Irish National Accreditation Board

Accreditation Certificate

MedLab Pathology Ltd

Unit 3, Sandyford Business Centre, Sandyford Business Park, Dublin 18

Medical Testing Laboratory

Registration number: 296MT

is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard **ISO 15189:2012 3rd Edition** *"Medical Laboratories - Particular requirements for quality and competence"*

(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)

Date of award of accreditation: **06:12:2011**

Date of last renewal of accreditation: **28:10:2016**

Expiry date of this certificate of accreditation: **28:10:2021**

This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager: _____ **Chairperson:** _____

Dr Adrienne Duff Mr. Tom O'Neill

Issued on 28/10/2016

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.
The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

The Metropolitan Building, James Joyce Street, Dublin 1, Ireland Tel 1890 289 389 E-mail inab@inab.ie Web inab@inab.ie

Schedule of Accreditation

(Annex to Accreditation Certificate)

Permanent Laboratory:
Category A

MEDLAB PATHOLOGY LTD

Medical Testing Laboratory

Initial Registration Date :	**6-December-2011**
Postal Address:	Unit 3, Sandyford Business Centre
(Address of other locations	Sandyford Business Park,
as they apply)	Sandyford,
	Dublin 18
Telephone:	+353 (1) 2933690
Fax:	+353 (1) 2933671
E-mail:	info@medlabpathology.ie
Contact Name:	Lisa Clarke
Facilities:	Public testing service

Schedule of Accreditation

Permanent Laboratory:
Category A

THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

Testing and Calibration Categories:

Category A: Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.

Category B: Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.

Category C: Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.

Category D: Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using

(a) portable test equipment

(b) a site laboratory

(c) a mobile laboratory or

(d) equipment from a mobile or site laboratory

Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

Glossary of Terms

Facilities:

Public calibration/testing service:	Commercial operations which actively seek work from others.
Conditionally available for public calibration/testing:	Established for another primary purpose but, more commonly than not, is available for outside work.
Normally not available for public calibration/testing:	Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will, on request, verify the status and scope.

Scope of Accreditation

Medlab Pathology Ltd

Permanent Laboratory:

Category A

Cytopathology Testing Laboratory

INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1052	**Cytopathology**		
.01	Gynaecological (Cervical)	ThinPrep LBC Sample	SOP-CY-39 sample processing on Hologic T5000
.01	Gynaecological (Cervical)	Unstained ThinPrep LBC Sample for Papanicolaou (PAP) Staining	SOP-CY-9-Operation & Maintenance of Leica Staining Machine & Coverslipper
.01	Gynaecological (Cervical)	Papanicolaou Stained LBC Slide Sample	SOP-CY-2-Cytology Screening & reporting SOP-CY-3-Private Cervical Smears SOP-CY-6-Cytology Internal Quality Audit SOP-CY11-Operation & Maintenance of Olympus BX-45 Microscope

Scope of Accreditation

Medlab Pathology Ltd

Permanent Laboratory:

Category A

Cytopathology Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1052 Cytopathology .01 Gynaecological (Cervical)	High-Risk HPV using the Roche 4800 Analyser	SOP-MB-9 Molecular Analysis of High-Risk HPV using the Roche 4800 Analyser. MB-10 HPV Reporting
.01	High-Risk HPV using H thin prep LBC sample Mrna Messenger Ribonucleic acid	MB-12, MB13
.01	High-Risk HPV using the Hologic Panther; thin prep LBC sample. Mrna Messenger Ribonucleic acid	Hologic Panther: MB-12, MB13

Scope of Accreditation

ISO 15189 INAB ACCREDITED TESTING DETAILED IN SCOPE REG NO.296MT

Medlab Pathology Ltd

Permanent Laboratory:

