HIV2 is stripped separately with HIV 1 and 2 specific antigens and a reagent control. Specimen is added and allowed to move along the membrane. Any antibodies, if present, bind to their respective antigens coated on the colloidal gold forming an antibody-antigen-gold complex. This complex moves along the membrane and gets captured by the HIV specific antigens coated on the membrane forming a red/purple coloured band. The unbound material moves to the other end of the membrane where goat anti-rabbit IgG captures rabbit IgG gold forming the control band.

REAGENTS AND MATERIALS SUPPLIED

ImmunoFlow HIV1-HIV2 kit has the following components:

1. Device: Stripped with HIV 1 and 2 specific antigens and goat anti rabbit IgG along with HIV specific antigen and rabbit IgG gold conjugate. Individually pouched along with sample dropper and desiccant.
2. Sample running buffer: Tris buffer with 1.5 % Tween 20 and 0.1 % sodium azide.
3. Product insert.

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial.
After first opening of the sample running buffer vial, the buffer is stable untill the expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.
7. If the colour of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for 24 hours. Maximun of two freeze/thaw cycles are allowed. For long storage, freeze at -20°C or below. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Specimen containing precipitate or particulate matter should be clarified by centrifugation prior to use.
7. Do not use turbid,lipaemic, haemolysed,clotted or contaminated specimens

Precautions under the HIV regulations:

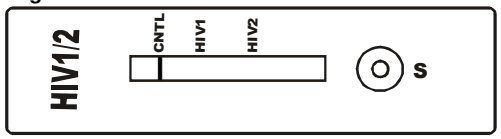
1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HIV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
4. Bring all reagents and specimen to room temperature before use.
5. Do not pipette any material by mouth.
6. Do not eat, drink or smoke in the area where testing is done.
7. Use protective clothing and wear gloves when handling samples.
8. Use absorbent sheet to cover the working area.
9. Immediately clean up any spills with sodium hypochlorite.
10. Dispose off all the reagents and material used as if they contain infectious agent.
11. Neutralize acid containing waste before adding hypochlorite.
12. Do not use kit after the expiry date.
13. Do not mix components of one kit with another

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1.Bring all reagents and specimen to room temperature before use.
2.Take out required number of devices and label them.
3.Add one drop (25 µl) of serum in the sample well marked 'S'
4.Add two drops sample running buffer in the same well marked 'S'
5.Read results after 15 minutes.
6.The time may be extended to 30 minutes in case background is not cleared at 15 minutes to read the results correctly.
7.Do not read results after 30 minutes.

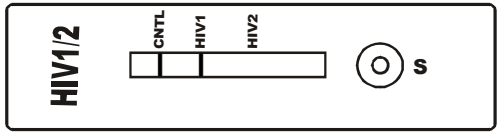
Interpretation of Results:

Negative

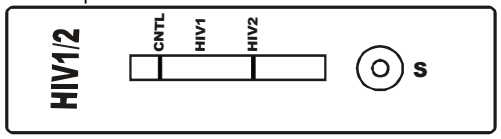


A coloured band appears only in the control area marked "CNTL".

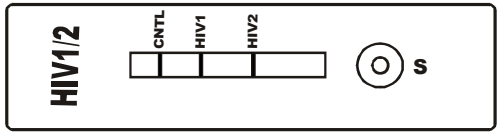
Positive



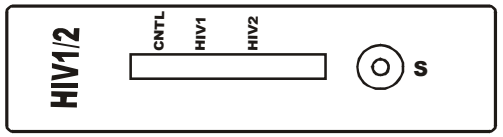
Positive HIV-1: A coloured band appears in control area as well as in the area marked "HIV1". The sample is reactive for HIV 1.



Positive HIV-2: A coloured band appears in control area as well as in the area marked "HIV2". The sample is reactive for HIV 2.



Positive HIV-1/2: A coloured band appears in control area as well as in the area marked "HIV1" and "HIV2". The sample is reactive for HIV 1 and HIV 2.



Invalid
No band appears in the control area. The test should be repeated with fresh device.

1. Although, depending on the concentration of antibodies to HIV in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
2. Some sample may take a longer time to clear. In such cases the result may be confirmed at 30 minutes. Do not read results after 30 minutes.

REMARK:

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. **Diagnostic specificity:**

A total of 1000 samples were tested with the ImmunoFlow HIV1-HIV2 at an European blood Transfusion Centre. No false positive was recorded. The diagnostic specificity is determined as 100%.

Centre	Number of samples tested	ImmunoFlow HIV1-HIV2	
		Negative	Positive
A	1000	1000	0
Total	1000	1000 (100%)	0

2. **Diagnostic sensitivity:**

501 HIV positive samples were tested with the ImmunoFlow HIV1-HIV2, all of them were found positive. The diagnostic sensitivity is determined as 100%.

HIV Type	Number of samples tested	ImmunoFlow HIV1-HIV2	
		negative	positive
HIV-1	360	0	360
HIV-2	101	0	101
HIV-1 subtype non-B	40	0	40

Possible Interferences:

The table below shows the results of the ImmunoFlow HIV1-HIV2 tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	ImmunoFlow HIV1-HIV2	
		negative	positive
clinical specimens	200	200	0
pregnant women	200	200	0
related infections (*)	100	100	0

(*) The results were negative for samples containing HBsAg (20), anti-HCV (20), anti-HTLV (15), Anti-HAV IgM (3), Anti-parvovirus B19 (15), Anti-Rubella (10), Anti-HBsAg (17).

To test interference by blood components on the performance of ImmunoFlow HIV1-HIV2 Precipath U was used as negative sample as well as diluent for positive samples.
Precipath U, is a lyophilized control based on human serum. The adjusted concentrations and activities of the components are in pathological range.
The results show that blood components present in the pathological range do not affect performance of ImmunoFlow HIV1-HIV2.

3. **Seroconverslon panels**

The sensitivity, evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.), complying with European Directives for evaluation of in vitro diagnostic rapid assay- Data available upon request.

4. **Precision**

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. The test detects the presence of antibodies to HIV in the specimen and hence should not be used as the sole criterion for the diagnosis HIV infection.
2. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow-up testing using other clinical methods is recommended.
3. A negative result at any time does not preclude the possibility of exposure to or infection with HIV.
4. A positive test result, even a very faintly positive, must be verified with a confirmation test.
5. Since HIV –1 and HIV-2 viruses are similar in genomic structure and morphology, antibodies to them may cross react. Reactive test bands for both HIV 1 and HIV 2 do not necessarily imply mixed infection.However,to reduce cross reactivity & better descrimination **, ImmunoFlow HIV1-HIV2** uses a synthetic peptide gp 36 with highly conserved epitopes for HIV –2 detection instead of recombinant gp 36 antigen. Despite this some HIV – 2 sera may show both the bands with **ImmunoFlow HIV1-HIV2**

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SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
IVD	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

CORE Diagnostics

akralab
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volver

ImmunoFlow HIV 1- HIV 2 (WB)

Rapid test for the detection and differentiation of Antibodies to Human Immunodeficiency Virus (HIV 1 and HIV 2) in Serum, Plasma and Whole Blood .
Cat N° HIV-110023

INTRODUCTION

ImmunoFlow HIV1- HIV2 is an in vitro, rapid, self performing, qualitative two site sandwich immunoassay used for the detection and differentiation of antibodies to HIV 1 and HIV 2 virus in human serum, plasma and whole blood.

SUMMARY

ImmunoFlow HIV1- HIV2 is using an immunochromatography method for the detection of antibodies to HIV 1 and 2 virus in human serum, plasma and whole blood. Highly purified antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide representing HIV-1 and gp 36 representing HIV-2 are used in this test to detect antibodies to HIV 1and 2.

PRINCIPLE

ImmunoFlow HIV1- HIV2 utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane.
A mixture of highly purified recombinant antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide, representing HIV-1 and gp36 representing HIV-2 are coated as two test bands on the membrane in the test region.A third band of goat anti-rabbit antiserum is coated in the control region.
As the test sample flows through the membrane assembly within the test device, the colored – HIV 1 and 2 specific antigen-colloidal gold conjugate complexes with HIV antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the HIV 1 and / or HIV 2 specific antigens coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

ImmunoFlow HIV1- HIV2 kit has the following components.

A Individually pouched devices comprising of:
   1. Test Device : Comprising of HIV 1 and 2 specific antigen-colloidal gold conjugate, rabbit IgG- colloidal gold conjugate, membrane assembly predispensed, with HIV 1 and HIV 2 specific antigens and goat anti-rabbit antiserum coated at the test region and the control region respectively.
   2. Disposable Plastic Dropper
   3. Desiccant Pouch.

B Sample Running Buffer: 0.1 M Tris buffer with 1.5% Tween 20 and 0.1% Sodium azide.

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial.
After first opening of the sample running buffer vial, the buffer is stable untill the expiration date, if kept at 4°C to 30°C.
Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

6. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.
7. If the colour of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

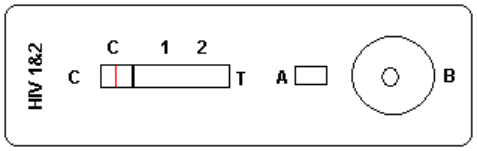
1. No prior preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Anticoagulated whole blood can also be used as specimen. Serum / plasma may be stored at 2- 80 C upto 24 hours in case of delay in testing. For long-term storage, freeze the specimen at –200 C. Whole blood should be used immediately and should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Do not use haemolysed, clotted, contaminated, viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not heat inactivate the sample.
7. Frozen samples for retrospective studies must be centrifuged at 3000 rpm for 15 minutes and the clear supernatant must be used for tests.

Precautions under the HIV regulations:

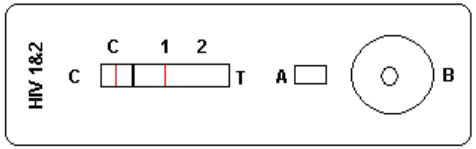
1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HIV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

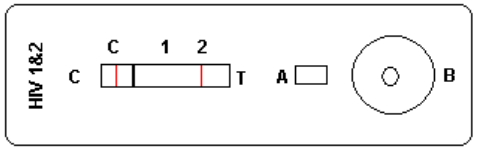
1. Let the sealed pouches attain room temperature (20-30 0C).
2. Tighten the cap of sample running buffer bottle clockwise to pierce the dropper bottle nozzle. The pin situated inside the buffer bottle cap will break through the plastic membrane which seals the opening of the dropper vial
3. Tear open the sealed pouches and retrieve the appropriate number of test device as required. Label the test device appropriately. Once opened, the devices must be used immediately.
4. The addition of the specimen and buffer must be done at the center of the sample/reagent addition ports holding the sample dropper / dropper bottles in a vertical position. Ensure the drops are free falling. Use a new sample dropper for each specimen to avoid cross contamination.
5. Dispense two drops (50 µl) of serum / plasma OR whole blood using the sample dropper provided into the sample port “A”
6. Dispense five drops of sample running buffer into reagent port 'B'.
7. At the end of fifteen minutes after addition of buffer ,read the results as follows:



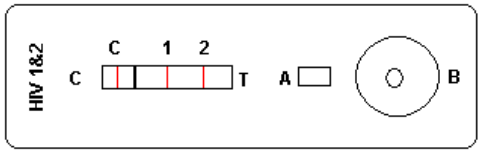
Negative : A colored band appears only in the control area marked “C ’’



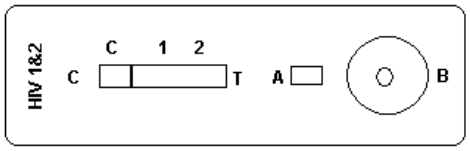
HIV – 1 Positive: A colored band appears in the control area as well as in the area marked “ 1 ”. The sample is reactive for HIV 1.



HIV – 2 Positive: A colored band appears in the control area as well as in the area marked “ 2 ”. The sample is reactive for HIV 2.



HIV– 1 & HIV- 2 Dual Positive : A colored band appears in the control area as well as in the area marked “ 1 ” & “ 2 ”. This indicates a mixed infection.



Invalid

The test should be considered invalid if the Control band “C ” does not appear.The test is also invalid if only the test band and no control band appear.Repeat the test with a new ImmunoFlow HIV 1-HIV 2 membrane test assembly.

8. Although, depending on the concentration of antibodies to HIV in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
9. Some sample may take a longer time to clear. In such cases the result may be confirmed at 30 minutes. Do not read results after 30 minutes.

REMARK:

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

In a clinical trial, One thousand five hundred negative specimens for antibodies to HIV 1 and 2 were tested with ImmunoFlow HIV 1- HIV2 as well as 320 HIV 1 and 41 HIV 2 positive samples.
The results are as follows:

Specimen	Total No. of samples tested	Results ImmunoFlow HIV 1-HIV 2
HIV 1&2 Negative	1500	1500
HIV1 Positive	320	320
HIV2 Positive	41	41

Based on above study the specificity and the sensitivity of ImmunoFlow HIV 1-HIV 2 is 100 %

Precision

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples. No variations were found in the outcome of the different tests.

Core Combo HIV-HBsAg-HCV

(Device)

INTRODUCTION

Core Combo HIV-HBsAg-HCV is an *in vitro*, rapid, self performing, qualitative two site sandwich immunoassay used for the detection of antibodies to HCV , HIV 1 / 2 virus and HBsAg in human serum / plasma or whole blood specimens.

Summary

Core Combo HIV-HBsAg-HCV is using an immunochromatography method for the detection of antibodies to HCV , HIV 1 / 2 virus and HBsAg in human serum/plasma and whole blood.

Hepatitis C virus (HCV) is a small, enveloped, and single-stranded RNA virus. It is the major cause of parenterally transmitted non-A, non-B hepatitis. Antibodies to HCV are reported in 80% of the non-A, non-B hepatitis patients.

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B Surface Antigen (HBsAg), earlier known as Australia Antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter.

Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infections.

Core HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml within 15 minutes.

Highly purified antigen of gp 41, representing HIV- 1 and gp 36 representing HIV-2, recombinant HCV antigens (Core, NS-3, NS-4 and NS-5) and Anti HBsAg antibodies are used in this test.

Principle

Core Combo HIV-HBsAg-HCV utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane.

In **Core Combo HIV-HBsAg-HCV,** a line containing a mixture Highly purified antigen of gp 41, representing HIV- 1 and gp 36 representing HIV-2 (line 1) , a line of Anti HBsAg antibodies (line2) and a line of recombinant HCV antigens (line 3) are coated on the membrane in the test region and anti- Rabbit antiserum at the control region.

As the test sample flows through the membrane assembly within the test device, the colored conjugated colloidal gold complex (HIV 1 / 2 specific recombinant antigen-colloidal gold conjugate, anti-HBsAg-colloidal gold conjugate, HCV specific recombinant antigen-colloidal gold conjugate) reacts with antibodies to HIV 1 / 2, HCV and HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized at individual lines coated with the HIV 1 / 2 Specific recombinant antigens (line 1) , Anti HBsAg antibodies (line2) and recombinant HCV antigens (line 3) coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Rapid Test For HIV-HBsAg-HCV kit has the following components.

A. Individually Pouched devices
2. Disposable Plastic Dropper
3. Desiccant Pouch.

B Sample Running Buffer.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

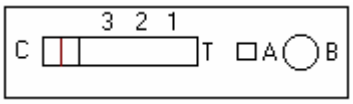
No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma/whole blood is preferable, specimens may be stored at 2-8 °C for upto 24 hours, in case of delay in testing. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used. Fresh blood from finger prick / puncture may also be used as a test specimen.

Do not freeze whole blood samples. Do not use turbid,lipamic and haemolysed specimens.

Do not use haemolysed, clotted or contaminated blood samples.

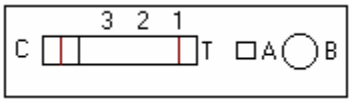
TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Label the test device with patients identity.
4. Add two drop of serum/ plasma or two drops of whole blood with the sample dropper provided in the well marked "A".
5. Add four drops of sample running buffer in the well marked "B".
6. At the end of 15 minutes read the results as follows.

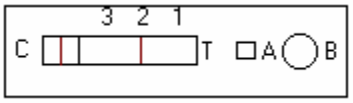


Negative : Only one coloured band appears on the control Window`C'

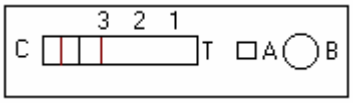
Positive In addition to the control band, a distinct colored band/bands appears on the test Window`T as follows.



