Client

Gurugram

Pathkind Diagnostics Pvt. Ltd.

Plot No. 55-56, Udhyog Vihar Ph-IV, Gurugram - 122015

Processed By

Pathkind Diagnostics Pvt. Ltd.

Plot No. 55-56, Udhyog Vihar Ph-IV, Gurugram - 122015

Name	:	**Mrs. PL14**	Billing Date	:	07/07/2023 12:26:15
Age	:	35 Yrs	Sample Collected on	:	10/07/2023 10:01:31
Sex	:	Female	Sample Received on	:	10/07/2023 11:02:13
P. ID No.	:	P1000100012827	Report Released on	:	15/07/2023 17:46:45
Accession No	:	**10002304883**	Barcode No.	:	10002304883-02, 10002304883-01
Referring Doctor	:	Self			
Referred By	:		Ref no.	:	

Report Status - Final

Test Name	Result	Biological Ref. Interval	Unit
SEROLOGY			
BOH Profile			
Anti Nuclear Antibodies (ANA), IFA			
Method: Sample : Serum			
Anti Nuclear Antibodies (ANA) by IFA *Sample: Serum*	Not Detected	Not Detected	
Cardiolipin IgG Antibodies *Sample: Serum* *Method: ELISA*	**15.00 H**	Negative : < 10 Positive: >=10	GPL-U/ml
Cardiolipin IgM Antibodies *Sample: Serum* *Method: ELISA*	0.02	Negative : <7 Positive: >/= 7	MPLU/mL
HAEMATOLOGY			
PTT & Mixing Studies Plasma			
PTT (Test) *Sample: Citrate Plasma*	**35.40 H**	24.80 - 34.40	Sec
PTT Control (Normal Pooled Plasma) *Sample: Citrate Plasma*	28.4	24.8 - 34.4	Sec
Lupus Anticoagulant Screen Time			
DRVV Screen Test *Sample: Citrate Plasma*	39.00	33.80 - 45.80	Sec
DRVV Screen Control *Sample: Citrate Plasma*	39.0	33.8 - 45.8	Sec
DRVV Screen Ratio *Sample: Citrate Plasma*	1.00	<1.20	Ratio
Lupus Anticoagulant			
Lupus Anticoagulant *Sample: Citrate Plasma*	Absent		Sec

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TSH 3rd Generation *Sample: Serum* *Method: ECLIA*	2.060	0.270 - 4.200	µIU/mL

SEROLOGY

Torch IgM Antibodies

Toxoplasma IgM Antibodies *Sample: Serum* *Method: ECLIA*	5.60	Negative : < 6 Equivocal : 6 - 8 Positive : > 8	AU/mL
Rubella IgM Antibodies *Sample: Serum* *Method: ECLIA*	11.20	Negative : < 20 Equivocal : 20 - 25 Positve : > 25	AU/mL
Cytomegalovirus (CMV) IgM Antibodies *Sample: Serum* *Method: ECLIA*	18.00	Negative : < 18 Equivocal : 18 - 22 Positive : > 22	U/mL
Herpes Simplex Virus (HSV) 1 & 2 IgM Antibodies (Combined) *Sample: Serum* *Method: ECLIA*	0.1	Negative : < 0.9 Equivocal : 0.9 - 1.1 Positive : > 1.1	Index

Anti Nuclear Antibodies (ANA), IFA

Antinuclear Antibodies (ANA) are antibodies directed against Nuclear/ Cytoplasmic components of the cell and are detected by Indirect immunofluorescence method(IIF). Presence of ANA indicate autoimmunity and together with other serological methods and clinical data form an important screening component in the diagnosis of Autoimmune Diseases. The IIF assay is a sensitive screening test using Hep-2 cells and is recommended as the screening test of choice by the task force of the American College of Rheumatology.