Category A

Medical Testing Laboratory

CHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 General Chemistry	SODIUM	Serum/plasma	ISE,Indirect	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-5
	POTASSIUM	Serum/plasma	ISE,Indirect	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-5
	CHLORIDE	Serum/plasma	ISE,Indirect	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-5
	BICARBONATE	Serum/plasma	Phosphoenolpyruvate (PEP)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-6
	UREA	Serum/plasma	Kinetic test with urease and glutamate dehydrogenase.	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-8
	CREATININE(JAFFE)	Serum/plasma	Alkaline Picrate	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-9
	ESTIMATED GFR(MDRD)	Serum/plasma	Calculated	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-9
	BILIRUBIN TOTAL	Serum/plasma	Azobilirubin/Colourmetric	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-10
	ALKALINE PHOSPHATASE	Serum/plasma	Colourimetric/p-nitrophenol	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-12
	ASPARTATE TRANSFERASE	Serum/plasma	NADH oxidation/L-malate(IFCC) without pyridoxal phosphate	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-13
	ALANINE TRANSFERASE	Serum/plasma	L-lactate and NAD+/IFCC	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-14
	GAMMA GLUTAMATE TRANSFERASE	Serum/plasma	Enzymatic colourimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-17
	LACTATE DEHYDROGENASE	Serum/plasma	Pyruvate + NADH + H+/UV assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-16
	TOTAL PROTEIN	Serum/plasma	Colourimetric	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-18
	ALBUMIN	Serum/plasma	Bromcresol Green/Colourimetric	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-7
	GLOBULIN	Serum/plasma	Calculated	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-7
	ALBUMIN/GOBULIN RATIO	Serum/plasma	Calculated	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-7
	CALCIUM	Serum/plasma	Schwarzenbach with o-cresolphthalein complexone.	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-19
	CORRECTED CALCIUM	Serum/plasma	Calculated	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-19
	PHOSPHATE	Serum/plasma	Molybdate UV	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-21
	MAGNESIUM	Serum/plasma	Colourimetric method with Chlorophosphonazo III	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-20
	URIC ACID	Serum/plasma	Enzymatic colourimetric test	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-23

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Medical Testing Laboratory

CHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 General Chemistry					
	AMYLASE	Serum/plasma	Enzymatic colourimetric assay/IFCC	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-54
	C-REACTIVE PROTEIN	Serum/plasma	Particle enhanced immuno-turbidimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-41
	C-REACTIVE PROTEIN - HIGH SENSITIVITY	Serum/plasma	Particle enhanced immuno-turbidimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-42
	CREATINE KINASE	Serum/plasma	D-6-phosphogluconate + NADPH + H+/UV Test	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-15
	TRIGLYCERIDE	Serum/plasma	Enzymatic colourimetric test	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-25
	CHOLESTEROL	Serum/plasma	Enzymatic/Colourimetric method	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-28
	HDL CHOLESTEROL	Serum/plasma	Homogeneous enzymatic colourimetric assay.	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-27
	LDL CHOLESTEROL	Serum/plasma	Homogeneous enzymatic colourimetric assay.	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-28
	GLUCOSE	Serum/ Fluoride oxalate	Enzymatic reference method with hexokinase	Roche Cobas c311 (MLP110044)& 6000 (MLP110144) & (MLP110079)	CC-1, CC-48, CC-22
	IRON	Serum/plasma	Colourimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-24
	UNSATURATED IRON BINDING CAPACITY	Serum/plasma	Direct determination with FerroZine	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-44
	TOTAL IRON BINDING CAPACITY	Serum/plasma	Calculated	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-44
	IMMUNOGLOBULIN G	Serum/plasma	Immunoturbidimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48,CC-31
	Troponin 1	Plasma	Electrochemilumin escence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144)	CC-49, EN-32
	Enzymatic Creatinine	Serum/plasma	Enzymatic	Roche Cobas 6000 (MLP110o79)	CC-48, CC-9
	TRANSFERRIN	Serum/plasma	Immunoturbidimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-40
	TRANSFERRIN SATURATION	Serum/plasma	Calculated	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-24

Scope of Accreditation

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Permanent Laboratory:

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CHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 General Chemistry	RHEUMATOID FACTOR	Serum/plasma	Immunoturbidimetric assay	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-43
	HAEMOGLOBIN A1C (IFCC)	WHOLE BLOOD	Turbidimetric inhibition immunoassay (TINIA)	Roche Cobas c311 (MLP110044)& Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-1, CC-48, CC-39
	FREE T3	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-2
	FREE T4	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-3
	THYROID STIMULATING HORMONE	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-1
	ESTRADIOL	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-15
	FOLLICULAR STIMULATING HORMONE	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-16
	ßeta-HCG	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-17
	LUTEINIZING HORMONE	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49 EN-18
	PROGESTERONE	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-19
	PROLACTIN	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-20
	TESTOSTERONE	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-21
	Anti-Mullerian Hormone (AMH)	Serum/plasma/ Capillary Blood	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, CC-58