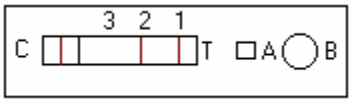
Positive for HIV 1/2



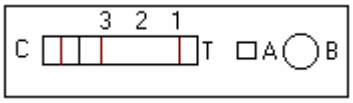
Positive for HBsAg



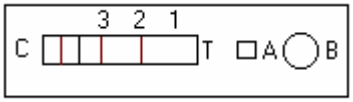
Positive for HCV



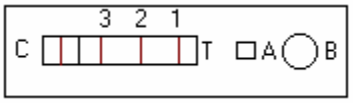
Positive for HIV 1/2 and HBsAg



Positive for HIV 1/2 and HCV



Positive for HBsAg and HCV



Positive for HIV 1/2 and HBsAg and HCV

7. The test should be considered invalid if neither the test band nor the control band appear. Repeat the test with a new device.
8. In case of a doubtful result at 15 minutes, the test may be extended upto 30 minutes to get a clear background.

CORE Diagnostics

Aspect Court, 4 Temple Row
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United Kingdom

CORE DIAGNOSTICS

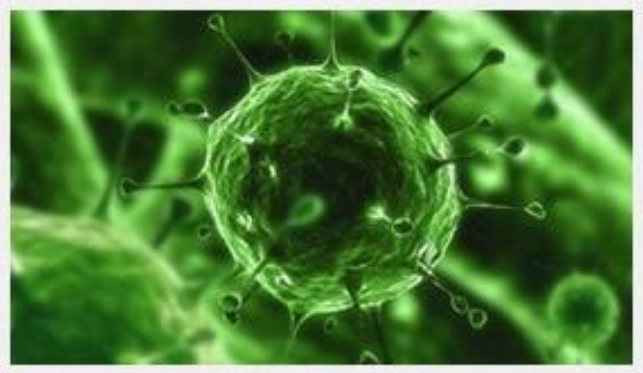
HEPATITIS

1.- INMUNOFLOW VHC

2.- ICORE DEL VHC

3.- CORE HBsAg

4.- CORE COMBO VIH HBsAg VHC



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SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests
Xn  R22 - S23-46-61 NaN_3	R22:Harmful if swallowed; S23:Do not breathe vapour S46:If swallowed, seek medical advice immediately and show this container or label S61:Avoids release to the environment. Refer to special instructions/safety data sheets

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UNITED KINGDOM

Version: Eng 03 – 05/2008

CE 0459

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ImmunoFlow HCV

Rapid test for the detection of Antibodies to Hepatitis C Virus (HCV) in human serum,

CE 0459

INTRODUCTION

ImmunoFlow ™ HCV is an in vitro, rapid, qualitative immunoassay used for the detection of antibodies to HCV virus in human serum. For Professional use.

SUMMARY

Hepatitis C virus (HCV) is a single stranded RNA virus of the Flaviviridae family. HCV is now known to be the causative agent for most, if not all non A , non B hepatitis (NANBH). Antibodies to the hepatitis C encoded antigens are prevalent in the sera of HCV infected individuals. Detection of these antibodies indicates exposure to the Hepatitis C virus.

PRINCIPLE

The membrane of ImmunoFlow HCV is striped with recombinant HCV antigens representing Core, NS3, NS4, NS5 and a reagent control. Specimen is added followed by sample running buffer and allowed to move along the membrane. The IgG present in the sample binds to Protein-A coated on the colloidal gold forming an IgG-Protein A-gold complex. This complex moves along the membrane and gets captured by the HCV specific antigens coated on the membrane forming a red/purple coloured band. The unbound material moves to the other end of the membrane where control reagent captures the complex forming the control band.

.

REAGENTS AND MATERIALS SUPPLIED

Kit Components

ImmunoFlowHCV kit has following components.

1. Device : Stripped with HCV specific antigens and control reagent along with Protein-A gold conjugate. Individually pouched.
2. Sample Running Buffer : Buffer containing surfactant and preservatives. Ready to use.
3. Instruction for use

Cat.No./ Component	HCV-120025	HCV-120050	HCV-120100
Test Device	25	50	100
SampleRunning Buffer	5 ml X 1 bottle	5 ml X 2 bottle	5 ml X 4 bottles

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipette 2. Timer

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C. Once the pouch is opened, device must be used immediately. Do not freeze the kit or components.

PRECAUTIONS

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides.

Flush with large volumes of water to prevent azide build up in the plumbing.

7. If the pouch of the test device is damaged, discard the device and take a new one for the test.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum is preferable, specimens may be stored at 2° C to 8° C for up to 7 days, in case of delay in testing. Care should be taken to avoid contamination.
Do not use contaminated, turbid, lipemic and haemolysed specimens.

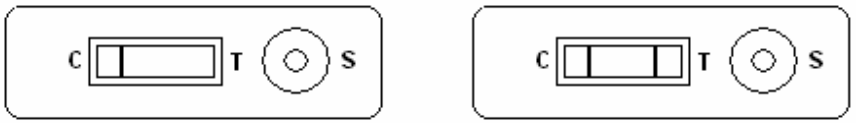
Precautions under the HCV regulations:

1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HCV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring all reagents and specimen to room temperature before use.
2. Take out required number of devices and label them.
3. Add 5 µl of serum in the sample port marked “S”.
4. Add two drops of sample running buffer in the same port. Allow first drop to soak in then add the second drop.
5. Read results at the end of 15 minutes.

NEGATIVE: POSITIVE:



Negative: Only one colored band appears on the control region 'C'
Positive: In addition to the control band, a distinct colored band also appears on the test region "T”

6. The test should be considered invalid if the control band does not appears. Repeat the test with a new device. In the absence of sample addition, control band does not appear.
7. Although, depending on the concentration of antibodies to HCV in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
8. In case of a doubtful results at 15 minutes, the test may be extended up to, but no longer than, 30 minutes to get a clear background.

REMARK:

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. **Diagnostic specificity:**
A total of 1000 samples were tested with the Immunoflow HCV at European Blood Transfusion Centres 2 samples were found repeatedly positive. The diagnostic specificity is determined as 99.80%.

Centre	Number of samples tested	ImmunoFlow HCV	
		Negative	Positive
A	1000	998	2
Total	1000	998	2

2. **Diagnostic sensitivity:**
402 HCV positive samples (genotypes 1to 5) were tested with the ImmunoFlow HCV, all of them were found positive.
The diagnostic sensitivity is determined as 100%.

	Number of samples tested	ImmunoFlow HCV	
		negative	positive
HCV	402	0	402

3. **Possible Interferences:**
The table below shows the results of the ImmunoFlow HCV tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	ImmunoFlow HCV	
		negative	positive
clinical specimens	200	200	0
pregnant women	200	200	0
related infections (*)	100	100	0

(*) The results were negative for samples containing HBs Ag (20), anti-HIV (4), anti-HTLV (15), anti-HBsAg (18), anti-Rubella (10), anti-parvovirus B19 (17) , anti-HAV –IgM(4), anti CMV (12).

4. **Seroconversion panels**
The sensitivity was evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.). It was found that ImmunoFlow HCV was as sensitive as some of the ELISAs assay.

5. **Precision**
Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HCV samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. The test detects the presence of antibodies to HCV in the specimen and hence should not be used as the sole criterion for the diagnosis of HCV infection.
2. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow-up testing using other clinical methods is recommended.
3. A negative result at any time does not preclude the possibility of exposure to or infection with HCV
4. A positive test result, even a weak positive, must be confirmed with blot assays such as RIBA.
5. It has been observed that Immunoflow HCV, like many other immunodiagnostic methods, may show negative result with HIV co-infected or immunodepressed patients. This possibility should be considered while interpreting results.

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Core HCV

Rapid test for the detection of antibodies to Hepatitis C Virus (HCV)
in human serum

INTRODUCTION

Core HCV is an in vitro, rapid, qualitative two site sandwich immunoassay used for the detection of antibodies to HCV in human serum. For professional use.

SUMMARY

Hepatitis C Virus (HCV) is a single stranded RNA virus of the Flaviviridae family. HCV is now known to be the causative agent for most, if not all non A, non B hepatitis (NANBH). Antibodies to the hepatitis C encoded antigens are prevalent in the sera of HCV infected individuals. Detection of these antibodies indicates exposure to the Hepatitis C Virus.

PRINCIPLE

Core HCV utilizes the principle of lateral flow immunochromatography, a unique two site double antigen sandwich immunoassay on a membrane. As the test specimen flows through the test device, the coloured HCV specific recombinant antigen-colloidal gold conjugate complexes with HCV antibodies in the sample. This complex moves further on the membrane to the test region 'T' where it is immobilized by the HCV specific recombinant antigens coated on the membrane leading to formation of a coloured band, which confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result. The unreacted conjugate and unbound complex, if any, along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region 'C', forming a coloured band. This control band serves to validate the reagent and assay performance.

REAGENTS AND MATERIALS SUPPLIED

Kit Components

1. Core HCV test device comprises of HCV specific recombinant antigen-colloidal gold conjugate co-dispensed with rabbit IgG colloidal gold conjugate; pre dispensed with HCV specific recombinant antigen at region 'T', and anti rabbit antiserum pre dispensed at the region 'C', along with a plastic sample dropper and desiccant.
2. Sample Running Buffer: Phosphate Buffer, 0.15 M, pH 8.0 with 1.5% Tween 20 and 0.1% sodium azide.
3. Package insert.

Cat. No./Component	HCV-130001	HCV-130010	HCV-130022	HCV-130050	HCV-130100
Test device	1	10	25	50	100
Sample Running Buffer	1 ml x 1 bottle	5 ml x 1 bottle	10 ml x 1 bottle	10 ml x 2 bottles	10 ml x 4 bottles

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STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C.Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%).Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.
7. If the colour of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum is preferable, specimens may be stored at 2°C to 8°C for up to 24 hours, in case of delay in testing.
Do not use turbid, lipemic and haemolysed specimens.

Precautions under the HCV regulations:

1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HCV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature (20 ºC -28 ºC) before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Label the test device with patient's identity.
4. Add two drops of serum (50 µl) using the sample dropper provided, in the well marked "A". A lab micropipette can also be used.
5. Add 3 drops of sample running buffer in the well marked "B" using the dropper vial.
6. At the end of 15 minutes read the results as follows:

NEGATIVE **POSITIVE**

Negative: Only one coloured band appears at the control region "C".
Positive: In addition to the control band, a distinct coloured band also appears at the test region "T".

7. The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new device.
8. Although, depending on the concentration of antibodies to HCV in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
9. In case of a doubtful result at 15 minutes, the test may be extended upto, but no longer than, 30 minutes to get a clear background.

REMARK

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. **Diagnostic specificity:**
   A total of 1003 samples were tested with the Core HCV at European Blood Transfusion Centres. 2 samples were found repeatedly positive .The diagnostic specificity is determined as 99.80%.

Centre	Number of samples tested	Core HCV	
		Negative	Positive
A	1003	1001	2
Total	1003	1001 (99.80%)	2

2. **Diagnostic sensitivity:**
   400 HCV positive samples were tested with Core HCV. The diagnostic sensitivity is determined as 98.25% as compared to ELISA methods.

	Number of samples tested	Core HCV	
		Negative	Positive
HCV	400	7*	393

* These samples were PCR negative and indeterminate with Blot-assays, 4 samples are confirmed HIV.

3. **Possible Interferences:**
   The table below shows the results of the Core HCV tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	CoreHCV	
		Negative	Positive
Clinical specimens	212	212	0
Pregnant women	200	200	0
Related infections (*)	107	107	0

(*) The results were negative for samples containing HBsAg (20), anti-HIV (6), anti-HTLV (14), anti-HSV(12),anti –VZV (9), anti- EBV (4), anti-HAV-IgM (15),anti CMV (20),RF (7).

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4. Seroconversion panels

The sensitivity was evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.).It was found that Core HCV was less sensitive than some of the ELISA's.

5. Precision

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HCV samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. The test detects the presence of antibodies to HCV in the specimen and hence should not be used as the sole criterion for the diagnosis of HCV infection.
2. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow –up testing using other clinical methods is recommended.
3. A negative result at any time does not preclude the possibility of exposure to or infection with HCV.
4. A positive test result, even a weak positive, must be confirmed with blot assays such as RIBA for example.
5. It has been observed that Core HCV**,** like many other immunodiagnostic methods, may show negative result with HIV co-infected or immunodepressed patients. This possibility should be considered while interpreting results.

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SYMBOLS USED ON THE CORE HCV LABELS

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests
Xn  R22 - S23-46-61 NaN_3	R22:Harmful if swallowed; S23:Do not breathe vapour S46:If swallowed, seek medical advice immediately and show this container or label S61:Avoids release to the environment. Refer to special instructions/safety data sheets

Manufactured by:

CORE Diagnostics

Aspect Court, 4 Temple Row
Birmingham B2 5HG
UNITED KINGDOM

Version En2 – 05/2009

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SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

Aspect Court, 4 Temple Row
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Version En1 - 10/2004.

Core™ HBsAg

Rapid test for the detection of Hepatitis B Surface Antigen (HBsAg) in serum, plasma and whole blood.
CAT N°: HBsAg-150020

INTRODUCTION

Core HBsAg is a rapid, self performing, qualitative, two site sandwich immunoassay for the determination of Hepatitis B surface antigen, a marker for Hepatitis B infection, in serum/plasma specimens or whole blood specimens.

SUMMARY

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B Surface Antigen (HBsAg), earlier known as Australia Antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter.
Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infections.
Core HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml with in 15 minutes.

PRINCIPLE

Core HBsAg utilizes the principle of Immunochromatography, a unique two site immunoassay on a membrane. As the test sample flows through the membrane assembly within the test device, the colored anti-HBsAg-colloidal gold conjugate complexes with HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-HBsAg coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test results. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region, forming a pink-purple colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Core HBsAg kit has the following components.

A. Individually Pouched devices comprising of :-
1. Test Device : Comprising of Anti-HBsAg Ab-colloidal gold conjugate, Mouse IgG- colloidal gold conjugate, membrane assembly pre-dispensed with Anti-HBsAg Ab and anti-mouse antiserum coated at the respective regions.
2. Disposable Plastic Dropper
3. Desiccant Pouch.

B Sample Running Buffer.

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.
7. If the pouch of the test device is damaged, discard the device and take a new one for the test.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma/whole blood is preferable, specimens may be stored at 2-8 °C for upto 24 hours, in case of delay in testing. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used. Fresh blood from finger prick / puncture may also be used as a test specimen. Do not freeze whole blood samples. Do not use turbid, lipamic and haemolysed specimens. Do not use haemolysed, clotted or contaminated blood samples .

Precautions under the HBV regulations:

1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HBV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Label the test device with patients identity.
4. Add two drops of serum using the sample dropper provided, in the well marked "A" .
   A lab micropipette can also be used.
5. Add four drops of sample running buffer in the well marked "B" using the dropper vial.
6. At the end of 15 minutes read the results as follows:

NEGATIVE:

POSITIVE:

Negative: Only one colored band appears on the control region 'C'
Positive: In addition to the control band, a distinct colored band also appears on the test region "T"

7. The test should be considered invalid if neither the test band not the control band appears. Repeat the test with a new device.
8. Although, depending on the concentration of HBsAg in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
9. In case of a doubtful results at 15 minutes, the test may be extended up to, but no longer than, 30 minutes to get a clear background.

REMARK:

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. **Diagnostic specificity:**
   A total of 250 samples were tested with the Core HBsAg. The diagnostic specificity is determined as 100%.

Centre	Number of samples tested	Core HBsAg	
		Negative	Positive
A	250	250	0
Total	250	250	0

2. **Diagnostic sensitivity:**
   150 HBsAg positive samples were tested with the Core HBsAg, all of them were found positive.
   The diagnostic sensitivity is determined as 100%.

HBsAg Type	Number of samples tested	Core HBsAg	
		negative	positive
HBsAg	150	0	150

3. **Precision**
   Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HBsAg samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. Presence of elevated levels of other antigens such as RF and cross reacting auto antibodies such as antibodies to HLA DR4 may yield false positive results. This may occur in less than 1% of the specimens. For confirmation of results, a confirmatory test must be used.
2. This test detects the presence of HBsAg in the specimen and hence should not be used as the sole criterion for the diagnosis of Hepatitis infection.
3. As with all diagnostic tests, the result must be correlated with clinical findings.

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Core Combo HIV-HBsAg-HCV

(Device)

INTRODUCTION

Core Combo HIV-HBsAg-HCV is an *in vitro*, rapid, self performing, qualitative two site sandwich immunoassay used for the detection of antibodies to HCV , HIV 1 / 2 virus and HBsAg in human serum / plasma or whole blood specimens.

Summary

Core Combo HIV-HBsAg-HCV is using an immunochromatography method for the detection of antibodies to HCV , HIV 1 / 2 virus and HBsAg in human serum/plasma and whole blood.