Sample Screening Dilution	Intensity of Immunofluorescence
1:160(Weak Positive)	+
1:320(Medium Positive)	++
1:640(Strong Positive)	+++

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1:1280(Very Strong Positive)	++++		

Location	Pattern	Target Antigen	Clinical Association
Nucleus	Homogeneous	dsDNA, Histones Nucleosome, RNA,Single Strand DNA	SLE Drug Induced Lupus, SLE , RA SLE, MCTD,RA, PM, DM, SS
	Speckled	Sm U1-snRNP SSA/Ro SSB/La Ku Cyclin1(PCNA) Mitosin/Cyclin II	SLE MCTD,SLE,RA, sharp syndrome Sjogren`s syndromes (SS)/SLE/Neonatal Lupus PM/DM/SLE/SS SLE/Overlap Syndromes DM
	Dense Fine Speckled (DFS)	Lens epithelium-derived growth factor (LEDGF),	Healthy individuals, Various Inflammatory conditions like atopic dermatitis, interstitial cystitis, Asthma.
	Centromere	CENP-A,B,C,D,E ,G & H	CREST syndrome, PBC, Raynaud's Syndrome
	Nuclear Dots	Sp-100 , PML protein	PBC,Rheumatic Disease
	Nuclear Membrane	Lamins, gp210, p62	SLE,SS, PBC,AIH
Nucleolus	Nucleolar homogeneous	PM-Scl 75, PM Scl-100 Rpp25	PM, DM, SS SS(cutaneous form)
	Nucleolar speckled	RNA-Polymerase I / NOR-90	Progressive Systemic Sclerosis (Diffuse)
	Nucleolar(clumpy)	U3-Nrnp Fibrillarin	Systemic Sclerosis(Diffuse)
Cytoplasm	Fine granular Fine dense granular	Jo -1 Histidyl- trna synthetase PL-7, PL-12	PM/ DM, PM/DM
	Homogeneous Very Fine Granular Mitochondria type-2 Multiple Dots	P proteins: P0, P1 and P2 Signal recognition particle Pyruvate dehydrogenase complex GW182, Su/Ago2, RAP55	SLE Myositis,Polymyositis,Necrotizing Myopathy PBC Cerebellar ataxia, SLE , PBC, Sjogren's Syndrome
Cell Cycle (mitotic spindle apparatus, Mphase)	Centriole Mid-Body NuMA-1	Pericentrin, ninein, enolase Aurora kinase B complex Nuclear mitotic apparatus,type 1	Systemic autoimmune disease SS, cancers SLE, MCTD

Abbreviations: SLE: Systemic Lupus Erythematosus, SCL: Scleroderma, MCTD: Mixed Connective Tissue Disease; CFS: Chronic Fatigue Syndrome; AIH: Autoimmune Hepatitis, PBC: Primary Bilary Cirrhosis, PM:Polymyositis, DM: Dermatomyositis, SS: Systemic sclerosis, RA:Rheumatoid Arthritis.

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Test Name	Result	Biological Ref. Interval	Unit

Cardiolipin IgG Antibodies

Clinical Significance :

ANTI-CARDIOLIPIN ANTIBODIES (ACA) are antibodies ofter directed against cardiolipin and found in several diseases

1. The presence of anti cardiolipin antibodies in Systemic Lupus Erythematosus (SLE) can be related to the development of thrombosis and thrombocytopenia.
2. In Gynecology practice they are associated with Intrauterine Death or recurrent abortions and unexplained infertility.
3. They are also found in some non thrombotic neurological disorders e.g. cerebrovacsular insufficiency, cerebral ischemia or chorea. Transient elevation can be seen inother autoimmune & intercurrent diseases. Persistent positive test with titre more than 40 GPL/ml and spaced atleast 12 weeks apart is significant in antiphopholipid antibody syndrome.