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Medical Testing Laboratory

CHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 General Chemistry	TOTAL PROSTATE SPECIFIC ANTIGEN	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-27
	FERRITIN	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-4
	FOLATE	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-6
	VITAMIN B12	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-5
	THYROXINE (T4)	Serum/plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, EN-31
	LITHIUM	SERUM	Colometric	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-48, CC-59
	VITAMIN D	SERUM/PLASMA	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-49, CC-61
	FAECAL IMMUNOCHEMICAL TESTING (FIT)	FAECES	Latex aggluination	Diana QC Sensor (MLP110113) & (MLP110114)	CC-55

Scope of Accreditation

Medlab Pathology Ltd

Permanent Laboratory:

Category A

Medical Testing Laboratory

HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1030 Haematology .01	FULL BLOOD COUNTS (INCLUDING RED CELL COUNT, HAEMOGLOBIN, HAEMATOCRIT, MEAN CELL VOLUME, MEAN CELL HAEMOGLOBIN, MEAN CELL HB CONC, WHITE CELL COUNT,TOTAL, NEUTROPHILS (ABSOLUTE), NEUTROPHILS (%),LYMPHOCYTES(ABSOLUTE), LYMPHOCYTES(%),MONOCYTES(ABSOLUTE), MONOCYTES(%),EOSINOPHILS(ABSOLUTE), EOSINOPHILS(%),BASOPHILS(ABSOLUTE), BASOPHILS(%) ,PLATELETS COUNT, RDW, MPV	WHOLE BLOOD	Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method , Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin method	Sysmex XE-2100(Flow Cytometer) (MLP110020) & Sysmex XS-1000i (MLP110143)	HM-1, HM-2, HM-19
.03	ERYTHROCYTE SEDIMENTATION RATE	WHOLE BLOOD	Sedivette	Sarstedt Sedivette ESR rack (MLP110042)	HM-1, HM-8
.02	BLOOD FILM MORPHOLOGY	WHOLE BLOOD	Romanowsky	Olympus BX45(Microscope) (MLP110056)	HM-1, HM-6
.09	EXAMINATION FOR MALARIA PARASITES	WHOLE BLOOD	Procedures for the investigation of malaria parasites	Olympus BX45(Microscope) (MLP110056)	HM-18
.02	Prothrombin Time	Citrate Plasma	Nephelometry	ACL Coagulation Analyser	HM-20, HM-23
.02	INR	Citrate Plasma	Nephelometry		HM-20, HM-23
.02	Activated partial thromboplastin time	Citrate Plasma	Nephelometry		HM-20, HM-21
.02	Fibrinogen	Citrate Plasma	Nephelometry		HM-20, HM-22
1335 Haematology .02	Prothrombin time	Citrate, Plasma	Nephelometry	ACL 9000 Coagulation Analyser	HM-20,HM-23
1335 .02	INR	Citrate Plasma	Nephelometry	ACL 9000 Coagulation Analyser	HM-20, HM-22
1335 .02	Activated Partical Thromboplastin time	Citrate Plasma	Nephelometry	ACL 9000 Coagulation Analyser	HM-20, HM-21
1335 .02	Fibrinogen (class & delivered	Citrate Plasma	Nephelometry	ACL 9000 Coagulation Analyser	HM-20, HM-22

Scope of Accreditation

Medlab Pathology Ltd

Permanent Laboratory:

Category A

Medical Testing Laboratory

MICROBIOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques	Anti-Hepatitis B Core (HBcAb)	SERUM/ plasma /CAPILLARY BLOOD	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas e411 (MLP110045)& Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-2, CC-49, SR-8
	Hepatitis B Surface Antibody (HBsAb)	SERUM/ plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-2, CC-49, SR-3
	Hepatitis B Surface Antigen (HBsAg)	SERUM/ plasma /CAPILLARY BLOOD	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-2, CC-49, SR-1
	Anti-Hepatitis C Virus (HCVAb)	SERUM/ plasma /CAPILLARY BLOOD	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-2, CC-49, SR-4
	Syphilis	SERUM/ plasma /CAPILLARY BLOOD	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-2, CC-49, SR-10
	HIV Combi (HIV)	SERUM/ plasma /CAPILLARY BLOOD	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	CC-2, CC-49, SR-5
1015 Detection and/or identifiaction of bacterial, parasite, fungal and viral nucleic acids	Chlamydia trachomatis (CT)	Urine/Swab	Real time PCR amplification	Roche Cobas 4800 MLP110096 & MLP110097	MB-11
	Neisseria gonorrhoeae (NG)	Urine/Swab	Real time PCR amplification	Roche Cobas 4800 MLP110096 & MLP110097	MB-11