Hepatitis C virus (HCV) is a small, enveloped, and single-stranded RNA virus. It is the major cause of parenterally transmitted non-A, non-B hepatitis. Antibodies to HCV are reported in 80% of the non-A, non-B hepatitis patients.

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B Surface Antigen (HBsAg), earlier known as Australia Antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter.

Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infections.

Core HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml within 15 minutes.

Highly purified antigen of gp 41, representing HIV- 1 and gp 36 representing HIV-2, recombinant HCV antigens (Core, NS-3, NS-4 and NS-5) and Anti HBsAg antibodies are used in this test.

Principle

Core Combo HIV-HBsAg-HCV utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane.

In **Core Combo HIV-HBsAg-HCV,** a line containing a mixture Highly purified antigen of gp 41, representing HIV- 1 and gp 36 representing HIV-2 (line 1) , a line of Anti HBsAg antibodies (line2) and a line of recombinant HCV antigens (line 3) are coated on the membrane in the test region and anti- Rabbit antiserum at the control region.

As the test sample flows through the membrane assembly within the test device, the colored conjugated colloidal gold complex (HIV 1 / 2 specific recombinant antigen-colloidal gold conjugate, anti-HBsAg-colloidal gold conjugate, HCV specific recombinant antigen-colloidal gold conjugate) reacts with antibodies to HIV 1 / 2, HCV and HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized at individual lines coated with the HIV 1 / 2 Specific recombinant antigens (line 1) , Anti HBsAg antibodies (line2) and recombinant HCV antigens (line 3) coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Rapid Test For HIV-HBsAg-HCV kit has the following components.

A. Individually Pouched devices
2. Disposable Plastic Dropper
3. Desiccant Pouch.

B Sample Running Buffer.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

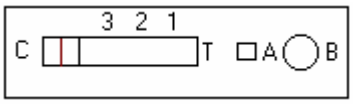
No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma/whole blood is preferable, specimens may be stored at 2-8 °C for upto 24 hours, in case of delay in testing. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used. Fresh blood from finger prick / puncture may also be used as a test specimen.

Do not freeze whole blood samples. Do not use turbid,lipamic and haemolysed specimens.

Do not use haemolysed, clotted or contaminated blood samples.

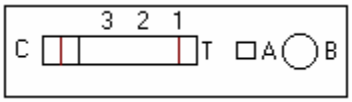
TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Label the test device with patients identity.
4. Add two drop of serum/ plasma or two drops of whole blood with the sample dropper provided in the well marked "A".
5. Add four drops of sample running buffer in the well marked "B".
6. At the end of 15 minutes read the results as follows.

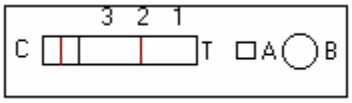


Negative : Only one coloured band appears on the control Window`C'

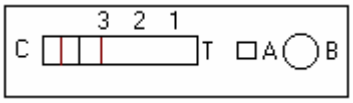
Positive In addition to the control band, a distinct colored band/bands appears on the test Window`T as follows.



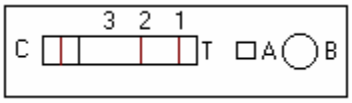
Positive for HIV 1/2



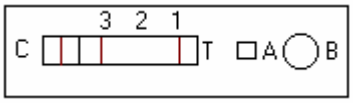
Positive for HBsAg



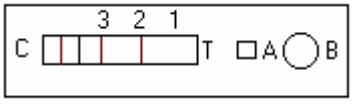
Positive for HCV



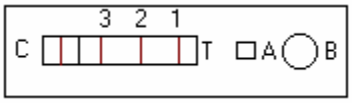
Positive for HIV 1/2 and HBsAg



Positive for HIV 1/2 and HCV



Positive for HBsAg and HCV



Positive for HIV 1/2 and HBsAg and HCV

7. The test should be considered invalid if neither the test band nor the control band appear. Repeat the test with a new device.
8. In case of a doubtful result at 15 minutes, the test may be extended upto 30 minutes to get a clear background.

CORE Diagnostics

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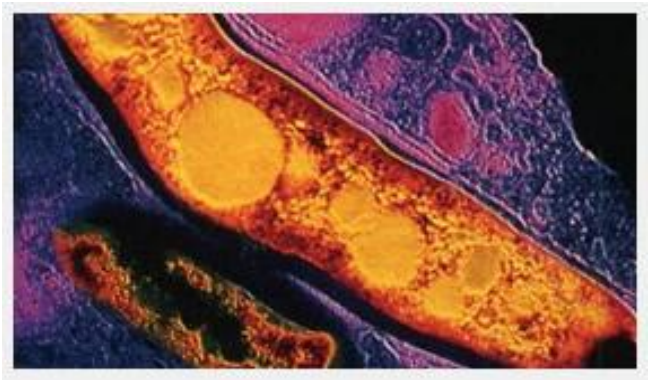
United Kingdom

CORE DIAGNOSTICS

TUBERCULOSIS

1.- CORE TUBERCULOSIS



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SYMBOLS USED

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
	Test Device
	Disposable Plastic Dropper
	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

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UNITED KINGDOM

Version En2 – 07/2010

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Core™ Tuberculosis

Rapid test for detection of antibodies to *Mycobacterium tuberculosis*
(Device)
CAT N°: TB-160002

INTRODUCTION

Core™ Tuberculosis is a rapid, self performing, qualitative, two site sandwich immunoassay for the detection of antibodies to *Mycobacterium tuberculosis* in human serum / plasma or whole blood.

SUMMARY

Lack of specificity of AFB smear, delayed reporting of mycobacteria by culture and requisite of expertise and expensive newer automated techniques, has led to the development of rapid and relatively simple serological tests based on the detection of serum antibodies to selected mycobacterial antigens , 14 kDa, 38 kDa , 16 kDa and 6 kDa.

PRINCIPLE

Core™ Tuberculosis utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device, after addition of the sample running buffer, the colored recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa)-colloidal gold conjugate complexes with *Mycobacterium tuberculosis* specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa) coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result for tuberculosis.
The unreacted conjugate and rabbit immunoglobulin conjugated to colloidal gold move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a pink-purple coloured band. The control band formation is based on the 'Rabbit / anti-Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Core™ Tuberculosis kit contains:
A. 25 Individual pouches, each containing:
1. Test device: Membrane assembly pre-dispensed with recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa) - colloidal gold conjugate, rabbit immunoglobulin-colloidal gold conjugate, recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa) and anti-rabbit antibody at the respective regions.
2. Disposable Plastic Sample Dropper.
3. Desiccant Pouch.

B. Sample Running Buffer in a dropper bottle.
C. Package insert.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Do not intermix reagents from different lots.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as potentially infectious.
6. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

7. Sample running buffer contains Sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

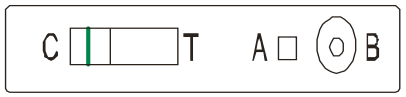
SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques.Though fresh serum / plasma is preferable, specimens may be stored at 2-8°C for upto 24 hours, in case of delay in testing. Do not use turbid, lipaemic and haemolysed serum / plasma specimens. Do not use haemolysed, clotted or contaminated whole blood samples. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used. Do not freeze whole blood samples.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **Core™ Tuberculosis** kit components to room temperature before testing.
2. Open the pouch and remove the device, sample dropper and desiccant. Check the color of the desiccant. It should be blue. If it has turned colorless or pink, discard the device and use another device. ***Once opened, the device must be used immediately.***
3. Label the test device with patients identity.
4. Tighten the vial cap of the sample running buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
5. Add one drop of serum / plasma or whole blood with the sample dropper provided in the sample port 'A'.
6. Immediately dispense 5 drops of sample running buffer into port 'B', by holding the plastic dropper bottle vertically.
7. At the end of 15 minutes read the results as follows:

Negative for antibodies to *Mycobacterium tuberculosis*:



Only one pink-purple band appears in the control Window 'C'.

Positive for antibodies to *Mycobacterium tuberculosis*:
In addition to the control band, a pink-purple band appears in the test window 'T'.

8. The test should be considered invalid if no bands appear on the device. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test results must always be correlated with clinical findings.
2. The results of the test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modifications to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Do not compare the intensity of the test line and control line to determine the concentration of the antibodies in the test specimen.
5. Testing of pooled samples is not recommended.
6. In immunocompromised TB patients, such as in patients with HIV, since antibodies to *Mycobacterium tuberculosis* may not be present at levels indicative of active disease, the test may give a negative result.
7. Patients with recent case of active tuberculosis infection may continue to have antibody titer within the detectable limits of the test and such samples may give positive test results, after such patients have been cured.
8. Positive test results may be obtained in Leprosy patients. However, the clinical presentation of leprosy cannot be confused with that of tuberculosis.

PERFORMANCE CHARACTERISTICS

In an in-house evaluation, thirty known positive and one hundred and ten known negative specimens were tested with **Core™ Tuberculosis** and compared with a licensed commercially available test. The results obtained are as follows:

Specimen Data	Number	Licensed Test	Core™ Tuberculosis
Negative for Ab. to M. tuberculosis	110	110	110
Positive for Ab. to M.tuberculosis	30	30	30

Based on the above study the specificity and sensitivity of **Core™ Tuberculosis** is 100%.

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MALARIA, DENGUE Y CHAGAS

1.- CORE Pf MALARIA

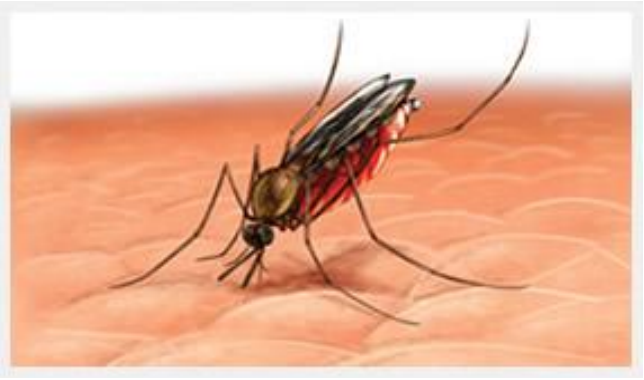
2.- CORE Pan MALARIA / Pf

3.- CORE MALARIA Pf / Pv

4.- CORE MALARIA Pan / Pv / Pf

5.- CORE DENGUE IgG - IgM

6.- CORE CHAGAS



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SYMBOLES USED

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
Σ	Contains sufficient <n> tests

CE

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volver

CE

Core™ Malaria Pf

Rapid assay for the detection of Malaria Plasmodium falciparum in whole blood.

CAT N°: MAL-190020

INTRODUCTION

Core Malaria Pf is a rapid self performing, qualitative, two site sandwich immunoassay for the determination of P. falciparum specific histidine rich protein –2 (Pf HRP-2) in whole blood samples.

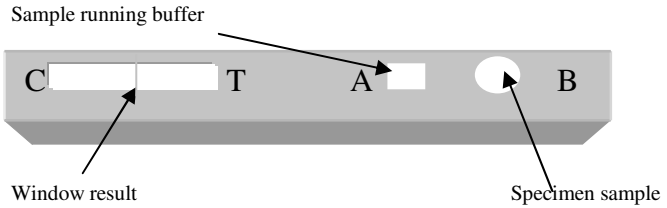
SUMMARY

Core Malaria Pf is a rapid test based on the principle of Immunochromatogarphy.

Four species of the Plasmodium parasites are responsible for malaria infections in human viz. P. falciparum , P.vivax, P.ovale and P.malariae. Of these P. falciparum is the most prevalent and severe species that is responsible for most of the morbidity and mortality worldwide. Early detection of P. Falciparum malaria is of paramount importance due to incidence of cereberal malaria and drug resistance associated with it. Pf HRP-2 is a water soluble protein that is released from parasitised erythrocytes of infected individuals and is specific to the P.falciparum species.

Core Malaria Pf detects the presence of Pf HRP-2 in whole blood specimen and is a sensitive and specific test for the detection of P. falciparum malaria

PRINCIPLE



Core Malaria Pf is a rapid test for the detection of P.falciparum malaria that utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored anti Pf HRP-2 colloidal gold conjugate (monoclonal) antisera complexes the Pf HRP-2 in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the anti Pf HRP-2 (monoclonal) antisera coated on the membrane leading to formation of a pink colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by anti mouse antibodies coated on the membrane at the control region, forming a pink band. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

1 kit contain :

1. 25 Individually pouched devices: Membrane assembly predispensed with anti Pf HRP-2 colloidal gold conjugated antisera, anti Pf. HRP-2 antisera and anti mouse antisera at the respective regions and sample applicator pipette.
2. Clearing buffer in a dropper bottle.
3. A capillary tube / applicator pipette
4. Package Insert.

STORAGE AND STABILITY

The test kit may be stored between 4℃- 30℃ till the duration of the shelf life as indicated on the kit and the pouch. DO NOT FREEZE.

NOTES

Read the instructions carefully before performing the test.
For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
Do not use beyond expiry date.
Do not inter mix reagents from different lots.
Handle all specimens as potentially infectious.
Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as a test sample and EDTA or Heparin or Oxalate can be used as suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2– 8℃ for up to 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick / puncture may also be used as a test specimen.

TEST PROCEDURE AND RESULTS INTERPRETATION

1. Bring the Core Malaria Pf kit components to room temperature before testing.
2. In case the pouch has been stored at 2– 8℃, allow at least 30 minutes for the device to come to room temperature. Check the colour of the desiccant. It should be blue. If it has turned colourless or faint blue, discard the device and use another device.
3. Open the pouch and remove the device. Once opened, the device must be used immediately.
4. Evenly mix the anti coagulated blood sample by gentle swirling. Touch the sample applicator pipette to the surface of the blood in the sample container.
   Blot the blood so collected on to the sample pad in the sample well 'A'. (This delivers approximately 5 µl of the whole blood specimen).

OR

In case finger prick blood is being used, touch the sample applicator pipette to the blood on the finger prick and immediately blot the specimen on to the sample pad in the sample well 'A' (Care should be taken that the blood sample has not clotted and the transfer to the sample pad is immediate).

OR

Alternatively, 5µl of the anti coagulated or finger prick specimen may be delivered to the sample pad in the sample well 'A' using a micro pipette.

NOTE : Ensure the blood from the sample applicator pipette has been completely taken up by the sample pad.

5. Dispense six drops (300 ul) of the clearing buffer into well 'B', by holding the plastic dropper bottle vertically.

6. At the end of 15 minutes, read the results as follows:

NEGATIVE: POSITIVE:

NEGATIVE for P. falciparum malaria :Only one pink coloured band appears in the control window 'C'.

POSITIVE for P. falciparum malaria :In addition to the control band, a distinct pink coloured band appears also in the Test window 'T'.

7. The test results should not be interpreted after 15 minutes.
8. The test should be considered invalid if no bands appear on the device. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

TEST PERFORMANCES :

Detection Limit:

Based on the studies of Core Malaria Pf, the test detects presence of HRP-2, in the whole blood, qualitatively, at a threshold of 10 parasites per micro litre. No hook effect was observed up to 480000 parasites per micro litre.

❖ **Sensitivity /Specificity**

In a prospective study including 300 samples, Core Malaria Pf has given a sensitivity of 99% and a specificity of 96%.

❖ **Interferences:**

Negatives samples in Plasmodium falciparum and positive in Rhumatoid Factor (128 IU/ml, 192 IU/ml and 250 IU/ml) were tested and found negative. There were no interferences observed between RF and Plasmodium falciparum.
However the presence of RF could interfere and give false positive results.

❖ **Cross Reactions**

50 whole blood samples with the following pathogies: Leishmaniose viscérale, Trypanosomiase african, Toxoplasmose of primo-invasion, Plasmodium Ovale, Plasmodium malariae, Plasmodium vivax were tested. No cross reactions were observed.

❖ **Reliability:**

The result obtained with Core Malaria Pf by using known positives and negatives samples were fully correlated to results obtained on other commercially available reagents : (Kappa value > 0.92.)

❖ **Precision inter and intra series :**

20 negatives and positives samples were tested 10 times on 2 different lot. All positives samples were positives and all negatives samples were negatives.

Limitation of the Test:

1. Since the Pf HRP-2 persists for upto a fortnight even after successful therapy, a positive test result does not indicate a failed therapeutic response.
2. In case the test needs to be used to monitor success of therapy, testing is advised only from 15 days after the completion of therapy.
3. As with all diagnostic tests, the results must always be correlated with clinical findings.

