Atlas Medical

Date: 05/Jan/2023

STATEMENT

We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature:

Date: 05.01.2023

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany,
Tel:+4933708355030

Regulatory Office: William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom
Tel: +44 (0) 1223 858 910

Middle East Site: P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan
Tel: +962 6 4026468

Digitally signed by Monastîrschii Viorica
Date: 2023.03.31 09:24:10 EEST
Reason: MoldSign Signature
Location: Moldova

Declaration Ref No: DC22-0065

CE Declaration of Conformity

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

We,

Atlas Medical GmbH
Head office: Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow, Germany.
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

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

Declaration Ref No: DC21-0194

Date: 06.09.2021

CE Declaration of Conformity

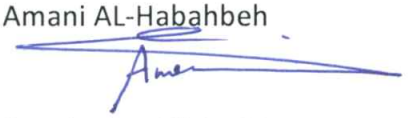
Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.00.19.0.0050	Atlas TPHA Kit , 50 Tests	51819
8.00.19.0.0100	Atlas TPHA Kit , 100 Tests	51819
8.00.19.0.0200	Atlas TPHA Kit , 200 Tests	51819

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	06.September.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh  Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

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

CE

TPHA TEST KIT

For the detection of antibodies to T.pallidum in human Serum using micro haemagglutination.

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

Store at 2° to 8° C

INTENDED USE

TPHA test kit is designed for the detection of antibodies to *Treponema pallidum* (IgG and IgM antibodies) in human serum or plasma based on the principle of passive haemagglutination.

INTRODUCTION

Syphilis is a venereal disease caused by the spirochaete micro-organism *Treponema pallidum*. As this organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

The TPI and FTA-ABS tests utilize pathogenic *Treponema pallidum* as the antigen but these tests present some difficulties for routine serodiagnosis. The TPI test requires living pathogenic *T.Pallidum* and the FTA-ABS test requires a flourescence microscope. Both tests require a high level of expertise.

TPHA test kit has been shown to be a convenient and specific test for the diagnosis of treponemal infection, having specificity similar to that of the TPI test and sensitivity comparable to that of the FTA-ABS test. It requires minimum laboratory equipment and is very simple to perform.

TPHA reagents are used to detect human serum antibody to *T.pallidum* by means of an indirect haemagglutination (IHA) method. Preserved avian erythrocytes are coated with antigenic components of pathogenic *T.pallidum* (Nichol's strain). These Test Cells agglutinate in the presence of specific antibodies to *T.pallidum,* and show characteristic patterns in microtitration plates.

Any non-specific reactions occurring are detected using the Control Cells, which are avian erythrocytes not coated with *T.pallidum* antigens. Non-specific reactions may also be absorbed out using these Control Cells.

Antibodies to non-pathogenic treponemes are absorbed by an extract of Reiter's treponemes, included in the cell suspension. Test results are obtained in 45-60 minutes and the cell agglutination patterns are both easily read and long lasting.

The test sample is diluted in absorbing diluent to remove possible cross-reacting heterophile antibody and to remove, block, or absorb potentially cross-reacting. Nonpathogenic treponemal antibodies.

MATERIALS

MATERIALS PROVIDED

- Test cells; preserved avian erythrocytes sensitised with T.pallidum antigen.
- Control cells; preserved avian erythrocyte.
- Diluent.
- Positive control serum; (prediluted 1:20), Use neat. This will give an equivalent titer of 1/640:/2560 in the quantitative test.
- Negative control serum; (prediluted 1:20), Use neat.
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Accurate pipettes for delivering 10:25:75 and 190 microlitres.
- U-Well microtitration plates.

PRECAUTIONS

The reagents and controls contain 0.1% sodium azide as a preservative. Avoid ingestion and contact with skin or mucus membrane. Normal laboratory precautions should be maintained while handling test reagents.

REAGENTS HANDELING

- All the reagents must be allowed to reach room temperature before use.
- Do not freeze any of the reagents.
- Do not use heamolysed, contaminated or lipaemic serum or plasma for testing as this will adversely affect the results.

