Atlas Medical

Declaration Ref No: DC21-0193

CE Declaration of Conformity

We,

Atlas Medical GmbH

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Declare our responsibility that the following product:

Product Code	Product Name	Class	GMDN code
8.00.18.0.0005	RPR Carbon Antigen Reagent, 5 ml/vial	General-IVD	32450
8.00.18.2.1000	RPR Carbon Antigen 1000ml/bottle	General-IVD	32450
8.00.18.0.0050	RPR Carbon Antigen Kit, 50 Tests	General-IVD	32450
8.00.18.1.0050	RPR Carbon Antigen Kit, 50 Tests, White Glass Slide.	General-IVD	32450
8.00.18.2.0500	RPR Carbon Antigen Kit, 500 Tests (2ml latex, 2x0.5 ml control) Without card.	General-IVD	32450
8.00.18.3.0500	RPR Carbon Antigen Kit, 500 Tests (10ml latex, 2x0.5 ml control) Without card, stirring sticks.	General-IVD	32450
8.00.18.0.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.2.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control +White Glass slide stirring sticks)	General-IVD	32450
8.00.18.0.0025	RPR Carbon Antigen Kit, 25 Tests (0.5ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.0.0150	RPR Carbon Antigen Kit, 150 Tests	General-IVD	32450
8.00.18.0.0200	RPR Carbon Antigen Kit, 200 Tests	General-IVD	32450
8.00.18.0.0250	RPR Carbon Antigen Kit, 250 Tests	General-IVD	32450

Atlas Medical Quality Products

Digitally signed by Monastîrschii Viorica
Date: 2022.12.21 11:06:21 EET
Reason: MoldSign Signature
Location: Moldova

Amani Al-Habashneh
RA Manager

Atlas Medical

Declaration Ref No: DC21-0193

8.00.18.0.0500	RPR Carbon Antigen Kit,500 Tests	General-IVD	32450
8.00.18.0.1000	RPR Carbon Antigen Kit, 1000 Tests	General-IVD	32450
8.00.18.4.0500	RPR Carbon Antigen Kit,500 Tests (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.5.0500	RPR Carbon Antigen Kit, 500 Tests, (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.8.0500	RPR Carbon Antigen 500 Test (10ml reagent) without Control's.	General-IVD	32450
8.00.18.9.0050	RPR Carbon Antigen Kit, (5x10ml Reagent,2x2ml Control) , white glass Slide, Stirring Stick.	General-IVD	32450
8.33.04.0.0001	RPR Positive control	General-IVD	32450
8.33.04.1.0001	RPR Positive control ,Bulk	General-IVD	32450
8.33.04.0.0100	RPR Positive control(100ml/vial)	General-IVD	32450
8.33.04.0.0500	RPR Positive control(500ml/bottle)	General-IVD	32450
8.33.08.0.0001	RPR Negative control	General-IVD	32450

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

Certificate N^0.: 36655 rev 1

Expiry Date: October 8 th.2023

and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016

EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,

EN 13612:2002, EN 13641:2002 , EN 13975:2003, ISO 13485:2016

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer
Atlas Medical GmbH
Ludwig-Erhard-Ring 3
15827 Blankenefelde-Mahlow Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021	Amer Al-Habahbeh RA Manager	

Declaration Ref No: DC22-0065

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

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Manufacturing Site: Sahab Free Zone Area, P. O. Box 204, Amman 11512, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^{0}.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	May.2022	21.05.2022		