Core Malaria Pan/Pf

RAPID TEST FOR MALARIA

Pan / Pf

(Device)

Ref: MAL-190024

INTRODUCTION

Core Malaria Pan/Pf is a rapid self-performing, qualitative, two site sandwich immunoassay, utilising whole blood for the detection of *P.falciparum* specific histidine rich protein-2 (Pf HRP-2) and pan specific pLDH. The test may also be used for differentiation of *P. falciparum* and other malarial species and for the follow up of antimalarial therapy, in whole blood samples.

SUMMARY

Four species of the Plasmodium parasites are responsible for malaria infections in human viz. *P. falciparum , P.vivax, P.ovale* and *P.malariae*. Of these *P. falciparum* and *P. vivax* are the most prevalent. Early detection and differentiation of malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with falciparum malaria and due to the morbidity associated with the other malarial forms.

Core Malaria Pan/Pf detects the presence of pan malaria specific pLDH released from the parasitised blood cells, for the detection of all malarial parasites. Whereas, for the detection of *P. falciparum* malaria, **Core Malaria Pan/Pf** utilises the detection of *P.falciparum* specific histidine rich protein-2 (Pf HRP-2), which is a water soluble protein that is released from parasitised erythrocytes of infected individuals.

In the absence of *P.falciparum* specific Pf HRP-2, the presence of the pan malaria specific band points to the presence of other malarial species; viz.; *P.vivax, P.ovale* or *P.malariae*. Speciation is done and results inferred in the context of prevalence rates of the malarial speceies prevalent in the particular region.

Since pLDH is a product of viable parasities, the pan band may also be used to monitor success of antimalarial therapy.

PRINCIPLE

Core Malaria Pan/Pf utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored monoclonal anti HRP-2 specific / anti pan specific colloidal gold conjugate antibodies complexes the proteins in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the monoclonal anti HRP-2 / anti pan specific antibody coated on the membrane leading to formation of pink-purple colored band/s which confirms a positive test result. While both the bands will appear at the test region in falciparum positive samples, only one band would appear in non-falciparum malaria positive samples. Absence of this colored band/s in the test region indicates a negative test result.

The unreacted conjugate along with the rabbit globulin colloidal gold conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by anti-rabbit antibodies coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test performance.

REAGENTS AND MATERIAL SUPPLIED

Core Malaria Pan/Pf kit contains:

A. Individual pouches, each containing:

1. Test Device: Membrane assembly predispensed with monoclonal anti HRP-2 -colloidal gold conjugate, monoclonal anti pan specific pLDH -colloidal gold conjugate, rabbit globulin–colloidal gold conjugate and monoclonal anti HRP-2 antibody, monoclonal anti pan specific pLDH antibody and anti-rabbit antibody at the respective regions.
2. Desiccant pouch.
3. 5 µl sample loop.

B. Clearing buffer in a dropper bottle.

C. Package insert.

OPTIONAL MATERIAL REQUIRED

Calibrated micro pipettes capable of delivering 5 µl sample accurately.

STORAGE AND STABILITY

The test kit may be stored between 4-30℃ till the duration of the shelf life as indicated on the pouch / carton. DO NOT FREEZE.

NOTE

Read the instructions carefully before performing the test. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. Do not use beyond expiry date. Do not inter mix reagents from different lots. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as a test sample and EDTA or Heparin or Oxalate can be used as suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2–8℃ for up to 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick / puncture may also be used as a test specimen.

TEST PROCEDURE

1. Bring the **Core Malaria Pan/Pf** kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample loop and desiccant. Check the color of the desiccant. It should be blue. If it has turned colorless or pink, discard the device and use another device. *Once opened, the device must be used immediately.*
3. Tighten the vial cap of the clearing buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample loop into the sample. Ensuring that a loop full of blood is retrieved, blot the blood so collected on to the sample pad in the sample port 'A'. (This delivers approximately 5 µl of the whole blood specimen)

OR

In case finger prick blood is being used, touch the sample loop to the blood on the finger prick. Ensuring that a loop full of blood is retrieved, immediately blot the specimen on to the sample pad in the sample port 'A' (Care should be taken that the blood sample has not clotted and the transfer to the sample pad is immediate).

OR

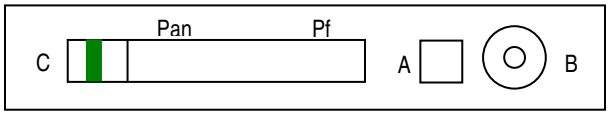
Alternatively, 5 µl of the anticoagulated or finger prick specimen may be delivered to the sample pad in the sample port 'A' using a micropipette.

NOTE: Ensure the blood from the sample loop has been completely taken up by the sample pad.

5. Dispense four drops of the clearing buffer into port 'B', by holding the plastic dropper bottle vertically.
6. At the end of 15 minutes read the results as follows:

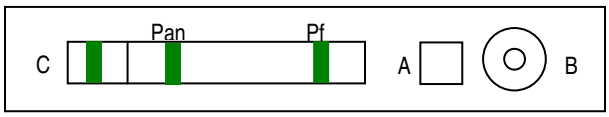
NEGATIVE for malaria:

Only one pink-purple band appears in the control window 'C'.

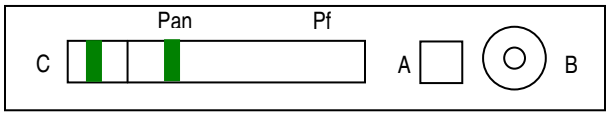


POSITIVE for malaria:

***P. falciparum* or mixed infection:** In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pan' in the test window 'T'.



Other species (Non falciparum): In addition to the control band, one pink-purple band appears only at region 'Pan' in the test window 'T'.



6. The test result should not be interpreted after 15 minutes.
7. **The test should be considered invalid if no bands appear on the device. Repeat the test with a new device ensuring that the test procedure has been followed accurately.**

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. The device and buffer of different lots must not be mixed and used.
5. In case of mixed infection (*P. falciparum* with other malarial species), both, Pf and pan malaria band will be positive. Hence differentiation of infection due to *P.vivax, P.ovale* or *P.malariae* cannot be done.
6. While monitoring therapy, using the pan band, if the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.
7. Usually, the pan band turn negative after successful anti malarial therapy. However, since treatment duration and medication used affect the clearance of parasites, the test should be repeated after 5-10 days of start of treatment.
8. In *P. falciparum* malaria infection, HRP-2 is not secreted in the gametogony stage. Hence, in "Carriers", the HRP-2 band may be absent.
9. HRP-2 levels, post treatment persist upto 15 days, the pan band can be used to monitor success of therapy, in *P. falciparum* malaria cases.
10. In a few cases, where the HRP-2 band is positive and the pan malaria band is negative, it may indicate a case of post treatment malaria. However, such a reaction pattern may also be obtained in a few cases of untreated malaria. Retesting after 2 days is advised, in such cases.

PERFORMANCE CHARACTERISITCS

In an inhouse study, a panel of 251 samples whose results were earlier confirmed with microscopy were tested with **Core Malaria Pan/Pf**. The results obtained are as follows:

Sample	Total No. of samples tested	**Core Malaria Pan/Pf**		Sensitivity	Specificity
		Positive	Negative		
P. falciparum +Ve	16	16	0	100%	-
P. vivax +Ve	25	25	0	100%	-
Malaria -Ve	210		210	-	100%

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Core Malaria Pv / Pf

Rapid Test for Malaria Pv/ Pf -(Device)

Ref: MAL-190022

INTRODUCTION

Core Malaria Pv/Pf is a self performing, qualitative, sandwich immunoassay for the detection and differentiation of vivax malaria and falciparum malaria in whole blood samples.

SUMMARY

Four species of the Plasmodium parasites are responsible for malaria infections in human viz. *P. falciparum , P.vivax, P.ovale and P.malariae*. Of these *P. falciparum* and P. vivax are the most prevalent. Early detection and differentiation of malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with falciparum malaria causing most of the morbidity and mortality world wide. ***Core Malaria Pv/Pf*** is based on the detection of an abundant intracellular metabolic enzyme produced by malarial parasites in the blood. The enzyme, Lactate DeHydrogenase (pLDH), is released from viable parasitized blood cells and is rapidly detected by a series of monoclonal antibodies. Differentiation between malarial species is based on antigenic differences between pLDH isoforms. Since the pLDH is the product of viable parasites the test may be used to monitor effective antimalarial therapy.

Core Malaria Pv/Pf detects the presence of vivax specific pLDH and falciparum specific pLDH in whole blood specimen and is a sensitive and specific test for the detection and differentiation of vivax malaria and falciparum malaria.

PRINCIPLE

Core Malaria Pv/Pf utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored anti pan specific pLDH colloidal gold conjugate (monoclonal) antisera complexes the pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the anti vivax specific pLDH(monoclonal) antisera and/ or the anti falciparum specific pLDH coated on the membrane leading to formation of pink-purple colored band/s which confirms a positive test result. A band will appear under Pf at the test region in falciparum malaria positive samples, while a band will appear under Pv in vivax malaria positive samples. Appearance of band under Pf as well as Pv in the test region suggests a mixed infection..Absence of colored band/s in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by anti rabbit antibodies coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test performance.

REAGENTS AND MATERIAL SUPPLIED

Core Malaria Pv/Pf kit contains:

A. Individually pouched devices:
   1. Membrane assembly predispensed with anti pan specific pLDH- colloidal gold conjugated antisera, rabbit antisera conjugated colloidal gold and anti vivax specific pLDH antisera, anti falciparum specific pLDH antisera , anti rabbit antisera at the respective regions.
   2. Desiccant pouch.
   3. 5 µl sample loop.

B. Clearing buffer in a dropper bottle.

C. Package insert

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

STORAGE AND STABILITY

The test kit may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch / carton. DO NOT FREEZE.

NOTE

Read the instructions carefully before performing the test.
For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
Do not use beyond expiry date.
Do not inter mix reagents from different lots.
Handle all specimens as potentially infectious.
Follow standard biosafety guidelines for handling and disposal of potentially infective material and kit materials.

SPECIMEN COLLECTION AND PREPARATION

Fresh blood from finger prick / puncture should be used as a test specimen. However, fresh anti coagulated whole blood may also be used as a test sample and EDTA or Heparin or Oxalate can be used as suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2– 8°C for upto 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick / puncture may also be used as a test specimen.

PROCEDURE

1. Bring the kit components to room temperature before testing.
2. In case the pouch has been stored at 2– 8°C, allow at least 30 minutes for the device to come to room temperature. Check the colour of the desiccant. It should be blue. If it has turned colourless or faint blue, discard the device and use another device.
3. Open the pouch and remove the device. Once opened, the device must be used immediately.
4. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample loop in to the sample .
   Blot the blood so collected on to the sample pad in the sample well 'A'. (This delivers approximately 5 µl of the whole blood specimen).
   OR
   In case finger prick blood is being used, touch the sample loop to the blood on the finger prick and immediately blot the specimen on to the sample pad in the sample well 'A' (Care should be taken that the blood sample has not clotted and the transfer to the sample pad is immediate). **OR**

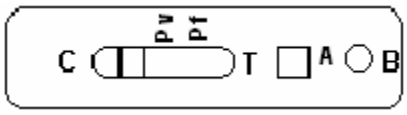
   Alternatively, 5µl of the anti coagulated or finger prick specimen may be delivered to the sample pad in the sample well 'A' using a micro pipette.

   NOTE : Ensure the blood from the sample loop has been completely taken up by the sample pad.

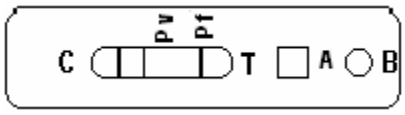
5. Dispense four drops of the clearing buffer into well 'B', by holding the plastic dropper bottle vertically.

6. At the end of 15 minutes, read the results as follows :

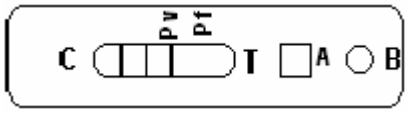
NEGATIVE for malaria :Only one colored band appears in the control window 'C'.



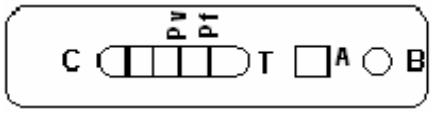
POSITIVE for *P.falciparum* malaria :In addition to the control band, a distinct colored band also appears under the region marked Pf in the Test window 'T'.



POSITIVE for *P.vivax* malaria :In addition to the control band, a distinct colored band also appears under the region marked Pv in the Test window 'T'.



POSITIVE for *P.falciparum* and *P.vivax* malaria :In addition to the control band, distinct colored bands appear under the region marked Pf and Pv in the Test window 'T'.



8. The test should be considered invalid if no bands appear on the device. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the results must always be correlated with clinical findings.
2. ***Core Malaria Pv/Pf*** is 100% sensitive to *P. falciparium* and *P. vivax* malaria.

PERFORMANCE CHRACTERISTICS

In an in house study a panel of 207 samples whose results were earlier confirmed with microscopy were tested with ***Core Malaria Pv/Pf*** . The results obtained are as follows:

Sample	Total No. of samples tested	***Core Malaria Pv/Pf***		Sensitivity	Specificity
		Positive	Negative		
P. Falciparum +Ve	22	22	0	100%	-
P. Vivax +Ve	17	17	0	100%	-
Malaria -Ve	168	0	168	-	100%

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1.Makler, M. T., et. al.(1993) Parasite lactate assay as an assay fo *Plasmodium falciparum* drug sensitivity. Am. J. Trop. Med. Hyg. 48(6), 739-741.
2. Piper, R. C., et. al., (1999) Immuno-capture diagnostic assays for malaria utilizing *Plasmodium* Lactate Dehydrogenase (pLDH) Am. J. Trop. Med. Hyg. 60(1) 109-118.
3. Srinivasan. S., et. al.,(2000) Comparison of blood – film microscopy, The OptiMAL dipstick, Rhodamine- 123 fluorescence staining and PCR for monitoring antimalarial treatment. Annals of Tropical Medicine and Parasitology, 94(3) 227-232.
4. Hunte-Cooke A., et. al., (1999) Comparison of a Parasite Lactate Dehydrogenase-based Immunochromatographic Antigen Detection assay (OptiMAL®) with Microscopy for the Detection of Malaria Parasites in Human Blood Samples. Am J.Trop Med 60(2). 173-176.
5. John, S. M., et. al.,(1998) Evaluation of OptiMAL , a dipstick test for the diagnosis of malaria. Ann. Trop. Med. Parasitol., 92, 621-622.
6. Quintana M., et. al.,(1998) Malaria diagnosis by dipstick assay in a Honduran Population with coendemic *Plasmodium falciparum* and *Plasmodium vivax*. Am. J. Trop. Med. Hyg. 59(6) 868-871.
7. Palmer, C. J.,(1998) Evaluation of OptiMal test for rapid diagnosis of *Plasmodium vivax* and *Plasmodium falciparum* . J. Clin Microbiol . 36(1) 203-206.
8. Moody A., et. al (2000) Performance of the OptiMAL® malaria antigen capture dipstick for malaria diagnosis and treatment monitoring. British Journal of Hematology, 109, 1-5

CORE Diagnostics

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Core Malaria Pan/Pv/Pf

RAPID TEST FOR MALARIA Pan / Pv / Pf- (Device)

Ref: MAL-190026

INTRODUCTION

Core Malaria Pan/Pv/Pf is a rapid self-performing, qualitative, two site sandwich immunoassay utilizing whole blood for the detection of *P.falciparum* specific histidine rich protein-2 (Pf HRP-2), *P.vivax* specific pLDH and pan malaria specific pLDH. The test can be used for the specific detection of *P. falciparum* and *P.vivax* malaria, differentiation of other malarial species and for the follow up of antimalarial therapy.

SUMMARY

Four species of the Plasmodium parasites are responsible for malaria infections in human viz. *P. falciparum, P.vivax, P.ovale* and *P.malariae*. Of these, *P. falciparum* and *P.vivax* are the most prevalent. Early detection and differentiation of malaria is of utmost importance due to incidence of cerebral malaria and drug resistance associated with falciparum malaria and due to the morbidity associated with the other malarial forms. As the course of treatment is dependent on the species, differentiation between *P. falciparum* and *P.vivax* is of utmost importance for better patient management and speedy recovery.

In **Core Malaria Pan/Pv/Pf** the detection system for *P. falciparum* malaria is based on the detection of *P. falciparum* specific histidine rich protein –2 (Pf HRP-2) which is a water soluble protein that is released from parasitised erythrocytes of infected individuals. The detection system of *P.vivax* is based on the presence of *P.vivax* specific pLDH. Further the detection of other malarial infections such as *P.ovale* and *P.malariae* is achieved through the pan malaria specific pLDH.

Since pLDH is a product of viable parasities, the pan band may also be used to monitor course of effective antimalarial therapy.

