

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
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Accreditation No: ML 009

Awarded to

**Dow Diagnostic Reference and Research Laboratory, Karachi,
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 **19-11-2014** by Pakistan National Accreditation Council.

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

The accreditation requires regular surveillance, and is valid until **12-11-2026**.

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 measurements/tests.

PAKISTAN NATIONAL ACCREDITATION COUNCIL

17-05-2024
Date

SD
Director General

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
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Medical Laboratory.

Permanent laboratory DOW DIAGNOSTIC REFERENCE AND RESEARCH
LABORATORY, DOW UNIVERSITY OF HEALTH SCIENCES, KARACHI, PAKISTAN

Field of Medical Testing Laboratory: Microbiology, Hematology, Molecular Pathology,
Chemical Pathology and Histopathology

Materials/Products tested	Testing field (e.g. environmental testing or mechanical testing)	Types of test/ Properties measured	Reference to standardized method/ Internal method reference
Serum	Microbiology	Rubella IgG	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618793 190
		Rubella IgM	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618831 190
		Toxo IgG	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618815 190
		Toxo IgM	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618858 190
		CMV IgG	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 07027117119
		CMV IgM	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 07027133119
		EBV-EBNA 1 IGG	enzyme-linked immunosorbent assay (ELISA) EUROIMMUN/Manual

17-05-2024
Date

Sd
Director



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 18/08/2020
Rev. No: 09
LAB 009

		EBV-CA IGG	enzyme-linked immunosorbent assay (ELISA) EUROIMMUN/Manual
		HIV Ag/Ab	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 International Standard NIBSC Ref# 05390095 190
		Anti-HBc II	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 International Standard NIBSC Ref# 07384764 119
Whole Blood	Hematology	WBC	Flowcytometry Optical / Alinity-hq (Ref: 07P7904)
		RBC	Flowcytometry Optical / Alinity-hq
		Hb	Spectrophotometry / Alinity-hq (Ref: 07P8104)
		PCV	Alinity formula: RBC x MCV/ 10

17-05-2024
Date

Sd
Director



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 18/08/2020
Rev. No: 09
LAB 009

		MCV	Flowcytometry Optical / Alinity-hq
		MCH	Alinity formula: Hb/RBCx10
		MCHC	Alinity formula: Hb/HCT x 100
		PLT	Flowcytometry Optical / Alinity-hq
Serum	Molecular Pathology	SARS-CoV-2 (Covid -19)	Abbott Molecular Alinity m REF:8N5302
		HCV Qauntitative / Viral Load	Abbott Molecular Alinity m REF:8N5302
		HBV Qauntitative / Viral Load	Abbott Molecular Alinity m REF:8N5302
Serum & Plasma	Chemical Pathology	TSH	Chemiluminescence/ Atellica Immunoassay Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) REF#: 10995704

17-05-2024
Date

Sd
Director



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 18/08/2020
Rev. No: 09
LAB 009

		GLUCOSE	Photometric/Atellica Chemistry Glucose Hexokinase_3 (Glu H_3) REF# 11097592
Tissue	Histopathology	H&E	<p>The H&E stain uses two dyes: Hematoxylin and Eosin .This combination is used as the dyes stain different tissue elements</p> <p>Hematoxylin: Merk(C.L.75290) hematoxylin monohydrate</p> <p>Eosin: Merk(C.L45380) Eosin Y(Yellowish)</p> <p>Control slide: Any well fixed paraffin section</p>

17-05-2024
Date

Sd
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	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
-----------------------------------------------------------------------------------	-----------------------------------	-----------------------------------------------------------------------------------------

Medical Laboratory.

**Permanent laboratory DOW DIAGNOSTIC REFERENCE AND RESEARCH
LABORATORY, DOW UNIVERSITY OF HEALTH SCIENCES, KARACHI, PAKISTAN**

Field of Medical Testing Laboratory: Microbiology, Hematology, Molecular Pathology,
Chemical Pathology and Histopathology

Field of measurement:			
Measured quantity	Range	*Expanded Uncertainty (±)	Technique, Reference Standard, Equipment
Rubella IgG	Cutoff Value 10 IU/ml	2.290	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618793 190
Rubella IgM	Cutoff Value for Positive >= 1.0	NA**	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618831 190
Toxo IgG	Non-Reactive < 1 IU/mL, Indeterminate 1 - < 3 IU/mL, Reactive > 3.0 IU/mL	2.66	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618815 190
Toxo IgM	Non-Reactive < 0.8 COI, Indeterminate >= 0.8 < 1.0 COI , Reactive >= 1.0 Col	NA**	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 04618858 190
CMV IgG	Non-Reactive < 0.5 U/ml, Indeterminate 0.5-<1.0 U/ml, Reactive 1.0 U/ml	2.450	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 Ref # 07027117119
CMV IgM		NA**	Electrochemiluminescence