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Item code	Product Description
8.00.01.0.0100	Atlas CRP Latex Kit with Buffer (100 Tests)
8.00.05.0.0100	Atlas RF Latex kit with Buffer(100 Tests)
8.00.11.0.0050	Atlas SLE Latex kit (50 Tests)
8.00.11.0.0100	Atlas SLE Latex kit (100 Tests)
8.00.12.0.0100	Atlas Staphylococcus Latex Kit (100 Tests)
8.00.17.0.0050	Atlas D-Dimer Latex Kit (50 Tests)
8.00.19.3.0100	Atlas TPHA Kit (100 Tests)
8.00.19.3.0200	Atlas TPHA Kit (200 Tests)
8.00.20.3.2500	Atlas VDRL Kit, 5ml+55ml buffer
8.04.38.0.0020	Atlas Fecal Occult Blood Test (FOB) Test Cassette , 20 Tests/Box
8.04.85.0.0050	Atlas Fecal Occult Blood Test (FOB) Test Strip, 50 Tests/Box
8.04.109.0.0020	Atlas Procalcitonin test (PCT) , 20 Tests/Box
8.16.78.0.0025	Atlas Calprotectin Test Cassette , 25 Tests/Box
8.04.45.0.0001	Atlas Troponin I Test Cassette, Bulk
8.04.45.0.0020	Atlas Troponin I Test Cassette , 20 Tests/Box.
8.04.45.0.0030	Atlas Troponin I Test Cassette , 30 Tests/Box.
8.04.46.0.0001	Atlas Myoglobin Test Cassette, Bulk
8.04.46.0.0020	Atlas Myoglobin Test Cassette , 20 Tests/Box.
8.04.46.0.0030	Atlas Myoglobin Test Cassette , 30 Tests/Box.
8.04.47.0.0001	Atlas CK-MB Test Cassette , Bulk.
8.04.47.0.0020	Atlas CK-MB Test Cassette , 20 Tests/Box.
8.04.47.0.0030	Atlas CK-MB Test Cassette , 30 Tests/Box.
8.04.48.0.0001	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), Bulk.
8.04.48.0.0020	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), 20 Tests/Box.
8.04.48.0.0030	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), 30 Tests/Box.
8.14.19.1.0096	Helicobacter pylori Antigen ELISA, 96 Tests.
8.51.00.0.0096	25-OH VITAMIN D Elisa Kit, 96 Tests.
8.57.00.0.0096	Vitamin B12 Elisa Kit, 96 Tests

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2023 (included)**
Etabli le */ Issued on :* **October 8th, 2020**

DocuSigned by:
Beatrice Lys
EE33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–1
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-0

GMED_SQ_plus3sites-F-V0-07-2018

Addendum au certificat n° 36655 rev. 1 page 1/1
Addendum of the certificate n° 36655 rev. 1
Dossier / *File* N°P601408

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

William James House
Cowley Road,
Cambridge, CB OWX
United Kingdom

French version:
Contact réglementaire
English version:
Regulatory Administration

****

3 sites / 3 *sites*

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical

HIV 1/2

Human Immunodeficiency Virus

A rapid test device for the qualitative detection of antibodies to human Immunodeficiency Virus-1 and/or 2 in Whole blood,serum or plasma.

IVD *For In-vitro diagnostic and professional use only*

Store at 2-30°C

INTENDED USE

Atlas HIV 1/2 Rapid Test cassette (Whole blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in whole blood,serum or plasma.

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoprotiens are on the omic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with a high potential risk for developing AIDS. HIV-2 has been isolated from West Africa AIDS patients and from seropositive asymptomatic individual. Both HIV-1 AND –2 elicit an immune response. Detection of HIV antibodies in whole blood, serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV. Despite the difference in their biological characteristics, serological activities and genome sequences of HIV-1 and –2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

Atlas HIV 1/2 Rapid Test device is a rapid test to qualitatively detect the presence of antibody to HIV-1 and/or –2 in Whole blood serum or plasma specimen. The test utilizes a combination of protein A coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in Whole blood , serum or plasma.