Core Malaria Pan/Pv/Pf detects the presence of *P. falciparum* specific Pf.HRP-2, *P.vivax* specific pLDH and pan specific pLDH in whole blood specimen and is a sensitive and specific test for the detection of all malaria species, differentiation for *P. falciparum and P.vivax* and monitoring successful antimalarial therapy.

PRINCIPLE

Core Malaria Pan/Pv/Pf utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored colloidal gold conjugates of anti-HRP-2 antibody, anti *P.vivax* specific pLDH antibody and anti pan specific pLDH antibody complexes the HRP-2 / corresponding pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the monoclonal anti Pf. HRP-2 antibody and / or monoclonal anti *P.vivax* specific pLDH antibody and / or monoclonal pan specific pLDH antibody coated on the membrane leading to formation of a pink-purple colored band in the respective regions which confirms a positive test result. Absence of a colored band in the test region indicates a negative test result for the corresponding antigen. The unreacted conjugate along with the rabbit antisera colloidal gold conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by anti-rabbit antibodies coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test performance.

REAGENTS AND MATERIAL SUPPLIED

Core Malaria Pan/Pv/Pf kit contains:

A. Individual pouches, each containing:

1. Test Device: Membrane assembly pre-dispensed with monoclonal anti- HRP-2 antibody–colloidal gold conjugate, monoclonal anti *P.vivax* specific pLDH antibody-colloidal gold conjugate, monoclonal anti pan specific pLDH antibody-colloidal gold conjugate, rabbit globulin colloidal gold conjugate, monoclonal anti Pf. HRP-2 antibody, monoclonal anti *P.vivax* specific pLDH antibody, monoclonal anti pan specific pLDH antibody and anti-rabbit antibody at the respective regions.
2. Desiccant pouch.
3. 5 µl sample loop.

B. Clearing buffer in a dropper bottle.

C. Package insert.

OPTIONAL MATERIAL REQUIRED

Calibrated micro pipettes capable of delivering 5 µl sample accurately.

STORAGE AND STABILITY

The test kit may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch / carton. DO NOT FREEZE.

NOTE

Read the instructions carefully before performing the test. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. Do not use beyond expiry date. Do not inter mix reagents from different lots. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as a test sample and EDTA or Heparin or Oxalate can be used as suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2–8°C for up to 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick / puncture may also be used as a test specimen.

TEST PROCEDURE

1. Bring the **Core Malaria Pan/Pv/Pf** kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample loop and desiccant. Check the color of the desiccant. It should be blue. If it has turned colorless or pink, discard the device and use another device. *Once opened, the device must be used immediately.*
3. Tighten the vial cap of the clearing buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample loop into the sample. Ensuring that a loop full of blood is retrieved, blot the blood so collected on to the sample pad in the sample port 'A'. (This delivers approximately 5 µl of the whole blood specimen). **OR**

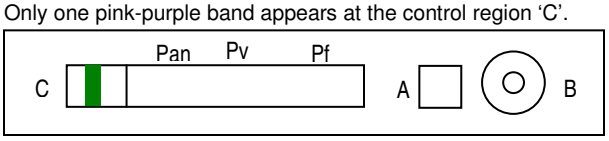
In case finger prick blood is being used, touch the sample loop to the blood on the finger prick. Ensuring that a loop full of blood is retrieved, immediately blot the specimen on to the sample pad in the sample port 'A'. (Care should be taken that the blood sample has not clotted and the transfer to the sample pad is immediate). **OR**

Alternatively, 5 µl of the anti coagulated or finger prick specimen may be delivered to the sample pad in the sample port 'A' using a micro pipette.

NOTE : Ensure that the blood from the sample loop has been completely taken up by the sample pad.

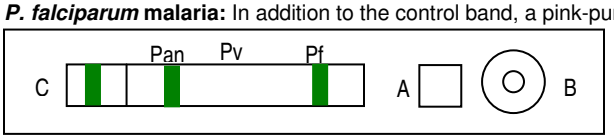
5. Dispense four drops of the clearing buffer into port 'B', by holding the plastic dropper bottle vertically.
6. At the end of 15 minutes read the results as follows:

NEGATIVE for malaria:
Only one pink-purple band appears at the control region 'C'.

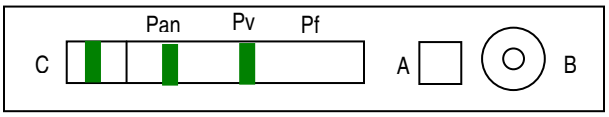


POSITIVE for malaria:

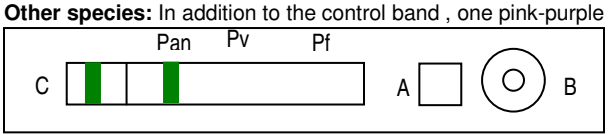
***P. falciparum* malaria:** In addition to the control band, a pink-purple band appears at the 'Pf' and 'Pan' regions respectively.



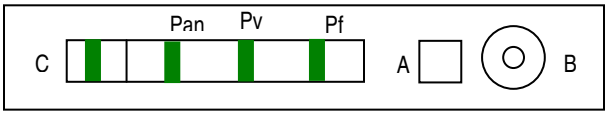
***P.vivax* malaria:** In addition to the control band, a pink-purple band appears at 'Pv' and 'Pan' regions respectively.



Other species: In addition to the control band , one pink-purple band appears only at 'Pan' region.



Mixed infection: In addition to the control band, a pink-purple band appears at 'Pf', 'Pv' and 'Pan' regions respectively.



7. The test should be considered invalid if no bands appear on the device. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. The device and buffer of different lots must not be mixed and used.
5. In case of infection due to *P.vivax* or *P.falciparum*, or due to mixed infection by these species, the pan malaria band will also be positive. Hence differentiation of infection due to *P.ovale* or *P.malariae* cannot be done.
6. While monitoring therapy, if the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.
7. Usually, the Pv and pan bands turn negative after successful anti malarial therapy. However, since treatment duration and medication used affect the clearance of parasites, the test should be repeated after 5-10 days of start of treatment.
8. In *P. falciparum* malaria infection, HRP-2 is not secreted in gametogony stage. Hence, in "Carriers", the HRP-2 band may be absent.
9. HRP-2 levels, post treatment persist upto 15 days, the pan band can be used to monitor success of therapy, in *P. falciparum* malaria cases.
10. In a few cases, where the HRP-2 band is positive and the pan malaria band is negative, it may indicate a case of post treatment malaria. However, such a reaction pattern may also be obtained in a few cases of untreated malaria. Retesting after 2 days is advised, in such cases.

PERFORMANCE CHARACTERISITCS

In an in house study, a panel of 251 samples whose results were earlier confirmed with microscopy were tested with Core Malaria. The results obtained are as follows:

Sample	Total No. of samples tested	**Core Malaria Pan/Pv/Pf**		Sensitivity	Specificity
		Positive	Negative		
P. falciparum +Ve	16	16	0	100%	-
P. vivax +Ve	25	25	0	100%	-
Malaria -Ve	210		210	-	100%

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6. Piper, R. C., et. al., (1999) Immuno-capture diagnostic assays for malaria utilizing *Plasmodium* Lactate Dehydrogenase (pLDH) Am. J. Trop. Med.Hyg. 60(1) 109-118.
7. Srinivasan. S., et. al.,(2000) Comparison of blood – film microscopy, The OptiMAL dipstick, Rhodamine- 123 fluorescence staining and PCR for monitoring antimalarial treatment. Annals of Tropical Medicine and Parasitology, 94(3) 227-232.
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9. John, S. M., et. al.,(1998) Evaluation of OptiMAL,a dipstick test for the diagnosis of malaria. Ann. Trop. Med. Parasitol., 92, 621-622.
10. Quintana M., et. al.,(1998) Malaria diagnosis by dipstick assay in a Honduran Population with coendemic *Plasmodium falciparum* and *Plasmodium vivax*. Am. J. Trop. Med. Hyg. 59(6) 868-871.
11. Palmer, C. J.,((1998) Evaluation of OptiMal test for rapid diagnosis of *Plasmodium vivax* and *Plasmodium falciparum* . J. Clin Microbiol . 36(1) 203-206.
12. Moody A., et. al (2000) Performance of the OptiMAL® malaria antigen capture dipstick for malaria diagnosis and treatment monitoring. British Journal of Hematology, 109, 1-5 .

CORE Diagnostics

Aspect Court, 4 Temple Row
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Core™ Dengue (IgG+IgM)

Rapid test for IgM & IgG antibodies to Dengue Virus
(Device)

INTRODUCTION

Core Dengue is a rapid immunochromatographic test for the simultaneous detection of IgM and IgG antibodies to Dengue virus in human serum/plasma/whole blood. The test can be used as a screening test for Dengue viral infection and as an aid for differential diagnosis of the self limiting primary Dengue infections and the potentially fatal secondary Dengue infections in conjunction with other criteria.

SUMMARY

Dengue fever virus (serotypes 1-4) belong to the family of Flaviviridae, which is widely distributed in the epidemic and endemic areas throughout tropical and subtropical regions of the world. Dengue virus infection is considered significant in terms of morbidity, mortality and economic cost associated with it an estimated 100 million cases of dengue fever occurring throughout the world yearly. Dengue virus is transmitted in nature principally by the day-biting Aedes aegypti and Aedes albopictus mosquitoes. The mosquito vector is highly domesticated and an urban species. Dengue presents typically as a fever of sudden onset with headache, retroorbital pain, pain in the back and limbs (break-bone fever), lymphadenopathy and maculopaplar rash.Patients diagnosed with dengue infection in endemic areas generally have secondary infection, whereas patients in non-endemic areas are usually diagnosed with primary infection. Specific antibody response to Dengue virus enables serodiagnosis and differentiation between primary and secondary dengue infections and detection of potentially life threatening conditions such as DHF and DSS.

Core Dengue is a new generation rapid Immunochromatographic test using highly specific and purified immunodominant, Recombinant Dengue 'Env.' antigens. It is a simple test for the differential diagnosis of Dengue virus infection.

PRINCIPLE

Core Dengue utilizes the principle of Immunochromatography, a unique two site, self performing immunoassay on a membrane. Specific human IgM and human IgG antibody binding proteins are immobilized on the nitrocellulose membrane as two individual test bands (IgM and IgG) in the test window "T" of the test device at region "M" and region "G" respectively. The IgM band in the test window "T" is closer to the sample well and the IgG band is close to the control window "C". As the test sample flows through the membrane assembly within the test device, the colored–Dengue specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and IgG) to Dengue virus, if present in the sample. This complex moves further on the membrane to the test region where it is immobilized by the Specific human IgM antibody and/or human IgG antibody binding proteins coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of these colored bands in the test window "T" indicates a negative test result. A built-in control band in the control window "C" appears when the test has been performed correctly, regardless of the presence or absence of anti-Dengue virus antibodies in the specimen and serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:

A.Individual pouches, each containing:

1.Core Dengue (Device): Membrane test assembly predispensed with recombinant Dengue virus specific antigen colloidal gold conjugate, streptavidin gold conjugate, anti human IgM at test region 'M' Protein A at the test region 'G' and Biotin at the control region 'C'.

2. Desiccant pouch

3. Sample loop

B. Sample Running Buffer

C. Package Insert

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4-30°C for the duration of the shelf life as indicated on the pouch.

NOTE

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimen as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

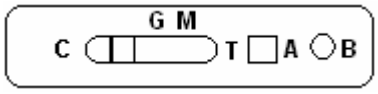
1. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
2. Though fresh serum/plasma is preferable, specimen may be stored at 2-8 °C for upto 24 hours, in case of delay in testing.
3. Whole blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used.
4. Do not use turbid,lipaemic, icteric and haemolysed specimen.
5. Repeated freezing, thawing of the specimen should be avoided.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only should be used for testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test device. Once opened, the device must be used immediately.
3. Label the test device with patient identity.
4. Add 5µl of serum/ plasma or whole blood with a micropipette into the sample port "A", OR using the 5µl sample loop provided with the kit. Dip the loop into the sample and then blot into the sample port 'A'.. Ensure that the loop does not retrieve clots or debris from the sample.
5. Add 5 drops of sample running buffer to the reagent port "B".
6. At the end of 15 minutes read the results as follows.

Interpretation of Results

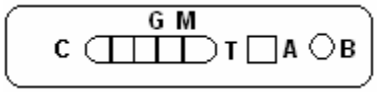
Negative Result:



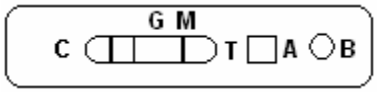
The presence of only the single red/purple coloured band in the control window "C" indicates the absence of specific antibodies against Dengue virus or that the amount of antibodies is below the detection limit of the test.

Positive Test Result:

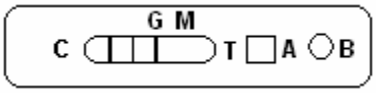
1) In addition to the band in the control window 'C', appearance of two red/purple coloured bands in the test window at region 'M' and region 'G' indicates the presence of Dengue virus specific IgM and IgG antibodies. (Acute secondary infection)



2) In addition to the control band in the control window 'C', appearance of a red/purple coloured band in the test window at region 'M' indicates the presence of Dengue virus specific IgM antibodies. (Acute primary infection)



3) In addition to the control band in the control window 'C', the appearance of a red/purple coloured band in the test window at region 'G' indicates the presence of Dengue virus specific IgG antibodies. (Acute secondary infection)



Invalid Result:If after 15 minutes no band is visible either in the test or control window , the result is considered invalid. The test should be re run with a new device.

Performance Characteristics

1.In an in-house evaluation, fifty known positive and one hundred and ten known negative specimen were tested with Core Dengue and compared with a licensed commercially available ELISA test. The results obtained are as follows:

Specimen Type	No. of Specimens Tested	LicensedTest	Core Dengue
Negative for Ab. to Dengue	110	110	110
Positive for Ab. to Dengue	50	50	50

Based on the above study the specificity and sensitivity of Core Dengue is 100%

2. 25 samples were evaluated in an external study comprising of primary, secondary and negative Dengue sera, along with Japanese Encephelitis sera (JE) in parallel with Dengue IgM/ IgG Elisa and JE Elisa. Core Dengue gave concordant results with all the samples with no cross reactivity with JE positive sera.

Remarks

1. Do not use test kit beyond expiration date.
2. While sample should be collected as soon as possible after onset of illness, it is recommended that follow up of testing should be done on day 10 after the first sample to allow seroconversion, especially when the test is negative and Dengue virus infection is clinically suspected.
3. Though Core Dengue does provide evidence to distinguish the past (secondary) infection from current (primary) ongoing infection, a negative result does not preclude the possibility of infection with Dengue virus.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should rather be made by a clinician after all clinical findings have been evaluated.
5. DHF is primarily the disease of children under 15 years in hyper endemic areas. Impending DSS symptoms include suspected abdominal pain, persistent vomitting, change in the level of conciousness, hypothermia and sudden decrease in platelet counts.
6. 80% of the patients may have detectable levels of IgM antibody by day 5 of illness and 99% by day 10.
7. IgM levels rise quickly and peak by two weeks after onset of symptoms and then fall to become undetecable over 2-3 months. IgG antibodies rise quickly and peak at about two weeks post infection and then decline slowly over 3-6 months.

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CORE Diagnostics

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Instructions for Use

Core Chagas (T. Cruzi)

Cat N◦ CHA-240024

Two Step Assay for the Detection of IgG Antibodies to Chagas Disease in Serum, Plasma or Whole Blood
For *In Vitro* Diagnostic Use

Description

Chagas disease is caused by the protozoan parasite Trypanosoma cruzi and it is widespread in Latin/South America. Transmission of T. cruzi can occur through contact with feces of blood sucking reduviid bugs (Triatominae), by the transplacental route, or through transfusion of blood products of people unaware of being infected. There are three stages of infection with Chagas disease. The acute stage, generally seen in children, is usually asymptomatic. Most acute cases resolve over 2-3 months into an asymptomatic chronic period. In the Indeterminate stage, seropositivity is the only indication of the existence of the disease. Severe chronic disease may lead to death, usually due to heart failure. Antibody based tests are the most useful assays for routine screening of Chagas disease and may include IHA and Elisa. New serological tests such as the Core Chagas rapid test are among the simplest and fastest means of identifying Chagas antibodies.

Principle of the Test

The Core Chagas test kit is a rapid membrane based screening test to detect the presence of antibodies to Chagas virus. This test is the newer generation lateral flow immunochromatographic type assay. These are among the simplest and easiest to use POC (point of care) assays.

The test can be used either with serum, plasma or whole blood. The test employs the use of an antibody binding protein conjugated to a colloidal gold particle and a unique conation of Chagas antigens immobilized on the membrane.