REAGENTS STORAGE

- The kit should be stored at 2-8º C in an upright position at all times.
- Under these conditions, kit performance characteristics will be maintained for at least 15 or 18 months from date of manufacture. See expiry date on kit label.
- Reagents should be discarded if they become contaminated or do not demonstrate correct activity with the controls.
- The reagents in each kit have been standardized to produce the proper reaction and reagents should not be interchanged with those from other batches.

SAMPLE PREPARATION

- The test is designed for use with serum only.
- Plasma samples should not be used.
- The samples should be free from haemolysis and contamination.
- Serum samples may be stored at 2-8° C if a preservative is added prior to storage.
- For long term storage sera should be stored at -20° C Strictly avoid contaminating any of the reagents or serum dilutions with saliva. This will cause confusing patterns similar to positive results with specimens which should be negative.

PROCEDURES

QUALITATIVE METHOD

Each sample requires 3 wells of a microtitration plate.

1. Add 190µl of diluent to Well 1.
2. Add 10µlserum to Well 1. (Sample dilution 1:20).
3. Using a micropipette, mix contents of Well 1 and transfer 25µl to Wells 2 & 3.
4. Ensure that the Test and Control Cells are thoroughly resuspended. Add 75µlof control cells to Well 2. Add 75µl of Test Cells to Well 3.
5. Tap the plate gently to mix the contents thoroughly.
6. Incubate 45-60 minutes at room temperature.
7. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
8. Read results. Results are stable for 24hrs if the plate is covered and the above precautions are observed.

NOTE

Kit controls can be run in parallel and are diluted and ready for use.

QUANTITATIVE TEST

Each sample requires 8 Wells of a microtitration plate, Labeled A through to H.

1. Add 25µl of diluent to Wells B to H inclusive.
2. Transfer 25µlof 1:20 serum dilution from screening test to Wells A and B.
3. Take 25µl of diluted serum from Well B and serially dilute from Wells B to H inclusive in 25µl aliquots, discarding 25µl of diluted serum from Well H.
4. Ensure that the Test Cells are thoroughly resuspended. Add 75µl of Test cells to wells A to H inclusive. This will give a dilution of serum of 1/ 80 in well A through 1/ 10240 Well H.
5. Shake the plate gently to mix the contents thoroughly.
6. Incubatefor45-60 minutes at room temperature.
7. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
8. Read results. Results are stable for 24hrs. if the plate is covered and the above precautions are observed.

RESULTS

RESULTS	TEST CELLS	CONTROL CELLS
Strong Positive	Full cell pattern covering the bottom of the well.	No agglutination tight button
Weak Positive	Cell pattern covers approx. 1/3 of well bottom	No agglutination tight button
Indeterminate	Cell pattern shows a distinctly open center	No agglutination tight button
Negative	Cells settled to a compact bottom, typically with a small clear center.	No agglutination tight button
Non-specific *	Positive reaction	Positive reaction

Non-specific absorption *

1. Add 10µl to a small tube then add 190µl of Control Cells. Mix well and stand for 30 minutes.
2. Centrifuge for 15 minutes at 1000 rpm and test the supernatant by the qualitative method.

Note:

If the result is repeatedly non-specific the sample should be tested by another method eg. Reagin or FTA-ABS.

Although TPHA test is highly specific, **false positive results** have been known to occur in patients suffering from leprosy, infectious mononucleosis and connective tissue disorders. For confirmation FTA-ABS test should be used.

INTERPRETATION OF RESULTS.

Strong positive reactions may show some folding at the edge of the cell mat.

When the Test well is positive, the Control well should be observed.

The Control cells should settle to a compact button. They should not be used as a comparison for Non-Reactive serum patterns since the Control Cells will give a more compact pattern than the Test Cells.

Weak positive may show partially not full cell pattern cover the well bottom

INVALID may show Agglutination in the Control well indicates the presence of non-specific agglutinins in the sample. A serum that gives this result may be absorbed using the Control Cells as detailed under Non-specific absorption.

