

ACCREDITATION CERTIFICATE

No.: LB-079

Dubai Accreditation Department (DAC)

has accredited

NATIONAL REFERENCE LABORATORY (NRL)- Dubai

In accordance with the requirements of ISO 15189: 2007 to undertake the tests in the field(s) of:

Medical Testing

For the tasks listed in the attached Scope of Accreditation

This Accreditation shall remain in force within the validity period printed below, subject to continuing compliance with the requirements of the accreditation program.

Validity of Certificate: from 07- 07- 2011 to 06- 07- 2014

- * The accreditation certificate is invalid without attached scope of accreditation
- * Initial accreditation date: 07 July 2011


Director, Dubai Accreditation Department

SCOPE OF ACCREDITATION (LB-MD)

NATIONAL REFERENCE LABORATORY (NRL)- Dubai

Scope Issue No: 01

Accreditation Certificate No: LB-079

Scope Validity Period: 07-07-2011 to 06-07-2014

Issued by (Head of Section):



Type of Task	Materials/Products	Task Name	Standard method
Clinical Chemistry	Serum	Albumin	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum	Alkaline Phosphatase	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum	Alanine Aminotransferase	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum	Amylase	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum	Aspartate Aminotransferase	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum	Bilirubin, total	Colorimetric by Cobas 6000 analyzer
	Serum	Bilirubin, direct	Colorimetric by Cobas 6000 analyzer
	Serum	BUN	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum,Plasma, Urine	Calcium	Colorimetric by Cobas 6000 analyzer
	Serum,Plasma, urine	Chloride	ISE by Cobas 6000 analyser
	Serum, plasma samples	CO2 Total	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum, urine, plasma samples	Creatinine	Colorimetric by Cobas 6000 analyzer
	Serum, plasma samples	Ferritin	Immunturbidimetric Assay
	Serum, plasma, urine samples	Glucose	Enzymatic by Cobas 6000 analyzer
	Serum, plasma samples	HDL cholesterol	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum, plasma samples	LDL cholesterol	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum, plasma, urine samples	Potassium	ISE by Cobas 6000 analyzer
	Serum, plasma, urine samples	Phosphorus	Colorimetric by Cobas 6000 analyzer
	Serum samples	Rheumatoid factor	Immunturbidimetric assay by Cobas 6000 analyzer
	Serum, plasma, urine samples	Sodium	ISE by Cobas 6000 analyzer
Serum, plasma samples	Total Protein	Colorimetric by Cobas 6000 analyzer	
Serum, plasma samples	Triglyceride	Enzymatic/Colorimetric by Cobas 6000 analyzer	

Note: For history details of accredited conformity assessment activities, please refer to Dubai Accreditation Department, Dubai Municipality.

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Clinical Chemistry	Serum, plasma, urine samples	Magnesium	Colorimetric by Cobas 6000 analyzer
	Serum, plasma samples	LDH	UV assay by Cobas 6000 analyzer
	Serum, plasma samples	Lipase	Colorimetric by Cobas 6000 analyzer
	Serum, plasma samples	GGT	Enzymatic (Colorimetric) Glutamyl-Carboxy-Nitroanilide by Cobas 6000 analyzer
	Serum, plasma samples	Uric acid	Enzymatic/Colorimetric by Cobas 6000 analyzer
	Serum, plasma samples	Digoxin	Immunoassay by Cobas 6000 analyzer
	Serum, plasma samples	Phenobarbital	Immunoassay by Cobas 6000 analyzer
	Serum, plasma samples	Phenytoin	Immunoassay by Cobas 6000 analyzer
	Serum, heparinized plasma samples	Theophylline	Immunoassay by Cobas 6000 analyzer
	Nonhemolyzed Serum or plasma samples	Tobramycin	Enzymatic Immunoassay by Cobas 6000 analyzer
	Nonhemolyzed Serum, plasma samples	Valproic acid	Immunoassay by Cobas 6000 analyzer
	Nonhemolyzed Serum, plasma samples	Vancomycin	Immunoassay by Cobas 6000 analyzer
	Serum samples	PSA (total)	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	PSA (free)	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	CA-125	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	CA 15-3	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	CA 19-9	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	CEA	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	AFP	ECLIA by Cobas 6000 analyzer
	Serum, plasma samples	hsCRP	Particle enhanced turbidimetric by Cobas 6000 analyzer
Serum, plasma samples	CK	Enzymatic/Colorimetric by Cobas 6000 analyzer	