17-05-2024

Date

Sd

Director

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
-----------------------------------------------------------------------------------	-----------------------------------	-----------------------------------------------------------------------------------------

	Non-Reactive < 0.7 COI, Indeterminate: Greater than equal to 0.7 -< 1.0 COI, Greater than equal to 1.0 COI		immunoassay (ECLIA) / COBAS e601 Ref # 07027133119
EBV-EBNA 1 IGG	< 16 RU/ml Negative >16-<22 RU/ml Borderline >22 RU/ml Positive	NA**	Enzyme Linked Immunosorbent Assay (ELISA) EUROIMMUN/Manual
EBV-CA IGG	< 16 RU/ml Negative >16-<22 RU/ml Borderline >22 RU/ml Positive	NA**	Enzyme Linked Immunosorbent Assay (ELISA) EUROIMMUN/Manual
HIV Ag/Ab	Non Reactive	NA**	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 International Standard NIBSC Ref# 05390095 190
Anti-HBc II	Non-Reactive	NA**	Electrochemiluminescence immunoassay (ECLIA) / COBAS e601 International Standard NIBSC Ref# 07384764 119
WBC	4.0 - 10.0 (Male/Female)	4.7	Flowcytometry Optical / Alinity-hq (Ref: 07P7904) Impedence / Sysmex- XN9000 Ref: ZPPCT661628

17-05-2024
Date

Sd
Director

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
-----------------------------------------------------------------------------------	-----------------------------------	-----------------------------------------------------------------------------------------

RBC	4.5-5.5 Male 3.9-4.8 Female	4.4	Flowcytometry Optical / Alinity-hq Impedence / Sysmex- XN9000 Ref: ZPPCT661628
Hb	13.0-17.0 Male 12.0-15.0 Female	0.88	Spectrophotometry / Alinity-hq (Ref: 07P8104) Calorimetry detection / Sysmex-XN9000 (Ref: BJ350971)
PCV	40.0-50.0 Male 36.0-46.0 Female	Calculated Parameters MCV,MCH,MCHC are not calibrated and variance of coefficiency of PCV is not provided by vendor of Alinity	Alinity formula: RBC x MCV/ 10 Sysmex formula: Same as above
MCV	80-100 Male/Female	Calculated Parameter	Flowcytometry Optical / Alinity-hq Impedence / Sysmex-XN 9000
MCH	27.0-32.0 Male/ Female	Calculated Parameter	Alinity formula: Hb/RBCx10 Sysmex formula: Same as above
MCHC	31.5- 34.5 Male/ Female	Calculated Parameter	Alinity formula: Hb/HCT x 100 Sysmex formula: Same as above
PLT	150 - 400	34.6	Flowcytometry Optical / Alinity-hq Impedence / Sysmex- XN9000 Ref: ZPPCT661628

17-05-2024
Date

Sd
Director

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
-----------------------------------------------------------------------------------	-----------------------------------	-----------------------------------------------------------------------------------------

SARS-CoV-2 (Covid -19)	-	NA**	Abbott Molecular Alinity m REF:8N5302
HCV Qauntitative / Viral Load	< 12 IU/ml Positive	4.85	Abbott Molecular Alinity m REF:8N5302
HBV Qauntitative / Viral Load	< 10 IU/ml Positive	4.55	Abbott Molecular Alinity m REF:8N5302
TSH	Atellica IM Thyroid Stimulating Hormone 3- Ultra (TSH3-UL) REF#: 10995704 Current revision date: 08-2019 Rev# 03	13.7	Chemiluminescence/ Atellica Immunoassay Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) REF#: 10995704
GLUCOSE	Atellica CH Glucose Hexokinase_3 (Glu H_3) REF# 11097592 Current revision date: 05-2019 Rev# 03	9.61	Photometric/Atellica Chemistry Glucose Hexokinase_3 (Glu H_3) REF# 11097592
H&E		NA**	Dyes used in H&E staining: Hematoxylin and Eosin .This combination is used as the dyes stain different tissue elements Hematoxylin: Merk(C.L.75290) hematoxylin monohydrate Eosin: Merk(C.L45380) Eosin Y(Yellowish)

17-05-2024
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	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 009
-----------------------------------------------------------------------------------	-----------------------------------	-----------------------------------------------------------------------------------------

			Control slide: Any well fixed paraffin section
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*** Expanded Uncertainty:**

- Expanded Uncertainty is the measurement uncertainty at a coverage probability of 95 %, which usually requires the use of a coverage factor of $k = 2$. This measurement uncertainty is a value for which the laboratory has been accredited using the procedure that was the subject of assessment. In certificates issued under its accreditation scope an accredited laboratory is not permitted to quote an uncertainty that is smaller than the published uncertainty for respective ranges as given above.

****NA:**

Not Applicable as parameters are qualitative.

17-05-2024
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