INDETERMINATEA may show a doubtful reaction with Test Cells This result may indicate a low level of antibody in early primary syphilis or yaws. This sample should be first retested in the qualitative test then a further sample should be tested at a later date to determine whether or not there is a rising titer. It is also advisable to perform a regain test and/or another confirmation test (FTA-ABS) to complete the profile of the test serum.

Negative may show cells settled as a dot at the bottom of the well

PERFORMANCE

SENSITIVITY

With clinical samples when compared to FTA-ABS and/or clinical diagnosis was 99.7% (298/299)

SPECIFICITY

With clinical samples was 99.3% (301/303).

CROSS REACTIVITY

Reactive results may indicate an active or successfully treated infection. The following have all been shown not to interfere with the test results (10 clinical samples of each)

- Rheumatoid Factor.
- Post Hepatitis B vaccination.
- Genital Herpes.
- Leptospirosis.
- EBV Infection.
- SLE.
- Lyme's Disease.

REFRENCES:

1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5.
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969; 22: 341-50.
5. Sequeira P, J, L. Eldridge A, E. – Treponemal Haemagglutination test. Br J Vener Dis 1973; 49: 242-8.
6. Larsen S.A., Hambie E.A., et coll., Specificity, sensitivity and reproducibility among the fluorescent treponemal antibody absorption test, the microhemagglutination assay for Treponema pallidum antibodies, and the hemagglutination treponemal test for syphilis. J. Clin. Microbiol., 1981 ; 14 : 441 – 445.
7. Houng H. - Syphilis: new diagnostic directions. Intern. J. STD and AIDS 1992; 3: 391-413.
8. Sluis J.J. Van Der. - Laboratory Techniques in the diagnosis of syphilis: a review. Genitourin Med. 1992; 68 : 413-9.

ATLAS MEDICAL

William James House, Cowley Rd,

Cambridge, CB4 4WX, UK

Tel: ++44 (0) 1223 858 910

Fax: ++44 (0) 1223 858 524

PPI080A01

Rev F (09.06.2016)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is **damaged**
	Manufacturer telephone number		

VDRL Antigen Test

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

2°C 8°C Store at 2 to 8°C

INTENDED USE
Use in flocculation tests for the serodiagnosis of syphilis.

INTRODUCTION
V.D.R.L Antigen is designed for use in flocculation tests for the serodiagnosis of syphilis. It is suitable for both the VDRL tube, (Harris et al., 1948; and Manual of Tests for Syphilis, 1969), and the VDRL slide flocculation techniques, (Harris & Coleman, 1963; Harris et al., 1946; and manual of Tests for Syphilis, 1969).

MATERIALS
MATERIAL PROVIDED
- VDRL Antigen (an ethanolic solution containing 0.9% cholesterol; 0.03% bovine heart cardiolipin and about 0.21% lethicin. The concentration of lethicin is adjusted to give the required sensitivity).
- Diluent (Sodium Chloride 10.0g; Formaldehyde 0.5ml; Disodium Hydrogen Phosphate 0.093g; Potassium Dihydrogen Phosphate 0.170g; Distilled water to 1,000ml).

MATERIAL NEEDED BUT NOT PROVIDED
For slide test.
- Glass ring slides .
- Rotating shaking table (optional).

For tube test
- Glass tubes 75x12mm.
- Khan shaking machine .

STORAGE
The VDRL Antigen and Buffer may be stored for up to two years at room temperature. It is essential that the bottle is firmly closed and stored in the dark. Under cold conditions cholesterol crystals may be observed in the antibody solutions. The stoppered bottle may then be gently warmed to 56°C until they redissolve.

Reagent preparation
QUALITATIVE METHOD
VDRL Antigen for Slide Test:
1. Pipette 0.4ml of the buffered saline diluent into a flat bottomed,stoppered bottle.
2. Using a dry pipette add 0.5ml of the VDRL Antigen drop wise to the diluent whilst rotating the bottle on a flat surface. Prolong the addition for about 6 seconds and continue rotating the bottle for a further ten seconds.
3. Add 4.1ml of saline diuent to the initial emulsion, stopper the bottle, and shake vigorously for at least 10 seconds.
4. The antigen is now ready for use. The prepared reagent may used for up to 24 hrs if kept at 4C.

