AIAO-BAR

INTERNATIONAL LABORATORY ACCREDITATION PROGRAM

CERTIFICATE OF ACCREDITATION

GRANTED TO

THE MEDICAL LABORATORIES (Pvt.) Ltd. (Zeenat Laboratory)

36-A Lawrence Road, Lahore – Pakistan

American International Accreditation Organization-Bureau of Accredited Registrars issues this certificate to the firm named above, having assessed and approved Laboratories Requirements with the standards

ISO 15189:2012

The Laboratories Requirements is applicable to the define scope below:

Chemistry & Haematology Laboratories (Appendix – 1 and 2 attached)

This approval is subject to the firm maintaining its lab system to the required standards, which will be monitored by AIAO-BAR. In the issuance of this certificate, AIAO-BAR assumes no liability to any party other than the firm named above, and then only in accordance with the agreed upon Agreement.

Certification Number:	*AIAO-P-TML-1701-002-B*
Original Approval:	*March 11, 2017*
Date of Issue:	*March 11, 2019*
Date of Expiration:	*March 10, 2022*

For and on Behalf of American International Accreditation Organization

American International Accreditation Organization
155 North Santa Cruz Ave, Suite 144
Los Gatos, CA 95030
www.aiao-bar.org

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Appendix-1

Chemistry Laboratory Accreditation Scope
ISO 15189:2012

Sample Type / Matrix	Types of Test/ Properties measured	Range of Measurements	Minimum Detection Limits	Uncertainty of Measurement (Where applicable) ±	Standard Specification/ Techniques/ Equipment Used
Serum/ Plasma	Clinical Chemistry/ Cholesterol	3.86- 800 mg/dL	3.86 mg/dL	1.7 mg/dL	Enzymatic Colorimetric/ Cobas 6000
Serum/ Plasma	Clinical Chemistry/ HDL-C	3- 121 mg/dL	3 mg/dL	1.12 mg/dL	Enzymatic Colorimetric/ Cobas 6000
Serum	Alanine Amino Transferase (ALT)	5-700 U/L	5 U/L	± 1.73 U/L	Photometry Cobas 6000
Serum	Albumin	0.2 – 6.0 g/dL	0.2 g/dL	± 0.08 g/dL	Photometry Cobas 6000
Serum	Alkaline Phosphatase	5 – 1200 U/L	5.0 U/L	± 1.74 U/L	Photometry Cobas 6000
Serum	Amylase	3.0 – 1500 U/L	3.0 U/L	± 1.11 U/L	Photometry Cobas 6000
Serum	Anti Streptolysin O	20 – 600 IU/mL	20.0 IU/mL	± 3.67 IU/mL	Photometry Cobas 6000
Serum	Aspartate Amino Transferase (AST)	5 – 700 U/L	5.0 U/L	± 1.48 U/L	Photometry Cobas 6000

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Serum	Bilirubin Direct	0.09 – 17.0 mg/dl	0.09 mg/dL	± 0.10 mg/dl	Photometry Cobas 6000
Serum	Bilirubin Total	0.15 – 38.0 mg/dl	0.15 mg/dL	± 0.14 mg/dL	Photometry Cobas 6000
Serum	C Reactive Protein (CRP)	1.0 – 250 mg/L	1.00 mg/L	± 4.70	Photometry Cobas 6000
Serum	Calcium	0.20 – 5.0 mmol/L	0.20 mmol/L	± 0.03 mmol/L	Photometry Cobas 6000
Serum	Ceruloplasmin	3 – 140 mg/dL	3 mg/dL	± 0.54 mg/dL	Photometry Cobas 6000
Serum	Cholesterol	4 – 800 mg/dL	4 mg/dL	± 2.20 mg/dL	Photometry Cobas 6000
Serum	CKMB	3 – 500 U/L	3 U/L	± 5.20 U/L	Photometry Cobas 6000
Serum	Complement C3	4.0 – 500 mg/dL	4.0 mg/dL	± 6.52 mg/dL	Photometry Cobas 6000
Serum	Complement C4	2.0 – 100 mg/dL	2.0 mg/dL	± 1.10 mg/dL	Photometry Cobas 6000
Serum	Creatine Kinase	7 – 2000 U/L	7 U/L	± 14.38 U/L	Photometry Cobas 6000
Serum	Creatinine	0.2 – 25.0 mg/dL	0.2 mg/dL	± 0.12 mg/dL	Photometry Cobas 6000
Serum / Plasma	Glucose	2 – 750 mg/dL	2 mg/dL	± 2.47 mg/dL	Photometry Cobas 6000
Serum	r-Glutamyl Transferase (GGT)	3.0 – 1200 U/L	3.0 U/L	± 0.98 U/L	Photometry Cobas 6000
Serum	High Density Lipoprotein (HDL)	3.0 – 121 mg/dL	3.0 U/L	± 2.22 mg/dL	Photometry Cobas 6000
Serum	Immunoglobulin A	50 – 800 mg/dL	50.0 mg/dL	± 5.94 mg/dL	Photometry Cobas 6000
Serum	Immunoglobulin G	300 – 5000 mg/dL	300 mg/dL	± 51.01 mg/dL	Photometry Cobas 6000