PRINCIPLE

Atlas HIV 1&2 Test employs chromatographic lateral flow device in a test cassette . Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HIV-1 gp120, gp41 and HIV-2 gp-36 are dry-immobilized at the end of nitrocellulose membrane strip. HIV 1+2 antigens are bond at the Test Zone (T) and rabbit anti-HIV 1+2 antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If there are HIV1 or HIV 2 antibodies in sample, they will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the sheet until the Test Zone (T) zone where they are captured by the HIV 1+2 antigens generating a visible red line. If there are no HIV 1 or HIV 2 antibodies in sample, no red line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the rabbit anti-HIV 1+2 antibodies aggregating in a red line, which indicates the validity of the test.

MATERIALS

Materials Provided

- Test device
- Dropper.
- Package insert

Materials Required But Not Provided

- Disposable Gloves.
- Sample buffer.
- Disinfectant.
- Safety Lancet.
- Alcohol Prep-Pad.
- Timer.
- Specimen Collection Container.
- Centrifuge.
- Biohazard Waste Container.

PRECAUTIONS

- For in-vitro diagnostic use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposable capillary tubes.
- Wear productive clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.
- ALL positive results must be confirmed by an alternate method.
- Cassette used for testing should be autoclaved before disposal.
- Do not interchange reagents from one kit lot to another.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30ºC).
- The test cassette is stable through the expiration date printed on the sealed pouch.
- The test cassette must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The human serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause Hemolysis and protein denaturation, should be avoided.
3. Patient samples are performed best when tested immediately after collection. Specimen may be stored, if the sample cannot be tested within 24 hours. The red blood cells should be removed to avoid hemolysis. Serum or plasma should be frozen until the test can be performed. Whole blood samples should be refrigerated at 2–8oC in stead of being frozen.
4. Allow sample to reach room temperature before proceeding.
5. Sodium azide can be added as a preservative up to 0.1% without affecting the test result.

QUALITY CONTROL

The control zone is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

PROCEDURE

A) Whole Blood sample Procedure:

1. Bring all materials and specimens to room temperature.
2. Remove the test cassette from the sealed foil pouch.
3. Label the test cassette with specimen identity.
4. Place the test device on a flat horizontal surface.
5. Dispense **2 drop (80-100µL)** of whole blood sample into the specimen well “S” using the sample dropper provided.
6. Read the result within 20 minutes. Reactive samples can be read as soon as distinct colored bands appear on both test zone and control zone. To confirm a negative result, please read the result at 20 minute after adding sample.

B) Serum/Plasma sample Procedure:

1. Bring all materials and specimens to room temperature.
2. Remove the test cassette from the sealed foil pouch.
3. Label the test cassette with specimen identity.
4. Place the test device on a flat horizontal surface.

5. Dispense **2 drops (80-100µL)** of sample into the specimen well "S" using the sample dropper provided.
6. Read the result within 20 minutes. Reactive samples can be read as soon as distinct colored bands appear on both test zone and control zone. To confirm a negative result, please read the result at 20 minute after adding sample.

Note: 1- Results read after 30 minutes may not be accurate.
2- Occasionally some whole blood samples are too sticky to move on the device .If it happens, re-test the sample by adding one drop of the blood sample and followed by adding one drop of the normal saline .

INTERPRETATION OF RESULTS

Positive:

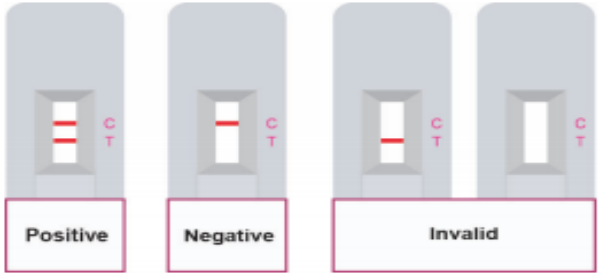
Two colored bands appear within 20 minutes. One colored band appears in the Control Zone (C) and another colored band appears in the Test Zone (T). The test result is positive and valid. No matter how faint the colored band appears in the Test Zone (T), the test result should be considered as positive result.

Negative:

One colored bands appears in the Control Zone (C) within 20 minutes. No colored band appears in the Test Zone(T). The test result is negative and valid.