Once the sample is added to the test cassette along with the diluent, the mixture passes through the antibody binding/gold complex, which then binds the immunoglobulins in the sample. As this complex passes over the immobilized antigens on the membrane, if any antibodies to Chagas are present the antigens capture them in turn. This produces a pink/purple band in the B zone of the test card. The remaining complex continues to migrate to a control area in the test card and produces a pink/purple band in the C area. This control band indicates that the test has been performed properly.

Kit Components

Each test kit contains:

1. Core Chagas test packs – 25
2. Diluent in dropper vial
3. Directions for Use

Needed but not provided:

1. Measuring pipet capable of delivering 5ul's and 10ul's

Stability and Storage Conditions

The Core Chagas test kit is stable at any room temperature between 8-30'C when in the unopened pouches.
DO NOT FREEZE the kit or expose to temperature extremes.
Stability of the kit is 24 months from the date of manufacture – dating is indicated on the Pouch and kit label.

General Precautions

- The test is for In Vitro Diagnostic Use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipet any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5'C for 1 hour or treat with Sodium hyprochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

The Core Chagas test can be run on serum or whole blood.
The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8'C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at –20'C or colder. Whole blood samples cannot be frozen and it is recommended that finger prick blood be used not samples collected in EDTA. Shipment of samples should comply with local regulations for transport of etiologic agents.

Test Procedure

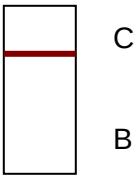
1. Remove as many test cards from the pouches as needed. Lay on a clean flat surface.
2. For WHOLE BLOOD - add 10 uls of sample to the (A) well of the test card using a measuring pipet.
   For SERUM or PLASMA – add 5 uls of sample to the (A) well of the test card using a measuring pipet.
3. Follow sample addition with **6 (six) drops** of the diluent provided in the dropper bottle by holding the bottle vertically over the (A) well. Add diluent slowly drop wise.
4. **Results are then read in as little as 5 minutes for strong positives or up to 20 minutes for weaker positives and to make sure negatives are confirmed.**

Do Not Read Results After 25 Minutes

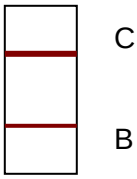
NOTE: If the dye has not cleared the membrane or blood is still present after 10-15 minutes, one more drop of diluent may be added to the (A) well.

Reading the Test Results

Negative
Only one pink/purple band
Appears in the C (Control)
area of the test card.



Positive
Two pink/purple bands appear.
One in the B (Test) area and
one in the C (Control) area of
the test card.



PLEASE NOTE: When reading this test, any visible **colored line** in the B (Test) area of the card within the prescribed time limit of the test indicates a POSITIVE result.

Indeterminate

If only one band appears in the B well – Test area, or no band appears at all in the C well – Control area. It is then recommended that a fresh device be used and the test repeated carefully following the directions in this insert.

Quality Control

A known positive and negative control should be run to insure proper performance. All controls should be handled in the same manner as patient samples.

Limitations of the Test

The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly.
The Core Chagas test is designed to detect antibodies against Chagas virus in serum or whole blood. Testing of any other body fluids has not been validated and may not yield appropriate results.

For samples that test positive by the Core Chagas test, more specific confirmatory testing should be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established. The use of a rapid test alone is not sufficient to diagnose Chagas infection even if antibodies are present. Also, a negative result does not preclude the possibility of infection with Chagas virus.

Performance Characteristics

As there are no true standards established for determining the absence or presence of Chagas antibodies in serum or whole blood samples it is recommended that the performance of the kit be compared to established serum panels or reference materials. The CORE CHAGAS Chagas kit is tested against characterized serum samples and has shown to be highly sensitive and specific for Chagas antibodies.

In samples assayed using **3 different test methods** (Chagas Elisa test, IHA and IFI) the Core Chagas rapid test yielded the following performance characteristics;

Specificity of > 98.5 percent
Sensitivity of > 98.8 percent

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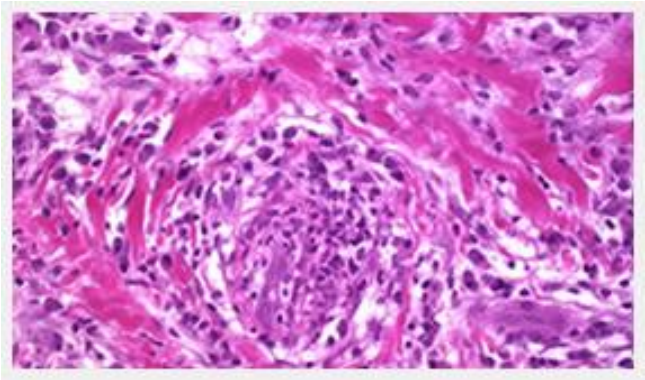
Version : EN 11/2010

SIFILIS

1.- CORE SIFILIS



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CORE SYPHILIS - WB

Rapid Test for Syphilis
(Modified TPHA)
(DEVICE)

INTRODUCTION

CORE SYPHILIS – WB is a rapid, qualitative, two site double antigen sandwich immunoassay for the detection of syphilis. For Professional use.

SUMMARY

Syphilis is a sexually transmitted (venereal) disease caused by the spirochete *Treponema pallidum*. The disease can also be transmitted congenitally thereby attaining its importance in antenatal screening. After infection the host forms non-treponemal anti lipoidal antibodies (reagins) to the lipoidal material released from the damaged host cells as well as Treponema specific antibodies. Serological tests for non-treponemal antibodies such as VDRL, RPR, TRUST etc. are useful as screening tests. Tests for Treponema specific antibodies such as TPHA, FTA-ABS, rapid Treponema antibody tests are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to *Treponema pallidum*.

CORE SYPHILIS - WB is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of Treponema specific antibodies during syphilis in whole blood, serum or plasma specimens within 15 minutes.

PRINCIPLE

CORE SYPHILIS – WB utilizes the principle of immunochromatography, a unique two –site immunoassay on a membrane. As the test sample flows through the membrane assembly of the test device , the recombinant Treponema antigens-colloidal gold conjugate forms a complex with Treponema specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant Treponema pallidum antigens coated on the membrane leading to the formation of a pink to deep purple coloured band at the test region 'T' which confirms a positive test result. Absence of this coloured band in test region 'T' indicates a negative test result. The unreacted conjugate and the unbound complex if any, along with rabbit IgG colloidal gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region ' C' ,forming a pink to deep purple coloured band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

A. Each individual pouch contains:

1. DEVICE : Membrane assembly predispensed with recombinant *Treponema pallidum* antigens-colloidal gold conjugate, recombinant *Treponema pallidum* antigens and goat anti- rabbit antiserum coated at the respective regions.
2. PIPETTE : Disposable plastic dropper.
3. Desiccant pouch.

B. BUF : 0.1 M Tris buffer with 0.1% Sodium azide.

REF	**SYP-170020**
Tests	25

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4 - 30°C for the duration of shelf life as indicated on the pouch.

NOTE

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Diluent buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION

- **Whole Blood as sample:**

Fresh blood from finger prick / puncture may be used as a test specimen. For collection of whole blood as a test specimen, EDTA or Heparin or Oxalate can be used as a suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2-8^{0}C for upto 72 hours before testing. Do not use haemolysed, clotted or contaminated blood samples for performing the test.

- **Serum or Plasma as sample:**

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/ plasma is preferable, serum/ plasma specimens may be stored at 2-8^{0}C for upto 24 hours, in case of delay in testing. Do not use haemolysed or contaminated specimens. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

Bring kit components, specimen to room temperature prior to testing.

1. Bring the sealed pouch to room temperature, if the pouch of the test device is damaged, discard the device and take a new one for the test. Open the pouch, remove the device and place it on a flat surface. Once opened, the device must be used immediately. Check the colour of the desiccant. It should be blue, if it has turned colourless or faint blue, discard the device and use another device.
2. With the help of the dropper provided dispense one drop of serum / plasma or whole blood to the sample port ‘A’.
3. Add four drops of diluent buffer from the diluent buffer bottle to reagent port ‘B’.
4. Read the results at the end of 15 minutes as follows:

   Negative: Appearance of only one pink to deep purple coloured band at the control window ‘C’.

   Positive: In addition to the control band, a distinct pink to deep purple coloured band also appears at the test window ‘T’.

5. The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new device.
6. Although, depending on the concentration of treponemal antibodies in the specimen, positive results may appear as early as 2 to 3 minutes, negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

CORE Syphilis – WB Rapid test for Syphilis was evaluated at various evaluation center for sensitivity and specificity, the combined result of **CORE Syphilis – WB** sensitivity is found to be 89.2% and of specificity is found to 96.2%.

In an in house evaluation **CORE Syphilis - WB** was run in parallel against standard TPHA, 100% correlation was found in 103 samples.

REMARKS

1. **CORE Syphilis – WB** detects the presence of treponemal antibodies; thus a positive result indicates a past or present infection. Positive results should be evaluated in co-relation with the clinical condition before arriving at a final diagnosis.
2. Low levels of antibodies to *Treponema pallidum* such as those present at a very early primary stage of infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection with *Treponema pallidum*. Retesting is indicated after two weeks if clinically syphilis is still suspected.
3. In order to assess the clinical response to treatment it is advisable to use a reagin test such as VDRL, RPR.
4. **CORE Syphilis - WB** detects Treponemal antibodies in whole blood/ serum/ plasma; other body fluids may not give accurate results.
5. In immunocompromised patients the test results must be interpreted with caution.

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SYMBOLS USED ON CORE Syphilis - WB LABELS

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
DEVICE	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Diluent Buffer
	Date of Manufacture
	Manufactured By
	Contains sufficient for <n> tests

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Manufactured by:
CORE DIAGNOSTICS
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TIFOIDEA

1.- CORE TIFOIDEA SALMONELLA

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5. The membrane is laminated with an adhesive tape to prevent surface evaporation. Air pockets or patches may appear, which do not interfere with the test results. Presence of a band at the test region even if low in intensity or formation is a positive result.
6. The deliberate slow reaction kinetics of CORE S. TYPHI IGM is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
7. Most positive results develop within 15 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.
8. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
9. CORE S. TYPHI IGM should be used as a screening test in clinically suspected cases only, and its results should be confirmed by other supplemental method before taking clinical decisions.

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SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

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Core™ S Typhi IgM

Rapid test for detection of IgM antibodies to S. typhi in serum / plasma / whole blood
Cat N°: TYP-180002

INTRODUCTION

CORE S. TYPHI IGM is a rapid, qualitative, sandwich immunoassay for the detection of IgM antibodies to S. typhi in human serum/plasma or whole blood specimen

SUMMARY

A febrile condition, Typhoid fever, is a bacterial infection caused by Salmonella serotypes including S. typhi, S. paratyphi A, S. paratyphi B and Salmonella sendai. The symptoms of the illness include high fever, headache, abdominal pain, constipation and appearance of skin rashes. Accurate diagnosis of typhoid fever at an early stage is not only important for etiological diagnosis but to identify and treat the potential carriers and prevent acute typhoid fever outbreaks. The conventional WIDAL Test usually detects antibodies to S. typhi in the patient serum from the second week of onset of symptoms. However, the detection may be earlier if specific IgM antibodies are detected instead of IgG or both IgG & IgM. CORE S. TYPHI IGM qualitatively detects the presence of IgM class of antibodies to Lypopolysaccharide (LPS) specific to S. typhi in human serum /plasma or whole blood specimens.

PRINCIPLE

CORE S. TYPHI IGM utilizes the principle of Immunochromatography, a unique two-site immunoassay on a nitrocellulose membrane. The conjugate pad contains two components – Anti-human IgM antibody conjugated to colloidal gold and rabbit IgG conjugated to colloidal gold. As the test specimen flows through the membrane test assembly, the highly specific anti-human IgM antibody-colloidal gold conjugate complexes with the S. typhi specific IgM antibodies in the specimen and travels on the membrane due to capillary action alongwith the rabbit IgG-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by the S. typhi specific LPS antigen coated on the membrane leading to formation of a pink to pink-purple coloured band. The absence of this coloured band in the test region indicates a negative test result.

The unreacted conjugate and unbound complex, if any, move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region (C), forming a pink to pink-purple coloured band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

Kit Components

A. Individual pouches each containing a -
   1. Test device: Membrane assembly pre-dispensed with Anti Human IgM - colloidal gold conjugate,rabbit IgG - colloidal gold conjugate,S.typhi LPS antigen and anti-rabbit antiserum coated at the respective regions.
   2. Desiccant pouch
   3. Sample loop
B. Sample Running Buffer

OPTIONAL MATERIAL REQUIRED: 5 µl precision micropipette

C. Package Insert STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4℃ to 30℃ for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4℃ to 30℃. Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiration date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

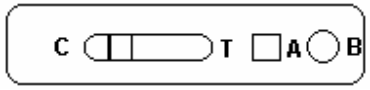
1. CORE S. TYPHI IGM uses human serum / plasma / whole blood as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. For whole blood, collect blood with a suitable anticoagulant such as EDTA or Heparin or Oxalate and use the freshly collected blood.
4. Whole blood should be used immediately and should not be frozen.
5. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8 ℃ for maximum up to 24 hrs.
6. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
7. Repeated freezing and thawing of the specimen should be avoided.
8. Do not use turbid, lipaemic and hemolysed serum/plasma.
9. Do not use hemolysed, clotted, contaminated,viscous/turbid specimens.
10. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
11. Refrigerated specimens must be brought to room temperature prior to testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components of CORE S. TYPHI IGM device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample loop. Once opened, the device must be used immediately.
4. Label the device with specimen identity.
5. Place the testing device on a flat horizontal surface.
6. Carefully dispense 5 µl of whole blood / serum / plasma into the specimen port "A" using a micropipette or the sample loop provided. Dip the sample loop in the sample container and blot the sample in the sample port "A".
7. Add five drops of sample running buffer into the reagent port "B".
8. At the end of 15 minutes, read results as follows:

Negative Result

If IgM antibodies to S.typhi are not present, only one coloured band appears in the Control Window (C).

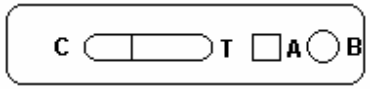


Positive Result

If IgM antibodies to S.typhi are present, two coloured bands appear in the Test (T) and Control Windows (C). The intensity of the test band may be more or less than the Control band, depending upon the concentration of IgM antibodies in specimen.

Invalid Result

The test is invalid if the Control band is not visible at fifteen minutes. Verify the test procedure and repeat the test with a new device.



TEST PERFORMANCE

Internal Evaluation

In an in-house study, the performance of CORE S. TYPHI IGM was evaluated using a panel of fifty specimens of WIDAL-positive (of varying reactivity) and WIDAL-negative sera in comparison with a commercially available DOT ELISA test kit. The results of the evaluation are as follows:

Specimen Data	Total	CORE S. TYPHI IGM	Commercially available Dot ELISA
Number of specimen tested	50	50	6
Number of Positive tested	6	6	6
Number of Negative tested	44	43	44

Based on this evaluation:
Sensitivity of CORE S. TYPHI IGM : 100%
Specificity of CORE S. TYPHI IGM : 97.7%

External Evaluation-I

Seventy samples that were blood-culture positive, blood-culture negative sera and potentially cross-reacting sera were evaluated with CORE S. TYPHI IGM. The results of the evaluation are as follows:

Specimen Data	Total	No. of Positives	No. of Negatives
Blood-culture positive sera	29	23	6
Blood-culture negative sera	10	1	9
Potentially cross-reacting negative sera	31	3	28

Based on this evaluation:
Sensitivity of CORE S. TYPHI IGM : 79.3%
Specificity of CORE S. TYPHI IGM : 90.2%

External Evaluation-II (Specificity & Precision study)

Thirty blood-culture negative sera were tested with CORE S. TYPHI IGM. The following are the results:

Specimen Data	Total	No. of Positives	No. of Negatives
Blood-culture negative sera	30	0	30

Based on this evaluation:
Specificity of CORE S. TYPHI IGM :100%

Intra-assay Precision study

One blood-culture positive sample was assayed 10 times on the same day.
Results: No variation in results was observed indicating 100% correlation.

Inter-assay Precision study

One blood-culture positive sample was assayed 3 times on 3 different days.
Results: No variation in results was observed indicating 100% correlation.

REMARKS

1. In some studies it has been reported that IgM antibodies to S.typhi persist for about 4 months post infection. Therefore, results within four months from an endemic area should be interpreted with caution.
2. The following chart would explain the IgM seroresponse in S.typhi infected subjects after onset of fever.