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Serum	Immunoglobulin M	25 – 650 mg/dL	25 mg/dL	± 3.79 mg/dL	Photometry Cobas 6000
Serum	Iron	5 – 1000 ug/dL	5.0 ug/dL	± 8.22 ug/dL	Photometry Cobas 6000
Serum	Lactate	2.0 – 140.0 mg/dL	2.0 mg/dL	± 0.70 mg/dL	Photometry Cobas 6000
Serum	Lactate Dehydrogenase (LDH)	10 – 1000 U/L	10 U/L	± 41.33 U/L	Photometry Cobas 6000
Serum	Lipase	3.0 – 300.0 U/L	3.0 U/L	± 1.24 U/L	Photometry Cobas 6000
Serum	Low Density Lipoprotein (LDL)	3.9 – 549 mg/dL	3.9 mg/dL	± 2.35 mg/dL	Photometry Cobas 6000
Serum	Magnesium	0.24 – 6.08 mg/dL	0.24 mg/dL	± 0.14 mg/dL	Photometry Cobas 6000
Serum	Phosphate (Inorganic)	0.3 – 200 mg/dL	0.3 mg/dL	± 0.22 mg/dL	Photometry Cobas 6000
Serum	Rheumatoid Factor	10 – 130 IU/mL	10 IU/mL	± 0.95 IU/ML	Photometry Cobas 6000
Serum	Total Protein	0.2 – 12 g/dL	0.2 g/dL	± 0.09 g/dL	Photometry Cobas 6000
Serum	Triglycerides	9.0 – 885 mg/dL	9.0 mg/dL	± 13.04 mg/dL	Photometry Cobas 6000
Serum	Urea	3 – 240 mg/dL	3 mg/dL	± 1.15 mg/dL	Photometry Cobas 6000
Serum	Uric acid	0.2 – 25 mg/dL	0.2 mg/dL	0.75 mg/dL	Photometry Cobas 6000

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Appendix-2

Haematology Laboratory Accreditation Scope
ISO 15189:2012

Sample Type / Matrix	Types of Test/ Properties measured	Range of Measurements	Minimum Detection Limits	Uncertainty of Measurement (Where applicable) ±	Standard Specification/ Techniques/ Equipment Used
Whole Blood	WBC	0– 100x10^3/uL	0–x10^3/uL	± 0.2x10^3/uL	Floucytometry Sysmex XE-5000
Whole Blood	RBC	0– 8x10^6/uL	0–x10^6/uL	± 0.03x10^6/uL	Floucytometry Sysmex XE
Whole Blood	Hb	0– 25xg/dl	0.0 x g/dL	± 0.2 g/dL	Floucytometry Sysmex XE
Whole Blood	PLT	0– 1000x10^3/ul	0–x10^3/uL	± 10x10^3/uL	Floucytometry Sysmex XE
Whole Blood	HCT	0– 600 %	0.0 %	± 1.0%	Floucytometry Sysmex XE
Whole Blood	Neutrophils	0– 100 %	0 %	----	Floucytometry Sysmex XE
Whole Blood	Lymphocytes	0– 100 %	0 %	----	Floucytometry Sysmex XE
Whole Blood	Monocytes	0– 100 %	0 %	----	Floucytometry Sysmex XE
Whole Blood	Eosinophils	0– 100 %	0 %	----	Floucytometry Sysmex XE
Whole Blood	Basophils	0– 100 %	0 %	----	Floucytometry Sysmex XE
Plasma	PT	0 – 600 Sec	0 Sec	----	Coagulation detection Ca-600 analyzer
Plasma	APTT	0 – 600 Sec	0 Sec	----	Coagulation detection Ca-600 analyzer