Cardiolipin IgM Antibodies

Clinical Significance :

ANTI-CARDIOLIPIN ANTIBODIES (ACA) are antibodies ofter directed against cardiolipin and found in several diseases

1. The presence of anti cardiolipin antibodies in Systemic Lupus Erythematosus (SLE) can be related to the development of thrombosis and thrombocytopenia.
2. In Gynecology practice they are associated with Intrauterine Death or recurrent abortions and unexplained infertility.
3. They are also found in some non thrombotic neurological disorders e.g. cerebrovacsular insufficiency, cerebral ischemia or chorea. Transient elevation can be seen inother autoimmune & intercurrent diseases. Persistent positive test with titre more than 40 GPL/ml and spaced atleast 12 weeks apart is significant in antiphopholipid antibody syndrome.

Lupus Anticoagulant

Medical Remarks: See Remark - 5. Correlate Clinically.

Test Description: Screening of Lupus Anticoagulant Confirmation is done by two different APTT reagents namely Lupus sensitive (LS) APTT Automate and RVVT. Lupus anticoagulant is an antiphospholipid antibody directed against negatively charged phospholipids that is identified functionally by prolongation of in vitro phospholipids dependent coagulation test. Lupus anticoagulant is often associated with a thrombotic tendency.

Interpretation :

1. Following is the final Interpretative Table using the findings of both the above mentioned tests:

APTT (LS)	APTT Mixing (Using	DRVVT (Screen)	DRVVT	DRVV screen to	Interpretation

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Test Name	Result		Biological Ref. Interval		Unit
	Rosner Index)		(Confirmation)	confirmation ratio	
Normal	-	Normal	-	-	LAC Absent
Abnormal	Corrected	Normal	-	-	Suspect Factor Deficiency
Abnormal	Not Corrected	Abnormal	Normal	> 1.2	LAC Present
Normal	-	Abnormal	Normal	> 1.2	LAC Present
Abnormal	Corrected/Partially Corrected	Abnormal	Normal	> 1.2	Factor Deficiency + LAC Present
Abnormal	Not Corrected	Abnormal	Abnormal	< 1.2	Either Inhibitor or LAC
Abnormal	Not Corrected	Normal	-	-	Suspect Inhibitor/heparin

2. Interpretation of APTT mixing based on Rosner Index (RI) Rosner Index = Clotting time of mixture - Clotting time of normal (PPP) X 100/Clotting time of patient plasma * If Rosner Index < 12 then APTT mixing is considered as corrected and Suspects the factor deficiency.
* If Rosner Index < 12 then APTT mixing is considered as corrected and Suspects the factor deficiency.
* If Ronser Index > 12 then APTT mixing is considered as not corrected and suspects the presence of inhibitor or Lupus.

3. All abnormal results od DRVV screening tests are confirmed by neutralization assay using Phospholipids. A normalized ratio > or = Biological Reference Interval confirms the presence of lupus anticoagulant (LAC).

4. Persistent Positive LAC results on two different occasions & 12 weeks apart are essential to suspect & diagnose Lupus anticoagulant.

5. In view of abnormal DRVV Screen, abnormal DRVV confirm and normalised ration <1.2, possibility of Lupus and/or Inhibitor needs exclusion. Advice repeat testing after 12 weeks.

Limitations :

1. False Positive: Patients on heparin or heparin substitute; Coagulation factor VIII inhibitors.
2. False Negative: Elevated factor VIII levels, as may be seen in an acute infection or with replacement therapy when someone has Hemophillia A, may shorten the aPTT time, leading to a temporary false negative test for lupus anticoagulant.

Reference : Update of the guidelines for lupus anticoagulant detection. Pengo V, Tripodi A, et al. J Thromb Haemost 2009;7:1737-40.