Detectable IgM Response

Onset of Fever	Percent Positive
4-6 days	43.50%
6-9 days	92.90%
>9 days	100%

3. A negative result, i.e., the absence of detectable IgM antibody does not rule out recent or current infection. However, if S. typhi infection is still suspected, obtain a second specimen 5-7 days later and repeat the testing.
4. Specific IgG may compete with the IgM for sites and may result in a false negative. Conversely, rheumatoid factor in the presence of specific IgG may result in a false positive reaction.

TROPONINA

1.- CORE TROPONINA I

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Core™ Troponin I

Rapid assay for detection of Human Cardiac Troponin I in serum/plasma and whole blood

CAT N°: TR-170002

INTRODUCTION

Core Troponin I is a rapid, two-site sandwich immunoassay for the detection and semi quantification of human cardiac Troponin I (cTnI) levels in human serum, plasma and whole blood.

SUMMARY

Discovered by Ebashi, Troponins are regulatory proteins in cardiac muscle that modulate the interaction between actin and myosin, during the calcium-mediated contraction of cardiac muscle. Three distinct tissue specific isoforms of Troponin I have been identified, two in skeletal muscle and one in cardiac muscle. The cardiac isoform of Troponin I (cTnI) has an additional sequence of 31 amino acids at the N terminal end that accounts for cardiac specificity, with a molecular weight of 22..5 kDa. This absolute specificity of Troponin I for cardiac tissue makes it an ideal biomarker for myocardial injury.

Clinical study results have demonstrated that elevated serum levels of cardiac Troponin I (cTnI) are detectable within 4 to 6 hours after the onset of chest pain, reach peak concentration in approximately 12 hours and remain elevated for 3-10 days following acute myocardial infarction. Thus cardiac Troponin I (cTnI) meets all the criterion laid down by National Academy of Clinical Biochemistry (NACB) for an ideal cardiac biomarker in early identification and risk stratification of patients with chest pain suggestive of ischaemia and identification of patients that present after infarction.

PRINCIPLE

Core Troponin I test utilizes the principle of immunochromatography, with a unique two-site sandwich immunoassay on a nitrocellulose membrane. The conjugate pad contains two components – monoclonal anti-cTnI conjugated to colloidal gold and rabbit IgG conjugated to colloidal gold. As the test sample flows through the membrane assembly of the device, the highly specific anti-cTnI antibody - colloidal gold conjugate complexes with cTnI in the sample and travels on the membrane due to capillary action along with rabbit IgG-colloidal gold conjugate. This sample moves further on the membrane to the test region (T) where it is immobilized by another specific anti-cTnI antibody coated on the membrane leading to the formation of a pink-purple band. A detectable coloured band is formed if cTnI level is equal to or greater than 0.3 ng/ml. The absence of this coloured band in the test region indicates cTnI concentration < 0.3 ng/ml.

The rabbit IgG-colloidal gold conjugate and unbound complex, if any, moves further to the reference region (R) that contains pre-calibrated anti rabbit IgG antibodies, corresponding to 1ng/ml cTnI, immobilised on the membrane. The intensity of the pink purple coloured band at the reference region (R) corresponds to a cTnI concentration of 1 ng/ml. The reference band would form even in a negative specimen. Semi-quantitative information about the concentration of cTnI can be deduced by comparing the intensity of the test band against the reference band. If the intensity of test band is less than the reference band, cardiac Troponin I (cTnI) concentration is equal to or above 0.3 ng/ml and less than 1 ng/ml. If the intensity of the test band is equal to or greater than reference band, cardiac Troponin I (cTnI) concentration is equal to or greater than 1 ng/ml.

The unreacted conjugate along with unbound complex if any, move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region (C), forming a pink-purple coloured band. This control band acts as a procedural control and serves to validate test results.

REAGENTS AND MATERIAL SUPPLIED:

Core Troponin I kit contains :

A**.**Individual pouches each containing-

1. Test device: Membrane assembly predispensed with monoclonal anti-cTnI colloidal gold conjugate, rabbit IgG colloidal gold conjugate, monoclonal anti- cTnI antibody and anti-rabbit antiserum coated at the respective regions.
2. Desiccant pouch .
3. Sample dropper.

B. Sample Running buffer in a dropper bottle.

C. Package insert.

OPTIONAL MATERIAL REQUIRED:

Calibrated micropipettes capable of delivering 25 µl sample accurately

STORAGE AND STABILITY:

The sealed pouches in the test kit and the kit components may be stored between 4-30°C for the duration of shelf life as indicated on the pouch/carton.

DO NOT FREEZE**.**

NOTE:

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Do not inter mix reagents from different lots.
5. Handle all specimens as potentially infectious.
6. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION:

1.**Core Troponin I** uses human serum, plasma or whole blood as specimen.

2.No special preparation of the patient is necessary prior to specimen collection by approved techniques.

3.Fresh anticoagulated whole blood should be used as test specimen. EDTA or Heparin or oxalate can be used as a suitable anticoagulant.

4.Whole blood should be used immediately and should not be frozen. Do not use haemolysed, clotted or contaminated whole blood specimens.

5.Preferably fresh serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum. Do not use turbid, lipaemic and haemolysed serum/plasma.

6.In case of delay in testing, sample may be stored at 2-8ºC for maximum upto 24 hours. Only one freeze thaw cycle is advisable for frozen specimen.

Refrigerated specimen must be brought to room temperature prior to testing.
7.Specimen containing precipitates or particulate matter must be centrifuged and clear supernatant only be used for testing.

IMPORTANCE OF SEQUENTIAL TESTING:

Immediately after a cardiac event, the damaged myocardial cells start releasing cardiac Troponin I (cTnI) in circulation and their level rises in a time specific manner. Since patients present at varying times for testing following the onset of chest pain in a cardiac event, it is necessary to perform sequential testing for optimal diagnostic accuracy.
A protocol for measuring cardiac Troponin I (cTnI) levels requires testing at admission or 3 hours after onset of chest pain and at 6 and 9 hours. Modification may be necessary depending upon specific clinical situation. Hence sequential testing of cardiac Troponin I (cTnI), together with ECG results and patient history and symptoms are necessary for differential diagnosis between acute myocardial infarction and unstable angina pectoris.

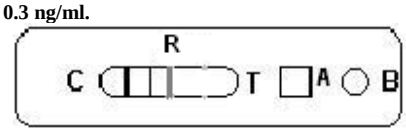
The positive and negative likelihood ratios correspond to the clinical concepts of ruling in and ruling out disease. Thus, a higher positive likelihood ratio means that a test result is better for ruling in disease when positive, and a lower negative likelihood ratio means that a test result is better for ruling out disease when negative. Examination of likelihood ratios reveals that levels of cardiac Troponin I (cTnI) are very useful at ruling out AMI when the value is negative at 10 or more hours from the onset of chest pain. However, a negative test value early in the course of episode of chest pain does very little to reduce the likelihood of AMI. A positive cardiacTroponin I (cTnI) value after 6 or more hours after the onset of chest pain appears to be very useful at ruling in AMI. Thus a negative cardiac Troponin I (cTnI) level identifies patient at low risk for adverse cardiac events.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS:

1. Bring the **Core Troponin I**- kit components to room temperature before testing.
2. Open the pouch by tearing along the notch.
3. Retrieve the device, sample dropper and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless or pink, discard the device and use another device.
4. Once opened the device must be used immediately.
5. Tighten the vial cap of the sample running buffer provided with the kit in clockwise direction to pierce the dropper bottle nozzle.
6. Label the device with specimen identity.
7. Place the testing device on a flat horizontal surface.
8. Holding the sample dropper vertically, carefully dispense **four (4) drops** of serum/plasma/whole blood into the sample port 'A'.
9. Add **four (4) drops** of sample running buffer in buffer port 'B'.
10. At the end of 15 minutes read results as follows:

Negative Result

Presence of two coloured bands at Reference (R) and Control (C) regions indicate absence of cTnI or the concentration of cTnI in the specimen is **below 0.3 ng/ml.**



Positive Result

1.If intensity of the Test band (T) is less than the Reference band - cTnI concentration is ≥ **0.3ng/ml and <1ng/ml.**

2.If intensity of the Test band is equal to or greater than the Reference band - cTnI concentration is ≥ **1ng/ml.**

Invalid Result

The test is invalid if the Control band and/or Reference band is not visible at fifteen minutes. Verify the test procedure and repeat the test with a new device.

PERFORMANCE CHARACTERISTICS:

Core Troponin I detects cardiac Troponin I at a concentration of ≥0.3 ng/ml..

Internal Evaluation

The performance of **Core Troponin I** was evaluated using a panel of 50 samples in comparison with a commercially available rapid test. The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	Core Troponin I	Commercially Available Rapid Test
No. of specimen tested	50	50	50
No. of Positive specimens	12	12	12
No. of Negative specimens	38	38	38

Based on this evaluation :
Sensitivity and Specificity of Core Troponin I -100%

External Evaluation

In an independent study conducted performance of **Core Troponin I** was evaluated using a panel of 20 samples in comparison with a commercially available automated chemiluminescence assay. The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	Core Troponin I	Chemiluminescence Assay
No. of specimen tested	20	20	20
No. of Positive specimens	11	11	11
No. of Negative specimens	9	9	9

Based on this evaluation：
Sensitivity and Specificity of Core Troponin I -100%

REMARKS:

1. Sequential testing of cTnI is important for diagnosing patients presenting with an evolving AMI. Diagnosis should not be made based on a single test result.
2. Samples with normal CK-MB levels and positive **Core Troponin I** result may occur in a patient with unstable angina pectoris and probably reflects a micro infarct not detected by CK-MB test .
3. Unstable angina pectoris and Non ST segment elevation myocardial infarction (NSTEMI) are closely related cardiac manifestations. Samples with normal CK-MB level and non-diagnostic ECG change, but positive test results indicates a subset of high-risk acute coronary syndrome patients and are classified under NSTEMI.
4. All serum cardiac enzyme markers may be positive with rhabdomyolysis, however cTnl is only slightly elevated despite significant elevations in both CK and CK-MB test.
5. cTnl levels may rarely rise in skeletal muscle disorders and renal failure.
6. cTnl levels may rise in other cardiac conditions causing myocardial damage namely myocarditis, cardiac contusion, recent cardiac surgery or catheterization.
7. cTnl is present only in cardiac tissue; serum levels are extremely low in normal healthy individuals.
8. cTnl levels are elevated upto 8 days, hence reinfarction may not de detected.
9. Interference due to heterophile antibodies, rheumatoid factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies.Though **Core Troponin I** uses sufficient amount of blocking agents to inhibit majority of these interference, nevertheless, some vigilant to this possibility of antibodies interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogeneous artifact and lead to appropriate investigation.
10. The membrane is laminated with a adhesive tape to prevent surface evaporation. Air pockets or patches may appear , which do not interfere with the test result. Presence of a band at the test region even if low intensity or formation is a positive result .
11. The deliberate slow reaction kinetics of **Core Troponin I** is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
12. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical laboratory findings have been evaluated.

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SYMBOLS USED

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

Version En2 - 12/2006.

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Birmingham B2 5HG
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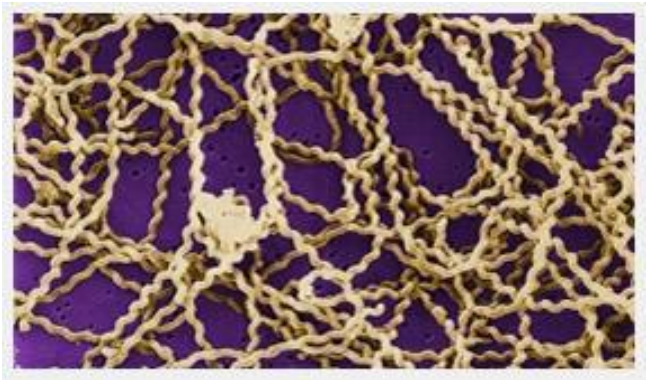
LEPTOSPIROSIS

1.- CORE LEPTOSPIROSIS



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CORE Leptospirosis

Rapid test for the detection of IgM antibodies to Leptospira
(Device)

INTRODUCTION

Core Leptospirosis is a rapid, self-performing, qualitative, sandwich immunoassay for the detection of Leptospira specific IgM antibodies in human serum/plasma or whole blood specimen. It is useful for the serodiagnosis of current or recent Leptospirosis. The broadly reactive genus specific antigen employed in the test allows the detection of Leptospira infections caused by a wide range of strains of different serovars.

SUMMARY

Leptospira are actively motile, delicate spirochaetes possessing a large number of closely wound spirals and characteristic hooked ends. There are several species of Leptospira and they may be saprophytic or parasitic. They can be distinguished only under dark ground illumination in the living state or by electron microscopy. Leptospirosis is a zoonotic disease of worldwide prevalence.Humans are infected when the water contaminated by the urine of carrier animals enters the body through cuts or abrasions on the skin or through intact mucosa of the mouth, nose or conjunctiva. Clinical symptoms include fever, chills, headache, conjunctivitis, myalgia and GI related symptoms, Kidney infection is a common sequelae.

Diagnosis may be made by demonstration of Leptospires microscopically in blood or urine, by isolating them in culture or by inoculation of guinea pigs, or by serological tests.

Core Leptospirosis, qualitatively detects the presence of IgM class of Leptospira specific antibodies in human serum /plasma or whole blood specimen.

PRINCIPLE

Core Leptospirosis-WB utilizes the principle of immunochromatography, a unique two-site immunoassay on a membrane. As the test sample flows through the membrane assembly of the test device, the anti human IgM -colloidal gold conjugate forms a complex with IgM antibodies in the sample. This complex moves further on the membrane to the test window 'T' where it is immobilized by the broadly reactive Leptospira genus specific antigens coated on the membrane, leading to the formation of a red to deep purple coloured band at the test region 'T' which confirms a positive test result. Absence of this coloured band in test region 'T' indicates a negative test result. The unreacted conjugate and the unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the control window 'C' of the membrane assembly, forming a red to deep purple coloured band. The control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:

A. Individual pouches, each containing:
1. Test Device: Membrane test assembly predispensed with Anti Human IgM -colloidal gold conjugate, Leptospira genus specific antigens at test window 'T' and anti- rabbit antiserum predispensed at the control window 'C'.
2. Desiccant pouch
3. 5µl sample loops.

B. Sample Running Buffer
C. Package Insert

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4-30°C for the duration of the shelf life as indicated on the pouch.

OPTIONAL MATERIAL REQUIRED: 10µl precision micropipettes.

NOTE

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

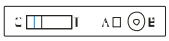
SPECIMEN COLLECTION AND PREPARATION

1. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used.
2. No prior preparation of the patient is required before sample collection by approved techniques.
3. Fresh serum / plasma is preferable. Anticoagulated whole blood can also be used as specimen. Serum / plasma may be stored at 2-8°C up to 24 hours in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods. Whole blood should be used immediately and should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
7. For each sample a new sample loop should be used.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test device. Once opened, the device must be used immediately.
3. Label the test device with the patient's identity.
4. Add 10µl of serum/ plasma or whole blood with a micropipette into the sample port "A", OR using the 5µl sample loop provided with the kit. Dip the loop into the sample and then blot into the sample port 'A'. Repeat this step twice for each sample. Ensure that the loop does not retrieve clots or debris from the sample.
5. Add 5 drops of sample running buffer to the reagent port "B"
6. At the end of 15 minutes read the results as follows.

Negative Test Result:



Positive Test Result:

7. The test should be considered invalid if neither the control band 'C' nor the test band 'T' appears. Repeat the test with a new device.

Performance Characteristics

Core Leptospirosis - WB was evaluated at the Royal Tropical Institute, Amsterdam in parallel with other licensed tests for the serodiagnosis of Leptospirosis. The 47 sera evaluated were from diverse serogroups of Leptospira. Core Leptospirosis-WB had a performance comparable to the other tests.

Remarks:

1. The intensity of the test line depends upon the stage of the disease and the titres of the antibodies in the test specimen.
2. As specific antibodies reach detectable levels about one week after the onset of disease, a sample collected very early may yield a negative test result.
3. If the test is negative and if Leptospirosis is still suspected the test should be repeated with the second sample collected at a later date in conjuction with clinical reexamination.
4. In endemic areas faint bands may appear occasionally due to borderline IgM titres present as a result of previous exposures.
5. It is recommended that the positive results obtained must be reconfirmed using a confirmatory test such as the MAT (Microscopic agglutination test).
6. High titres of RF and heterophile antibodies may interfere with the test, in such cases the results must be interpreted with caution.
7. The results must be correlated with clinical findings to arrive at the diagnosis.
8. Do not use the test kit beyond expiration date.

