Declaration Ref No: DC21-0035

CE Declaration of Conformity

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

We,

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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
	March 2021	09.03.2021		

Digitally signed by Monastirschi Viorica
Date: 2022.12.18 13:35:01 EET
Reason: MoldSign Signature
Location: Moldova

Atlas Medical

CE Declaration of Conformity

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

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical
Quality Diagnostic Products

Declaration Ref No: DC22-0065

CE Declaration of Conformity

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

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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
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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

Date: 15/Jan/2022

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, Chişinău 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: 15.01.2022

Atlas Medical
Quality Diagnostic Products

Atlas Medical CE

Atlas D-Dimer Latex Kit

IVD *For In Vitro Diagnostic Use Only.*

Store at 2°C to 8ºC.

INTENDED USE

Atlas D-Dimer Latex Test is intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (XL-FDP) in human plasma.

INTRODUCTION

During blood coagulation, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerize to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, but only degradation products from cross-linked fibrin contain D-Dimer. Therefore, cross-linked fibrin degradation products (XL-FDP) are a specific marker of fibrinolysis.

PRINCIPLE

Atlas D-Dimer Latex is a rapid agglutination assay utilizing latex beads coupled with a highly specific D-Dimer monoclonal antibody. XL-FDP present in a plasma sample bind to the coated latex beads, which results in visible agglutination occurring when the concentration of D-Dimer is above the threshold of detection of the assay.

MATERIALS

MATERIALS PROVIDED

- D-Dimer Latex Reagent: a 0.83% suspension of latex particles coated with murine anti-D-Dimer monoclonal antibody, 10mg/mL BSA and 0.1% sodium azide.
- D-Dimer Positive Control: a solution containing purified human D-Dimer fragment, 5mg/mL BSA and 0.1% sodium azide.
- D-Dimer Negative Control: a buffer solution containing 5mg/mL BSA and 0.1% sodium azide.
- Dilution Buffer
- Reaction slide
- Stirring Sticks
- Instructions for Use

MATERIALS NEEDED BUT NOT PROVIDED

- Precision pipettes and tips - 20 µL and 100 µL
- Plastic test tubes and rack
- Stopwatch or timing device
- Disposable gloves
- Tissue (for wiping dropper bottle tips)

PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- Harmful if swallowed. Avoid contact with skin and eyes. Do not empty into drains.
- Wear suitable protective clothing.
- CAUTION: All reagents in Atlas D-Dimer Latex Kit contain sodium azide (0.1%) as preservative. Do not ingest or allow to contact skin or mucous membranes. Sodium azide may form explosive azides in metal plumbing. Use proper disposal procedures.
- CAUTION: The Positive Control in Atlas D-Dimer Latex Kit contains components of human origin. Each individual blood donation intended for the production of this reagent is tested for HBsAg, anti-HCV, anti-HIV1 and anti-HIV2. Only donations with negative findings are employed. As complete absence of infectious agents can never be assured, all materials derived from human blood should be treated as potentially infectious and handled with due care following the precautions recommended for biohazardous material.

STORAGE AND STABILITY

- Store at 2°C to 8ºC.
- DO NOT FREEZE.
- Stability: Refer to outer package and vial labels for expiration date.
- Indication of Reagent Deterioration
  Reagent deterioration is indicated by failure of the Latex Reagent to agglutinate with the Positive Control, agglutination with the Negative Control, or evidence of microbial contamination.

SPECIMEN COLLECTION AND PREPARATION

Plasma prepared from whole blood anticoagulated with sodium citrate is recommended. The use of EDTA and heparin will result in an increased level of false positive reactions. After separation of the plasma by centrifugation (1500g for 15 minutes at 4°C - 10°C), specimens may be tested directly for the presence of XL-FDP. Defibrination of the plasma is not recommended.
Plasma storage/stability: - 20ºC: 2 weeks
Thaw frozen specimens rapidly at 37ºC and centrifuge before testing.

PROCEDURE

- Equilibrate reagents to room temperature (20°C to 25°C) before use.
- Latex Reagent should be mixed by inversion immediately prior to use.

Qualitative Method

1. Bring reagents and specimens to room temperature before use.
2. Place 20 µL of the reagent within a well on a reaction slide. **AVOID** touching the surface of the Reaction slide
3. Accurately pipette 20 µL of undiluted plasma or of control solution inside the same well next to the drop of Latex Reagent.
4. Mix the Latex Reagent and sample with a stirrer until the Latex is uniformly distributed.
5. Rock the reaction slide gently by hand for exactly 3 minutes.
6. At exactly 3 minutes, check for agglutination under a strong light source.

NOTE

If test reading is delayed beyond 3 minutes, the latex suspension may dry out **giving a false agglutination pattern. If this is suspected, the specimen must be retested.**

Semi quantitative Method

1. Prepare serial dilutions of the test plasma with Buffer as follows:
1:2 dilution 100 µL plasma plus 100 µL Buffer solution
1:4 dilution 100 µL 1:2 dilution plus 100 µL Buffer solution
1:8 dilution 100 µL 1:4 dilution plus 100 µL Buffer solution
2. Test each dilution as described in the qualitative method.