VDRL Antigen for Tube Test
5. To one volume of the antigen emulsion prepared as for the Slide Test, add four volumes of 1% sodium chloride solution.
6. Mix well and stand for at least 5 minutes before use. Do not use after 2 hours.

SAMPLES FOR TESTING
VDRL test are normally carried out on the serum - which should be clear, and free from bacterial contamination or obvious haemolysis.
Sera must be inactivated by heating at 56 C for 30 minutes before use. If more than 4 hours elapses between heating and testing the sera, they should be reheated at 56°C for 10 minutes.
Tests may be carried out on spinal fluid, which must be free from blood or contamination but does not require heat inactivation.

PROCEDURE
A. Slide test
1. Place (0.05ml) of inactivated serum on a ring slide.
2. Shake the antigen emulsion and add one small drop (0.02 ml) to the serum.
3. Mix and spread to fill the ring. Rotate the slides for 4 minutes at two revolutions per second, either by hand or using a mechanical rotator.
4. The tests should be inspected with the naked eye and results confirmed by microscopic examination.

RESULT of Slide Test
Negative: Finely dispersed particles with no clumping
Weakly Positive: Finely dispersed particles with some clumping
Positive: Medium and large clumps, the clumps are usually fairly uniform in size. With some sera, however, prozone reaction may be experienced which are characterized by irregular fluffy clumps. These sera should be tested quantitatively.

QUANTITATIVE METHOD
The Quantitative VDRL slide test is similar to the Qualitative test. Serial doubling dilutions of the sera in isotonic saline are tested and the results Expressed as a titer. This titer is the greatest dilution that produces a positive reaction.
Tube Test
1. Place 0.5ml of inactivated test serum in a tube.
2. Add 0.5ml of the diluted working antigen emulsion to each tube.
3. Shake using the Kahn shaker for 5 minutes.
4. Centrifuge at 2,000 rev./min for 10 minutes.
5. Shake for one minute and read immediately.Clumping in a clear or slightly turbid medium indicates a positive result. All other results are negative.

INTERPRETATION OF RESULTS
In common with all lipoidal antigen tests the VDRL test will give a small proportion of false positive results. False positive results may be encountered as a result of viral and bacterial diseases, but titres are usually less than 1:8. Such acute false positives are normally eliminated by retesting after several weeks. Non-Venereal treponemal infections will also give positive results. Results with VDRL Antigen may differ from those obtained using Reiter's trepomemal Antigen.

VDRL	Maltaner	Reiters	Interpretation
+	+	+	Highly probable past or present treponemal infection
-	-	+	Rare False positive; Early syphilis; Late or latent infection
+	+	-	Treated disease; Lipoidal antigen false positive may indicate a non-treponemal disease

PERFORMANCE CHARACTERISTICS
1.Analytical Sensitivity: Accurate titer determination of the Reference Material , under the described assay conditions (see , calibration).
2.Prozone effect: No prozone effect was detected up to titers ≥ 1/128.
3.Diagnostic sensitivity: 100 %.
4.Diagnostic specificity: 100 %.

REFERENCES

1. Harris, A. & Coleman, M, B,.(Eds). 'Diagnostic Procedures and Reagents', th (4 Edition). Amor, Pub, Health Ass, Inc,. New York, (1963)
2. Harris, A,. et al. J. Ven. Dis. Information. 27, 169, (1946)
3. Harris, A., et al. J. Ven. Dis. Information, 29, 72 (1948)
4. 'Manual of Tests for Syphilis', P.H.S. Publication No. 411, U.S. Govt. Printing Office (1969)

ATLAS Medical
William James House
Cowley Rd, Cambridge, CB4 0WX,UK
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

PPI776A01
Rev E (31.10.2017)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is **damaged**
	Manufacturer teleph one number		