

	ACCREDITATION DOCUMENT	F-06/06 Issue Date: 02/05/12 Rev. No: 00 ML 011
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Accreditation No: ML 011

Awarded to

Kulsum International Hospital Laboratory, Islamabad, Pakistan

The scope of accreditation is in accordance with the standard specifications outlined in the following page(s) of this document. The accredited scope shall be visible and legible in areas such as customer service, sample-receiving section etc and shall not mislead its users.

The accreditation was first time granted on **20-05-2015** by Pakistan National Accreditation Council.

The laboratory complies with the requirements of **ISO 15189:2012**.

The accreditation requires regular surveillance, and is valid until **19-11-2018**.

The decision of accreditation made by Pakistan National Accreditation Council implies that the organization has been found to fulfill the requirements for accreditation within the scope.

The organization however, itself is responsible for the results of performed tests.

PAKISTAN NATIONAL ACCREDITATION COUNCIL

23-07-2018
Date

Director General

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Medical Laboratory.

Accreditation Scope of KIH Lab. Islamabad, Pakistan.

Permanent laboratory premises

Field of Medical Testing Laboratory:

Sample Type/ Matrix	Types of test/ Properties measured	Range of measurement	Minimum detection limit	Uncertainty of Measurement (where applicable) MU (\pm)	Standard specification/ Techniques/ equipment used	*Quality Control Measures
Serum/Plasma	Clinical Chemistry/ Cholesterol	3.86 – 800 mg/dL	3.86 mg/dL	1.7 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1, 3, 5
Serum/Plasma	Clinical Chemistry/ HDL-C	3 – 121 mg/dL	3 mg/dL	1.12 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Triglyceride s	8.85 – 885 mg/dL	8.85 mg/dL	1.37 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Urea/BUN	3.0 – 240 mg/dL	3.0 mg/dL	1.89 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Creatinine	0.17 – 24.9 mg/dL	0.17 mg/dL	0.0643 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Sodium (Na)	100 – 150 mmol/L	100 mmol/L	2.0 mmol/L	Ion Selective Electrode (ISE)/9180	1,3,5
Serum/Plasma	Clinical Chemistry/ Potassium	1.8 – 5.0 mmol/L	1.8 mmol/L	0.05 mmol/L	Ion Selective Electrode (ISE)/9180	1,3,5

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Serum/Plasma	Clinical Chemistry/ Chloride (Cl)	72 – 115 mmol/L	72 mmol/L	1.5 mmol/L	Ion Selective Electrode (ISE)/9180	1,3,5
Serum/Plasma	Clinical Chemistry/ Glucose	2 – 750 mg/dL	2 mg/dL	1.63 mg/dL	Ultra Violet Test/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Uric Acid	0.2 – 25 mg/dL	0.2 mg/dL	0.0388 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Total Bilirubin	0.1 – 35.1 mg/dL	0.1 mg/dL	0.0684 mg/dL	Diazo Method Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ SGOT/AST	5 – 700 U/L	5 U/L	0.859 U/L	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ SGPT/ALT	5 – 700 U/L	5 U/L	0.638 U/L	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Alkaline Phosphatase	5 – 1200 U/L	5 U/L	1.25 U/L	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Total Calcium	0.4 – 20 mg/dL	0.4 mg/dL	0.0217 mg/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Phosphorus	0.31 – 20.0 mg/dL	0.31 mg/dL	0.0437 mg/dL	Molybdate UV, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Total Protein	0.2 – 12 g/dL	0.2 g/dL	0.0262 g/dL	Enzymatic, Colorimetric/ Cobas C 311	1,3,5

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Serum/Plasma	Clinical Chemistry/ Albumin	0.2 – 6.0 g/dL	0.2 g/dL	0.0594 g/dL	Colorimetric Assay/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ LDH	10 – 1000 U/L	10 U/L	1.63 U/L	UV Assay, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ CPK(CK)	7 – 2000 U/L	7.0 U/L	2.37 U/L	UV Assay, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Amylase	3 – 1500 U/L	3 U/L	1.64 U/L	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Gamma GT	3 – 1200 U/L	3 U/L	1.25 U/L	Enzymatic, Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Iron	5.0 – 1000 µg/dL	5.0 µg/dL	2.18 µg/dL	Colorimetric/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ UIBC	16.8 – 700 µg/dL	16.8 µg/dL	4.18 µg/dL	Colorimetric Direct Determination with FeroZine/ Cobas C 311	1,3,5
Serum/Plasma	Clinical Chemistry/ Magnesium	0.24 – 6.08 mg/dL	0.24 mg/dL	0.017 mg/dL	Colorimetric with Chlorophosphonazo III/ Cobas C 311	1,3,5
Serum/Plasma	Immunology/ Total T3	0.195 – 6.51 ng/mL	0.195 ng/mL	0.026 – 0.227 ng/mL	Electrochemiluminescence, Cobas e 411	1,3,5
Serum/Plasma	Immunology/ Free T4	0.023 – 7.77 ng/dL	0.023 µg/dL	0.022 – 0.107 ng/dL	Electrochemiluminescence, Cobas e 411	1,3,5

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Serum/Plasma	Immunology/TSH	0.005 – 100.0 μIU/mL	0.005 μIU/mL	0.00 – 0.02 μIU/mL	Electrochemiluminescence, Cobas e 411	1,3,5
Blood	Haematology/WBC Count	1.0 – 299.9 (x 10 ³ /μL)	1.0 (x 10 ³ /μL)	1.5 (x 10 ³ /μL)	DC detection method/ Sysmex KX- 21	1,3,5
Blood	Haematology/ RBC Count	0.30 – 19.99 (x 10 ⁶ /μL)	0.30 (x 10 ⁶ /μL)	1.0 (x 10 ⁶ /μL)	DC detection method/ Sysmex KX- 21	1,3,5
Blood	Haematology/ Haemoglobin	0.1 – 25.0 (g/dL)	0.1 (g/dL)	0.50 (g/dL)	DC detection method/ Sysmex KX- 21	1,3,5
Blood	Haematology/ HCT	10 – 60 (%)	10 %	5 %	DC detection method/ Sysmex KX- 21	1,3,5
Blood	Haematology/ Platelet Count	10 – 1999 (x 10 ³ /μL)	10 (x 10 ³ /μL)	5 (x 10 ³ /μL)	DC detection method/ Sysmex KX- 21	1,3,5

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