QUALITY CONTROL

- It is recommended that both Positive and Negative Controls be included in each batch of tests to ensure proper functioning of the system. Control solutions should be tested by the same procedures as patient samples.
- D-Dimer Positive Control consists of a solution of human D-Dimer at a level of approximately ≥ 0.80 mg/L (≥ 800ng/mL).

RESULTS

A. Qualitative Assay

For the qualitative assay protocol, the following pattern of results should be obtained:
Undiluted Plasma D-Dimer (XL-FDP) concentration
Negative Less than 0.20 mg/L (200ng/mL)
Positive Greater than 0.20 mg/L (200ng/mL)
Note: All values in mg/L (ng/mL) are approximate

B. Semiquantitative Assay

Approximate levels of XL-FDP, containing the D-Dimer domain, for specimen dilutions are shown in Table 1. As with all semiquantitative tests, some variability in dose-response can be expected.

Approximate Range of D-Dimer (XL-FDP) mg/L (ng/ml)	Sample Dilution			
	Undil.	1:2	1:4	1:8
< 0.2 (< 200)	-	-	-	-
0.2 – 0.4 (200 – 400)	+	-	-	-
0.4 – 0.8 (400 – 800)	+	+	-	-
0.8 – 1.6 (800 – 1600)	+	+	+	-
1.6 – 3.2* (1600 – 3200*)	+	+	+	+

"+" = agglutination, "-" = no agglutination
* Levels of XL-FDP greater than 3.20 mg/L (3200 ng/mL) can be estimated by further dilutions beyond 1:8.

EXPECTED VALUES

A positive result, indicating active fibrinolysis, should be obtained with D-Dimer Latex Test when XL-FDP (D-Dimer) levels are at or

greater than approximately 0.20 mg/L (200ng/mL). Plasma specimens from normal subjects are expected to give negative results because their plasma XL-FDP concentrations are typically less than 0.20 mg/L (200ng/mL). Due to many variables that may affect results, each laboratory should establish its own normal range.

Elevated levels of XL-FDP (containing the D-Dimer domain) have been demonstrated in patients by a combination of immunoprecipitation and gel electrophoresis techniques. Monoclonal antibodies allow the specific detection of the D-Dimer domain. Monoclonal antibody based D-Dimer assay is of diagnostic value in disseminated intravascular coagulation (DIC) and acute vascular diseases, including pulmonary embolism (PE) and deep venous thrombosis (DVT), conditions that are difficult to detect reliably by clinical examination.

The amount of XL-FDP detected in a specimen will depend on several interrelated factors in vivo, such as the severity of the thrombotic episode, the rate of cross linked fibrin formation, and the time elapsed after the thrombotic event until blood is drawn from the patient.

Elevated levels of XL-FDP as an indication of reactive fibrinolysis have also been reported in surgery, trauma, sickle cell disease, liver disease, severe infection, sepsis, inflammation, and malignancy. D-Dimer levels also rise during normal pregnancy but very high levels are associated with complications.

LIMITATIONS

Clinical diagnosis should not be based on the result of D-Dimer Latex alone. Clinical signs and other relevant test information should be included in the diagnostic decision.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Plasma from one hundred and seventy (170) apparently healthy, voluntary blood donors was tested using Atlas D-Dimer Latex. A negative result was obtained for one hundred and sixty-two (162) of the samples. This equates to a specificity of 95.3% (162/170).
- One hundred and forty-five (145) plasma samples from patients judged to be suffering from, or having a high probability for thrombotic episode, were tested by Atlas D-Dimer Latex and another agglutination reference method. The correlation coefficient was r=0.94 and the regression equation was y=1.19x.
- Intra-assay (within run) reproducibility was determined for 10 replicates of 3 plasma samples that contained different levels of XL-FDP. The results were equivalent for all replicates.
- Inter-assay (run-to-run) reproducibility was determined using 10 plasma samples with XL-FDP titers ranging from 1 to 16. In 10 runs, the replicates of these specimens did not vary by more than one titer.
- In an anticoagulant study of 50 parallel citrated, EDTA and heparin plasma samples, the correlation between the titers obtained with Atlas D-Dimer Latex and the expected titers (based on ELISA XL-FDP values) was r = 0.91 for citrated samples, r = 0.73 for EDTA samples and r = 0.78 for heparin samples. Citrate is the anticoagulant of choice.
- Atlas D-Dimer Latex does not cross-react with fibrinogen, factor XIIIa cross-linked fibrinogen, or fibrinogen degradation products.
- The interference due to presence of rheumatoid factor (RF): in a study of samples from patients with rheumatoid arthritis ,17 were found to agglutinate with D-Dimer latex. In all 17 sample ,the agglutination could be inhibited by the addition of the D-Dimer specific monoclonal antibody DD3B6/22, but not with a non - specific monoclonal antibody of the same subgroup ,IgG3K. This suggests that D-Dimer latex is insensitive to rheumatoid factor disturbances.
- No assay interference was demonstrated with Atlas D-Dimer Latex with spiked specimens containing potential interfering substances at the following concentrations:
- Bilirubin 0.2 mg/mL
- Hemoglobin 5.0 mg/mL
- Lipids (triglycerides) 30 mg/mL
- Protein (gamma globulin) 0.06 g/mL