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TSH 3rd Generation

Clinical Significance :

TSH levels are elevated in primary hypothyroidism and low in primary hyperthyroidism. Evaluation of TSH is useful in the differential diagnosis of primary from secondary and tertiary hypothyroidism. In primary hypothyroidism, TSH levels are elevated, whil secondary and tertiary hypothyroidism, TSH levels are low or normal. High TSH level in the presence of normal FT4 is subclinical hypothyroidism and low TSH with normal FT4 is called subclinical hyperthyroidism. Sick, hospitalized patients may have falsely low or transiently elevated TSH. Significant diurnal variation is also seen in TSH levels.

Guidelines for TSH levels in pregnancy, as per American Thyroid Association, are as follows:

PREGNANCY TRIMESTER	BIOLOGICAL REFERENCE INTERVAL	UNIT
FIRST TRIMESTER	0.100 - 2.500	µIU/mL
SECOND TRIMESTER	0.200 - 3.000	µIU/mL
THIRD TRIMESTER	0.300 - 3.000	µIU/mL

Toxoplasma IgM Antibodies

Interpretation

Negative	Presumed not to have had active Toxoplasmosis infection.
Equivocal	May be due to low levels of IgM antibodies. These results should be retested with a second sample after 2 3 weeks, if clinically indicated.
Positive	Indicates active Toxoplasmosis.

Clinical Significance:

● Nonreactive results do not preclude recent primary Toxoplasma gondii infection. A suspected diagnosis of acute toxoplasmosis should be confirmed by detection of Toxoplasma gondii nucleic acid in cerebrospinal fluid or amniotic fluid by PCR.

Rubella IgM Antibodies

Interpretation:

Negative - Presumed not currently infected with Rubella.

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Equivocal - Low levels of IgM antibodies. It is recommended to re-test after 2-4 weeks on a fresh sample.

Positive - Indicates current infection or reactivation.

Clinical Significance:

- A suspected diagnosis of Rubella should be used in conjunction with other clinical data like symptoms, clinical impressions, etc.
- If the rubella IgM results are inconsistent with clinical evidence, additional testing is suggested to confirm the result by PCR.

Cytomegalovirus (CMV) IgM Antibodies

Interpretation

Negative -Presumed not currently infected with CMV.,

Equivocal-Indicates low levels of IgM antibodies during the acute stage of infection/nonspecific, binding reactions. Repeat the test with a second sample after 2 weeks, if clinically indicated.,

Positive- Indicates a recent infection (primary, reactivation, or reinfection).,

Clinical Significance:

- A suspected diagnosis of CMV infection should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical, impressions, etc.
- High concentrations of IgM rheumatoid factor in combination with CMV specific IgG can lead to false reactive results with CMV, IgM, potential cross-reactivity may occur with specimens positive for antibodies to EBV and parvovirus B19.

Herpes Simplex Virus (HSV) 1 & 2 IgM

Interpretation

Negative : Presumed not currently infected/antibodies have not yet reached detectable levels.
Equivocal : May be due to low levels of IgM antibodies during the early stage of infection or nonspecific

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binding reactions. Repeat the test with a second sample after 2 3 weeks, if clinically indicated.
Positive: Indicates a recent infection (primary, reactivation, or re infection).

Clinical Significance:

- This test should not be used as the sole criterion for the diagnosis of current herpes simplex infection.

Torch IgM Antibodies

Interpretation

1. This assay is used for quantitative detection of specific IgM antibodies to TORCH in serum samples.

2. Positive result for TORCH IgM indicates possible acute infection with TORCH. False positive reaction due to rheumatoid factor and persistence of positive IgM (except Herpes Simplex virus) for upto 2 years is not uncommon.

3. An equivocal result requires repeat testing in 10-14 days.

4. Negative result indicates no serological evidence of infection with TORCH. False negative can be due to immunosuppression or due to low/undetectable level of IgM antibodies. A suspected diagnosis of acute TORCH infection should be confirmed by PCR analysis or repeat test after 10-14 days.

5. The diagnosis should not be established on the basis of single test and the results should be interpreted in conjunction with clinical findings

6. The magnitude of the measured result is not indicative of the amount of antibody present

** End of Report**

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