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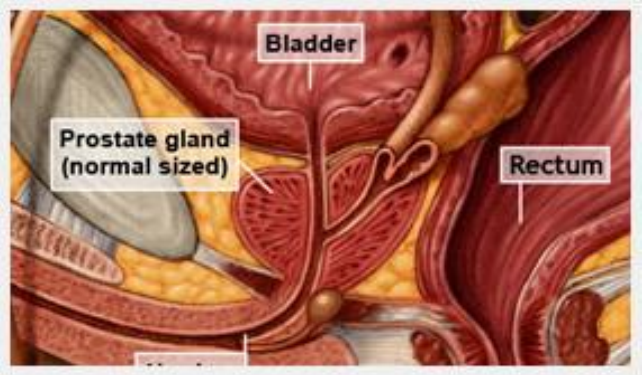
PSA - ANTÍGENO PROSTÁTICO ESPECÍFICO

1.- CORE PSA



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CORE – PSA

DEVICE

Rapid test for detection of Prostate Specific Antigen in serum / plasma / whole blood

INTRODUCTION

CORE -PSA is a rapid, semi-quantitative, two site sandwich immunoassay for the detection of Prostate Specific Antigen (PSA) levels in human serum / plasma / whole blood.

SUMMARY

PSA is a glycoprotein produced almost exclusively by the epithelial component of the prostate gland. It has a molecular mass of 33 kDa and is a single-chain glycoprotein with 237 amino acid residues. PSA is synthesized in the epithelial cells along the acini and in the ductal epithelium of the prostate gland. Its function is to bring about lysis of the semen coagulum thus accounting for the critical role it plays in male fertility.

The tissue specificity of PSA makes it the most useful tumour marker available for the diagnosis and treatment of prostate cancer. Complete removal of the prostate should result in an undetectable PSA level. Any measurable PSA after radical prostatectomy would indicate residual prostate tissues or metastasis. In such patients, increasing PSA concentrations after successful surgery strongly indicate recurrent disease. However, if the detectable serum PSA after radical prostatectomy is a result of incomplete resection of the gland and not persistent disease, the level should remain unchanged on extended follow-up.

CORE-PSA is a rapid test for the semi-quantitative determination of PSA in human serum / plasma / whole blood.

PRINCIPLE

CORE-PSA utilizes the principle of Immunochromatography, a unique two-site immunoassay on a nitrocellulose membrane.The conjugate pad contains two components - monoclonal anti-PSA antibody conjugated to colloidal gold and rabbit IgG conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the highly specific monoclonal anti-PSA antibody-colloidal gold conjugate complexes with the PSA in the specimen and travels on the membrane due to capillary action alongwith the rabbit IgG-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by another specific monoclonal anti-PSA antibody coated on the membrane leading to formation of a pink to pink-purple coloured band. A detectable coloured band is formed if PSA level is equal to or higher than 4 ng/ml. The absence of this coloured band in the test region indicates PSA concentration < 4 ng/ml in the specimen.

The rabbit IgG-colloidal gold conjugate and unbound complex, if any, moves further to the reference region(R) that contains pre-calibrated anti-rabbit IgG antibodies, corresponding to 10 ng/ml PSA, immobilised on the membrane. The intensity of the coloured band formed at the reference region(R) corresponds to a PSA concentration of 10ng/ml. This reference band would form even in a negative specimen. Semi-quantitative information about the concentration of PSA can be deduced by comparing the intensity of the test band against the reference band.

The unreacted conjugate and unbound complex, if any, move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region (C), forming a pink to pink-purple coloured band.This control band acts as a procedural control and serves to validate the test results.

NORMAL REFERENCE VALUES

0-4 ng/ml	: Normal
4-10 ng/ml	: Probable benign prostatic hypertrophy (BPH)
Above 10 ng/ml	: Probable adenocarcenoma of the prostate

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:

A. Individual pouches each containing a -

1.Test device: Membrane assembly pre-dispensed with monoclonal anti-PSA antibody-colloidal gold conjugate, rabbit IgG-colloidal gold conjugate, monoclonal anti-PSA antibody and anti-rabbit antiserum coated at the respective regions.

2.Desiccant pouch
3.Sample dropper

B. Sample Running Buffer: 0.1 M Tris buffer with 0.1% Sodium azide.

C. Package Insert

Cat. No.	PSA-121210	PSA-121212
Tests	10	25

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4-30°C for the duration of shelf life as indicated on the pouch / carton. DO NOT FREEZE.

NOTE

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use
2. Do not use beyond expiration date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. Sample Running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. **CORE-PSA** uses human serum / plasma / whole blood as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques. However, please refer chart below of “PRE-ANALYTICAL FACTORS” for appropriate time of collection of sample.
3. For whole blood, collect blood with a suitable anticoagulant such as EDTA or Heparin or Oxalate and use the freshly collected blood.
4. Whole blood should be used immediately and should not be frozen.
5. Though fresh specimen is preferable, in case of delay in testing, it may be stored **at 2-8 °C for maximum up to 24 hrs.**
6. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
7. Repeated freezing and thawing of the specimen should be avoided.
8. Do not use turbid, lipaemic and hemolysed serum/plasma.
9. Do not use hemolysed, clotted or contaminated blood specimens.
10. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
11. Refrigerated specimens must be brought to room temperature prior to testing.

PRE-ANALYTICAL FACTORS AFFECTING PSA VALUES

Several factors affect PSA results in immunoassays. The time of sample collection is crucial to obtain a correct picture. The best time to collect sample is before any procedure / event like DRE, ejaculation etc. (depicted below in the chart). However, if the procedure has already taken place, then the following chart would indicate the time of sample collection.

Pre-analytical factors	**Effect on Total-PSA**	**When to collect sample**
Digital Rectal Examination	Elevated	After 1 week
Ejaculation	Elevated	After 48 hours
Needle biopsy	2-50 fold increase	After 6 weeks

Transurethral resection of prostate	6-50 fold increase	After 6 weeks
Prostate massage	Minor increase	After 1 week
Transrectal Ultrasound	Elevated	After 1 week
Cystoscopy	Elevated	After 1 week
Finasteride therapy	Lowered by 50%	Before therapy

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components of **CORE-PSA** device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample dropper. Once opened, the device must be used immediately.
4. Label the device with specimen identity.
5. Place the testing device on a flat horizontal surface.
6. Holding the dropper vertically, carefully dispense exactly **one drop** (25µl) of serum / plasma / whole blood into the specimen port "A".
7. Add **five drops** of sample running buffer into the reagent port "B".
8. At the end of **15 minutes** read results as follows:

Negative Result

Presence of two coloured bands at Reference (R) and Control (C) regions indicate absence of PSA or the concentration of PSA in the specimen is below 4 ng/ml.

Positive Result

a) If intensity of the Test band (T) is less than the Reference band - PSA concentration is **between 4-10ng/ml.**

b) If intensity of the Test band is equal to or greater than the Reference band - PSA concentration is ≥ **10ng/ml.**

Invalid Result

The test is invalid if the Control band and/or Reference band is not visible at fifteen minutes. Verify the test procedure and repeat the test with a new device.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

In an in-house study, the performance of **CORE-PSA** device was evaluated using a panel of 155 specimens of positive (of varying reactivity) and negative sera in comparison with commercially available ELISA kit. 100% correlation with ELISA was observed. The results of the evaluation are as follows:

SPECIMEN DATA	Total	CORE-PSA	Commercially available ELISA
Number of specimen tested	155	155	155
Number of Positive serum/plasma specimens	10	10	10
Number of Negative serum/plasma specimens	100	100	100
Number of Negative whole blood specimens	45	45	45

Based on this evaluation:
Sensitivity of CORE-PSA : 100%
Specificity of CORE-PSA : 100%

External Evaluation N°1
30 samples were evaluated in parallel with **CORE-PSA** & CHEMILUMINISCENCE method by a NABL-accredited reputed reference laboratory in India. 100% correlation with CHEMILUMINISCENCE was observed. The results of the evaluation are as follows:

SPECIMEN DATA	Total	CORE-PSA	CHEMILUMINISCENCE assay
Number of specimen tested	30	30	30
Number of Positive specimen	10	10	10
Number of Negative specimen	20	20	20

Based on this evaluation:
Sensitivity of CORE-PSA : 100%
Specificity of CORE-PSA : 100%

External Evaluation n°2
196 samples were evaluated in parallel with **CORE-PSA** & chemiluminescence method by a hospital laboratory in France. The results of the evaluation are as follows:

	Core PSA			
Commercial kit on anlayzer	<4 ng/mL	4-10 ng/mL	≥10 ng/mL	**Total**
<4 ng/mL	120	5	0	125
4-10 ng/mL	1	28	1	30
≥10 ng/mL	0	3	38	41
Total	121	36	39	196

Agreement with chemiluminescence method on analyzer is 95%, with a kappa= 0,905. 9 of 10 discrepant results are either comprised between 4 and 10 ng/mL or > 10 ng/mL. Such a result will be followed by a quantification of both free PSA and Total PSA. 1 sample was found <4 ng/mL with **CORE-PSA** and measured 4,42 ng/mL by the chemiluminescence method.

REMARKS
1. The sensitivity and specificity of the PSA test and the threshold at which a result should prompt a biopsy are unclear. The results of prostatic biopsies are often considered as gold standard, but biopsies are generally performed only when the results of a PSA test or digital rectal examination arouse concern, which leads to a workup bias with respect to defining the sensitivity and specificity of the PSA test, and to an overestimation of the sensitivity of the test in particular. Moreover, the majority of small prostate cancers present in many older men is not clinically important and should not be included in the spectrum of disease used to determine the sensitivity of the PSA test. To overcome these problems, Gann *et al* assessed the relation between PSA

levels in base-band serum specimens and the subsequent clinical diagnosis of prostate cancer among the male subjects in the Physicians 'Health Study. Based on this study, a PSA value of 4.0 ng/ml has been accepted as the upper limit of the normal level.

2. Based on many independent investigations it is now clear that the PSA level increases with advancing age. As men age, the prostate gland enlarges and contains more PSA-producing tissue. Bigger prostates are associated with higher PSA values. In fact, the PSA concentration correlates directly with prostate size.

To improve clinical staging, prostate-specific antigen (PSA) levels (> 10 ng/ml), sonographic tumour volume (> 3 cc), maximum tumour diameter, length of capsular tumour abutment, and overall impression of capsular irregularity suggesting periprostatic tumour spread may also be assessed.

4. A recent trial evaluating the effect of finasteride on PSA serum concentrations determined that a patient who has taken finasteride for at least 12 months would be able to multiply his PSA concentration by a factor of 2 to establish what that value would have been had he not been taking the drug. According to the same study, the ability of finasteride to lower the PSA levels begins to decline at age 80, and the PSA concentration subsequently begins to increase.

Interferences due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immnoassays, has been reported in various studies. Though **CORE-PSA** uses sufficient amounts of blocking reagents to inhibit the majority of this interference; nevertheless, some samples with high titers may still express clinically important assay interference. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.

6. The membrane is laminated with an adhesive tape to prevent surface evaporation. Air pockets or patches may appear, which do not interfere with the test results. Presence of a band at the test region even if low in intensity or formation is a positive result.

7. The deliberate slow reaction kinetics of **CORE-PSA** is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.

8. Most positive results develop within 15 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.

9. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

10. **CORE-PSA** should be used as a screening test in clinically suspected cases only, and its results should be confirmed by a quantitative method before taking clinical decisions.

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Symbols used on CORE- PSA Labels

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
IVD	In vitro diagnostic medical device
	Device
	Disposable Plastic Dropper
	Sample Running Buffer
	Date of Manufacture
	Manufactured By
	**Contains sufficient for <n> tests**

Manufactured by:

Core Diagnostics, LTD
Aspect Court
4 Temple Row
Birmingham B2 5HG
United Kingdom

Version No./Date: 01/ 05.03.2008

PRUEBA DE EMBARAZO

1.- BETA HCG CLEAR

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Beta-Clear™ HCG
Device.
Cat N°: HCG-210020
One step test for the determination of human chorionic gonadotropin (HCG).

► INTRODUCTION
One-step pregnancy test is a rapid, self-performing, qualitative, two-site sandwich immunoassay for the determination of human chrorionic gonadotropin (HCG), a marker for pregnancy, in urine/serum specimens.

► INTRODUCTION
Human chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by variable placental tissue during pregnancy. The levels of HCG rise rapidly reaching peak levels after 60-80 days.
The appearance of HCG soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and conformation of pregnancy. However elevated HCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.
HCG one-step pregnancy test detects the presence of HCG in urine/serum specimens, qualitatively, at concentrations as low as 10 mlU/ml.

►PRINCIPLE
One-step pregnancy test utilizes the principle of Immunochromatography, a unique two-site immunoassay on a membrane. As the test sample flows trough the membrane assembly of the dipstick, the colored anti-HCG-colloidal gold conjugate complexes with the HCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-HCG coated on the membrane leading the formation of a pink colored band, which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region, forming a pink band. This control band serves to validate the test results.

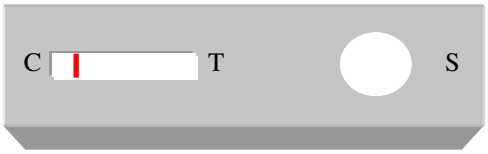
►REAGENTS AND MATERIALS SUPPLIED
Each individual pouch contains:
1. Device: Membrane predisposed with anti-HCG antisera – colloidal gold conjugate and anti-HCG antisera and anti-mouse antisera at the respective regions.
2. Disposable plastic dropper.
3. Desiccant pouch.

►SPECIMEN COLLECTION AND PREPARATION (Urine)

Though random urine specimens can be used, first morning urine specimen is preferable as it contains the highest concentration of HCG. Specimens should be collected in clean glass or plastic containers. If testing is not immediate, the urine specimens may be stored at
2 – 8°C for up to 72 hours. Turbid specimen should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

►SPECIMEN COLLECTION AND PREPARATION (Serum)
No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma is preferable, serum/plasma specimens may be stored at 2-8°C for up to 24 hours, in case of delay in testing. Do not use haemolysed specimens.

►TEST PROCEDURE AND INTERPRETATION OF RESULTS
1. Bring the sealed pouch to room temperature, open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense two drops of urine/serum specimen into the sample well "S" using the dropper provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of five minutes (for urine samples) or 15 minutes (for serum samples), read the results as follow:



Negative: Only one colored band appears on the controls region "C".

Positive: In addition to the control band, a distinct colored band also appears on the test region "T".

4. The test should be considered invalid if no band appears. Repeat the test with a new device.
5. Although, depending on the concentration of HCG in the specimen, positive results may start appearing as early as 30 seconds, negative results must be confirmed only at the end of five minutes (urine) / fifteen minutes (serum).

►STORAGE AND STABILITY
The sealed pouches in the test kit may be stored between 4 - 30° C till the duration of the shelf life as indicated on the pouch.

►NOTE

1. For in vitro diagnostic use only.
2. NOT FOR MEDICINAL USE
3. Do not use beyond expire date.

►LIMITATIONS OF THE TEST

1. A number of conditions other than pregnancy including trophoblastic and non-trophoblastic neoplasms such as hydatidiform choriocarcinoma etc. cause elevated levels of HCG. Such clinical conditions must be ruled out before a diagnosis of pregnancy can be made.
2. Highly dilute urine specimens and specimens from very early pregnancy may not contain representative levels of HCG. If pregnancy is still suspected, repeat the test with first morning urine after 48-72 hours after the initial test.
3. As with all diagnostic tests, the results must be correlated with clinical findings.

►PERFORMANCE CHARACTERISTICS

1. **Sensitivity:**
   HCG one-step pregnancy test detects the presence of HCG in urine/serum specimens, qualitatively, at concentrations as low as
   10 mlU/ml. Concentrations of about 100 mlU/ml of HCG are reached by the first missed menstrual period in normal pregnancy. Thus HCG one step pregnancy test is able to detect pregnancy at very early stages.
2. **Specificity:**
   Normally men and non-pregnant women do not have detectable levels of HCG by the HCG one step pregnancy test. Homologous hormones and other potentially interfering substances spiked beyond peak physiological concentrations did not cross-react with HCG one step pregnancy test.
3. Accuracy:
   The results obtained by HCG one step pregnancy test correlated very well when run in parallel with other commercially available tests for pregnancy, using known positive and negative specimens.

►WARRANTY

This product is designed to perform as described on the label and the package insert, the manufacturer disclaims any implied warranty of use and sale for any other purpose.

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SYMBOLS USED ON THE

	**Consult instructions for use**
	**Storage temperature**
	**Use by**
LOT	**Batch code**
REF	**Catalogue number**
IVD	**In vitro diagnostic medical device**
CARD	**Test Device**
PIPETTE	**Disposable Plastic Dropper**
	**Manufactured By**
	**Date of Manufacture**
	**Contains sufficient <n> tests**

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