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11. Smith, R.T. et al. Fibrin Degradation Products in the Postoperative Period. Evaluation of a New Latex Agglutination Method. Am. J. Clin. Pathol. 60 (5): 644-647; 1973.
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PPI139A01
Rev E (03.03.2016)

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		

Atlas Medical

ATLAS SLE LATEX TEST

A latex agglutination slide test for the qualitative and semi-quantitative detection of DNP antibodies associated with Systematic Lupus Erythematosis (SLE) in human serum

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

Store at 2°-8°C

INTENDED USE

The SLE TEST is intended to be used as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) through the detection and quantitation of serum antinucleoprotein factors associated with SLE..

INTRODUCTION AND PRINCIPLE

The detection of antinuclear antibodies by laboratory methods include immunofluorescence, LE cell test and agglutination of coated particles. The antibodies that are believed to be most characteristic of SLE are those that are directed against deoxyribonucleoprotein (DNP). These antibodies are believed to cause the formation of the LE cell in vitro, with this unusual event occurring in 75-80% of those patients diagnosed as having SLE. It is not necessary to have a positive LE cell test for the diagnosis of SLE as this test had been found negative in certain individuals having symptoms suggestive for SLE. In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.

The principle of the SLE TEST is based on the agglutination reaction between latex particles coated with DNP being brought into contact with a serum, which contains antinuclear antibodies. Agglutination indicates a positive reaction. The reaction time for this occurrence is within one minute.

MATERIALS

MATERIALS PROVIDED

- SLE Latex Reagent: polystyrene latex particles coated with DNP extracted from fetal calf thymus. Sodium azide (0.1%) is used as preservative. Shake well prior to use.
- SLE Positive Control: Human serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.
- SLE Negative Control: Human serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.
- Disposable stirring sticks.
- Glass slide.

MATERIALS NEEDED BUT NOT PROVIDED

- Timer.
- Micropipette.
- Physiological saline (0.9%NaCl).
- Test tubes 12x75mm.
- Serological pipettes (1ml delivery).
- Lab rotator (optional).

PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- Even though the control sera supplied in the SLE TEST Kit have been tested by an FDA approved method for the presence of Hepatitis B Surface Antigen (HBsAg) and HTLV-III antibodies and found to be non-reactive, all human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The preservative sodium azide may react with metal plumbing to form explosive metal oxides.
- In disposal, flush with a large volume of water to prevent metal azide build up.

STORAGE & STABILITY

- When not in use, store reagent and controls at 2-8°C.
- DO NOT FREEZE.
- Prior to use, allow reagents and controls to warm up to room temperature.
- Expiration date is specified on the kit label and on each vial. Biological indication of product instability is positive and negative controls.

SPECIMEN COLLECTION

- The test should be performed on serum.
- The test sera and controls should not be heat inactivated.
- Fresh specimens (less than 24 hours) should be used in performing the test.
- If testing is delayed, specimens should be refrigerated (or frozen where applicable).
- Bacterial contamination may cause false positive agglutination.

PROCEDURES

A. Method I (Qualitative)

1. Bring all reagents and serum samples to room temperature.
2. Positive and Negative Controls should be tested with each series of test sera. Using micropipette, place 0.040ml of test serum on one circle of the test slide. Use separate pipette tip for each test serum.
3. Important: The SLE Latex Reagent must be shaken vigorously for 30 seconds prior to using on each day's testing. This is to insure that there is no aggregation of the latex particles which may occur upon standing. Do not use a vortex mixer.
4. Deliver one drop of SLE Latex to each circle that contains specimen on the slide. Spread the resulting mixture by using the plastic stick provided. Do not use the same plastic stick to mix each test serum or control as this will cause cross-contamination.
5. Gently tilt and rotate slide by hand for one minute (rotator can be used).
6. Observe for macroscopic clumping using the indirect oblique light source. The reaction of the test serum is compared to the SLE positive and negative control sera.
7. Observe for agglutination no longer than one minute.

* Sera that are positive in the screening test should be retested in the titration test (semi-quantitative test) to provide verification for borderline interpretations.

B. Method II (Semi-Quantitative)

1. For each test serum to be titrated, label 6 test tubes (12x75 mm).
2. To each tube add 0.2 ml physiological saline.
3. To Tube No.1 add 0.2 ml of undiluted test serum.
4. Serially make two-fold dilutions by mixing contents of tube No.1 with a pipette and transferring 0.2 ml to tube No.2. Repeat serial transfers for each tube. For the 6 tubes, the dilutions range from 1:2 to 1:64. If required, additional serum dilutions can be added.
5. Repeat Steps 3 to 7 as given in Method I (Qualitative).

RESULTS:

1. Positive Result:
Presence of agglutination within 1 minute.

2. Negative Result:
Smooth milky suspension within 1 minute.

LIMITATION

Those patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is tested with the SLE TEST latex. In recent studies, it has been reported that many widely used drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce a systemic lupus erythmatosis (SLE) syndrome.

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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		