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Clinical Chemistry	Serum	CK-MB	Electrochemiluminescence Immunoassay (ECLIA) by Cobas 6000 analyzer	
	Urine samples	Routine Urine Analysis	Reflectance spectrophotometer for reagent strip urinalysis by Clinitek Advantus analyzer	
	Urine samples	Microalbumin	Immunturbidimetric by Cobas 6000 analyzer	
	Urine, CSF samples	Total Protein Urine/CSF	Turbidimetric-Benzethonium chloride by Cobas 6000 analyzer	
	Serum, plasma samples	Thyroid Stimulating Hormone (TSH)	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	Free Thyroxine (FT4)	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	Thyroxine (Total T4)	ECLIA by Cobas 6000 analyzer	
	Serum	Triiodothyronine (T3)Total	ECLIA by Cobas 6000 analyzer	
	Serum, plasma	Beta HCG, Quant	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	Luteinizing Hormone	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	Estradiol	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	Progesterone	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	FSH	ECLIA by Cobas 6000 analyzer	
	WHOLE BLOOD	HgbA1C	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	Testosterone	ECLIA by Cobas 6000 analyzer	
	Serum	Prolactin	ECLIA by Cobas 6000 analyzer	
	Serum, plasma samples	FT3	ECLIA by Cobas 6000 analyzer	
	Serum	T3 Uptake	ECLIA by Cobas 6000 analyzer	
	Immunology	Serum, plasma samples	eHIV 1/0/2	ICMA by Advia Centaur XP analyzer
		Serum, EDTA-plasma samples	HAV IgM	ICMA by Advia Centaur XP analyzer

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Type of Task	Materials/Products	Task Name	Standard method
Immunology	Serum, EDTA-plasma samples	HBcAb Total	ICMA by Advia Centaur XP analyzer
	Serum, EDTA-plasma samples	HBcAb IgM	ICMA by Advia Centaur XP analyzer
	Serum, EDTA-plasma samples	HBsAg with confirmatory	ICMA by Advia Centaur XP analyzer
	Serum, EDTA-plasma samples	HCV antibody	ICMA by Advia Centaur XP analyzer
	Serum, EDTA-plasma samples	HBsAb	ICMA by Advia Centaur XP analyzer
	Serum, EDTA-plasma samples	HAV Total	ICMA by Advia Centaur XP analyzer
	Serum samples	CMV IgG	Chemiluminescent – Immunometric by Immulite 2000 analyzer
	Serum samples	HSV I & II IgG antibodies	Chemiluminescent – Immunometric by Immulite 2000 analyzer
	Serum samples	Rubella IgG Quantitative	Chemiluminescent – Immunometric by Immulite 2000 analyzer
	Serum samples	Toxoplasma IgG antibodies	Chemiluminescent – Immunometric by Immulite 2000 analyzer
	Serum samples	Toxoplasma IgM antibodies	Chemiluminescent – Immunometric by Immulite 2000 analyzer
	Serum, plasma samples	ANA Test system	Multiplex Microparticle-based Immunoassay by Bioplex 2200 analyzer
	Serum samples	EBV IgG	Multiplex Microparticle-based Immunoassay by Bioplex 2200 analyzer
	Serum samples	EBV IgM	Multiplex Microparticle-based Immunoassay by Bioplex 2200 analyzer
Serum, EDTA-plasma samples	RPR Syphilis screening test	Non-treponemal carbon flocculation by SA Scientific card test	
Hematology	EDTA Whole Blood	CBC with Differential	Radio-frequency / Direct Current Detection, Hydro Dynamic Focusing, Flow Cytometry & SLS-Hemoglobin by XE-5000 analyzer

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Type of Task	Materials/Products	Task Name	Standard method
Hematology	EDTA Whole Blood	Platelet Count	Radio-frequency / Direct Current Detection, Hydro Dynamic Focusing, Flow Cytometry & SLS-Hemoglobin by XE-5000 analyzer
	EDTA Whole Blood	Reticulocyte Count	Radio-frequency / Direct Current Detection, Hydro Dynamic Focusing, Flow Cytometry & SLS-Hemoglobin by XE-5000 analyzer
	EDTA Whole Blood	Hematocrit	Radio-frequency / Direct Current Detection, Hydro ADynamic Focusing, Flow Cytometry & SLS-Hemoglobin by XE-5000 analyzer
	Serum, plasma samples	Iron	Colorimetric Assay by Cobas 6000 analyzer
	Serum, plasma samples	Unsaturated Iron binding capacity	Direct determination with Ferrozine by Cobas 6000 analyzer
	Serum, plasma samples	Ferritin	Colorimetric Assay by Cobas 6000 analyzer
	EDTA Whole Blood	Sedrate (ESR) - Westergren & Modified Westergren	Modified Westerngren-Sedioplast/ Polymedco
	Sodium citrate plasma samples	Prothrombin (PT)	Optical clot detection by Sysmex CA1500 analyzer
	Sodium citrate plasma samples	aPTT	Optical clot detection by Sysmex CA1500 analyzer
Sodium citrate plasma samples	Fibrinogen	Optical clot detection by Sysmex CA1500 analyzer	

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