Invalid:

No colored band appears in the Control Zone (C) within 20 minutes. The test result is invalid. Repeat the test with a new test device. **(SEE ILLUSTRATION BELOW:)**



LIMITATION:

1. Negative results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure (seroconversion) to HIV may not be detectable. For positive or reactive results, line intensity cannot be used to evaluate the anti-HIV antibody levels. A test giving an invalid result should be repeated. Rapid HIV I&II Test is not intended use for differentiation between recognition of HIV-1 antibodies and HIV-2 antibodies.
2. If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many highly sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity.
3. This kit is intended ONLY for testing of individual sample. Do not use it for testing of cadaver sample, saliva, urine or other body fluid, or pooled (mixed) blood.
4. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

PERFORMANCE CHARACTERISTICS

In a clinical evaluation of the performance of Rapid HIV I&II Test using 2567 confirmed negative and 510 positive samples sensitivity was 99.6% and specificity was 99.7% . The overall agreement with the reference ELISA tests is 99.7%.

Sites	**HIV positive sera**		**HIV negative sera**	
	TOTAL	POSITIVE	TOTAL	POSITIVE
one	101	99	149	142
two	7	7	1784	1784
three	300	300	436	436
four	102	102	198	198
Total	**510**	**508**	**2567**	**2560**
Agreement	**99.6%**		**99.7%**	

The precision of three lots tested showed 100% agreement. In order to check possible interferences with potentially cross-reactive sera, an independent evaluation was performed with one hundred samples. The variety of sera samples containing possibly interfering substances were tested and found no interfering with Rapid HIV I&II Test.

Serum type	**No. Of samples tested**	**Rapid HIV I&II Test**	
		Negative	**Positive**
RF positive	15	15	0
Acute Hepatitis A	10	10	0
Syphilis Positive	5	5	0
Hepatitis A Recovery Phase	10	10	0
Hepatitis C	16	16	0
Infectious	20	20	0
disease with non hepatitis B			
HBsAg, HBeAg and HBcAb Positive	20	20	0
Fetal Serum	4	4	0

REFERENCES

1. Essex, M. (1999) Human immunodeficiency viruses in the developing world. Adv Virus Res 53: 71-88.
2. Kanki, P.J., Hopper, J.R. and Essex, M. (1987) The origins of HIV-1 and HTLV-4/HIV/2. Ann N Y Acad Sci 511: 370-375.
3. Gallo, R.C., Saluahuddin, S.Z., Popovic, M., et al. (1984) Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. Science 224: 500-503.
4. Kenealy, W., Reed, D., Cybulsky, R., et.al. (1987) Analysis of human serum antibodies to human immunodeficiency virus (HIV) using recombinant ENV and GAG antigens. AIDS Res Human Retrovir 3: 95-105.

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PPI1776A01
Rev A (02.09.2019)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

Atlas Medical

RPR SYPHILIS CARD TEST
A qualitative and Semi- quantitative rapid card test for the detection of Non-Treponema (reagin) in serum or plasma

For *In-Vitro* and professional use only
Store at 2 to 8 C

INTENDED USE
For the qualitative and quantitative detection of Non-Treponema in serum or plasma.

INTRODUCTION & PRINCIPLE
Besides other antibodies, *Treponema Pallidium* produces non-Treponemal antibodies (reagin) in syphilitic persons. These antibodies can be detected by RPR antigen. ATLAS RPR card test is a macroscopic screening test for the qualitative and Semi-quantitative detection of reagin antibodies in serum or plasma. The kit contains RPR antigen which is based on the easy to use VDRL carbon antigens. In the presence of the reagin, the antigen causes flocculation of the carbon particles, which appears as black clumps. The charcoal particles contained in the antigen suspension enhances the visual appearance of the coagglutination in positive samples.

MATERIALS
MATERIALS PROVIDED
- RPR carbon antigen reagent.
- Positive and negative controls.
- RPR test cards.
- Plastic sticks.
- Dispensing Dropper.

MATERIALS NEEDED BUT NOT PROVIDED
- Saline 0.9%.
- Rotator (100rpm).
- Accurate pipette to deliver 50 µl and.
- Timer.

PRECAUTIONS
- Always use a fresh pipette tip for every test.

STORAGE AND STABILITY
- The reagents in this kit should be stored in an upright position and refrigerated between 2 to 8°C . Never Freeze. Test cards need not to be refrigerated and can be kept at room temperature.
- Reagents should be brought to room temperature and mixed well to obtain a uniform suspension of carbon particles.

PREPARING THE SPECIMEN
- ATLAS RPR kit can be used with either unheated plasma or heated serum samples.
- Serum samples can stay stable for up to 5 days if stored at 2 to 8 °C.
- Plasma samples collected with EDTA can stay stable up to 24 hours if stored at 2 to 8 °C.

PROCEDURES
QUALITATIVE PROCEDURE
1. Bring reagents to room temperature.
2. Dispense 50µl of sample onto a single circle on the test card.
3. Repeat step 2 for the positive and negative controls.
4. Spread the sample of each test specimen over the entire test circle.
5. Mix the carbon antigen suspension well.
6. Dispense one drop (20 µl) of the carbon antigen onto each test circle containing specimen. Do not mix the antigen with the sample.
7. Using the rotator, rotate the card at 100rpm for 8 minutes.
8. Read the results in good light immediately after 8 minutes.
9. Don't read the results after more than 8 minutes.

READING THE QUALITATIVE RESULTS
POSITIVE
- If large aggregates appear in the centre or the periphery of the test circle containing the sample,then the test should be read as positive (reactive)
- If the aggregates are visible, but weak or small, then the test should be read as weak positive (weakly reactive).
- If test is positive, then results should be confirmed by the quantitative procedure mentioned below.

NEGATIVE
If no aggregates appear and the specimen has smooth grey appearance (non-reactive)

SEMI-QUANTITATIVE PROCEDURE
1. Dispense 50µl of 0.9% saline to test circles numbered 2 to 5. Saline should not be spread. Dispense 50 µl of specimen onto test circle 1.
2. Dispense 50 µl of specimen onto test circle 2. Prepare serial two-fold dilutions by drawing the mixture up and down the pipette 5-6 times (avoid any bubble formation. Transfer 50 µl from circle 2 to 3, to 4 and to 5. Dispose 50 µl from circle 5 after mixing.
3. Starting from circle 5 and onto 4,3,2 and 1, mix and spread the serum over the entire area of each test circle.
4. Continue with steps 6-9 of the qualitative procedure.

READING THE SEMI-QUANTITATIVE RESULTS
The dilution of the circles are as follows:

Circle	1	2	3	4	5
Dilution	-	1:2	1:4	1:8	1:16

The titer of the sample is read as follows (P:Positive, N:Negative)

Positive 1:2	P	P	N	N	N

Positive 1:4	P	P	P	N	N
Positive 1:8	P	P	P	P	N
Positive 1:16	P	P	P	P	P

Positive and negative results are read as in the reading qualitative results procedure.

If the result in circle 5 is positive, then further dilution to 1:32, 1:64, 1:128 and 1:256 is required. Use steps 3 in semi-quantitative procedure and steps 6-9 in qualitative procedure to obtain the required dilutions.

**The titer , in the semi- quantitative method , is defined as the highest dilution showing a positive results.

LIMITATION

- This test provides a presumptive diagnosis of syphilis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- In positive specimens, it is recommended to confirm the result by another serological test such as the TPHA.

REFERENCES

1. Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.
2. Larsen S.A., *et. al.*, ata on file, Treponemal Research and Immunology lab, CDC.
3. McGrew B.E., Stout G.W., Falcon V.H., AM. J. Med. Techs., 34:634, 1969
4. Manual of Tests for Syphilis, PHS publication No.411, 1969.

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