

# Schedule of Accreditation



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Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	15/12/2021
Scope Classification	Microbiology and virology
Scope Classification	Haematology
Scope Classification	Chemical pathology
Services available to the public <sup>1</sup>	No

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Unit T, M7 Business Park, Newhall, Naas, Kildare

# Scope of Accreditation

## Head Office

### Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Alanine transferase (ALT)	Serum/Plasma	Tris buffer without P5P	Abbott Alinity-c	CE	EMSPC073
	Albumin		Bromocresol Purple	Abbott Alinity-c	CE	EMSPC073
	Amylase		Enzymatic/Colorimetric	Abbott Alinity-c	CE	EMSPC073
	Aspartate Transferase (AST)		Tris buffer without P5P	Abbott Alinity-c	CE	EMSPC073
	Bicarbonate (CO2)		PEP Carboxylase	Abbott Alinity-c	CE	EMSPC073
	C- Reactive protein high sensitivity (CRP-HS)		Immunoturbidimetric	Abbott Alinity c	CE	EMSPC073
	Calcium		Arsenazo	Abbott Alinity-c	CE	EMSPC073
	Chloride		ISE indirect	Abbott Alinity-c	CE	EMSPC073

Creatine Kinase		NAC (N-acetyl-L-cysteine)	Abbott Alinity-c	CE	EMSPC073
Creatinine Enzymatic		Enzymatic	Abbott Alinity-c	CE	EMSPC073
eGFR		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
Gamma Glutamyl Transferase (GGT)		L-gamma glutamyl-3-carboxy-4-nitroanilide substrate	Abbott Alinity-c	CE	EMSPC073
Globulin		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
Glucose	Plasma	Enzymatic (Hexokinase/G-6-PDH)	Abbott Alinity-c	CE	EMSPC073
High Density Lipoprotein (HDL)	Serum/Plasma	Accelerator Selective Detergent	Abbott Alinity-c	CE	EMSPC073
Lactate-Dehydrogenase (LDH)		L to P IFCC	Abbott Alinity-c	CE	EMSPC073
Lithium		Colorimetric	Abbott Alinity c	CE	EMSPC073
Low Density Lipoprotein (LDL)		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
Magnesium		Enzymatic	Abbott Alinity-c	CE	EMSPC073
Non-HDL Cholesterol		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
Phosphorous		Phosphomolybdate enzymatic	Abbott Alinity-c	CE	EMSPC073
Potassium		ISE indirect	Abbott Alinity-c	CE	EMSPC073
Sodium		ISE indirect	Abbott Alinity-c	CE	EMSPC073
Total Cholesterol		Enzymatic	Abbott Alinity-c	CE	EMSPC073
Total Protein		Biuret reaction, end point	Abbott Alinity-c	CE	EMSPC073
Triglycerides		Glycerol Phosphate Oxidase	Abbott Alinity-c	CE	EMSPC073
Urea		Urease, kinetic	Abbott Alinity-c	CE	EMSPC073
Uric acid		Uricase	Abbott Alinity-c	CE	EMSPC073

1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Adjusted Calcium		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
	Alkaline phosphatase (ALP)		P-NPP	Abbott Alinity c	CE	EMSPC073
1061 Clinical Chemistry - .20 Hormones	Anti-Mullerian hormone (AMH)	Serum	Simultaneous one- step immunoenzymatic (sandwich) assay	Beckman Coulter Access 2	CE	EMSPC076
	Estradiol (E2)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Follicle stimulating hormone ( FSH)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Free (FT4)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Free T3 (FT3)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Human chorionic gonadotropin ( $\beta$ HCG)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Luteinizing hormone (LH)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Progesterone		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Prolactin		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Testosterone		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
Thyroid Stimulating Hormone (TSH)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073		

	Total Prostate Specific antigen (TPSA)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
1061 Clinical Chemistry - .40 Iron studies	Ferritin		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Iron	Serum/Plasma	Ferene	Abbott Alinity-c	CE	EMSPC073
	Transferrin		Immunoturbidimetric	Abbott Alinity-c	CE	EMSPC073
	Transferrin saturation		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
	Unsaturated Iron-binding capacity (UIBC)		Ferene	Abbott Alinity-c	CE	EMSPC073
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate	Serum	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Vitamin B12		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D - 25(OH)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
1061 Clinical Chemistry - .61 Hb A1c	Glycated Haemoglobin test (HbA1c)	Whole Blood EDTA	Enzymatic using IFCC units	Abbott Alinity-c	CE	EMSPC073

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Haematocrit (HCT)	EDTA Whole Blood	Measured as a function of the numeric integration of FBC	0.1 to 75.0 L/L / Sysmex XN	CE	EMSPH021
	Mean Cell Haemoglobin Concentration (MCHC)		Calculated parameter	N/A / Sysmex XN	CE	EMSPH021
	Mean Cell Volume (MCV)		Calculated parameter	N/A / Sysmex XN	CE	EMSPH021
	Haemoglobin (Hb)		Sodium Lauryl Sulphate (SLS) Haemoglobin method	0.1g/dL to 26.0 g/dL / Sysmex XN	CE	EMSPH021
	Mean Cell Haemoglobin (MCH)		Calculated parameter	N/A / Sysmex XN	CE	EMSPH021
	Platelet Count (PLT)		Impedence technology	2 x 10 <sup>9</sup> /L to 5000 X10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Red Cell count (RBC)		Impedence technology	0.01 x 10 <sup>12</sup> /L to 8.6 X10 <sup>12</sup> /L / Sysmex XN	CE	EMSPH021
	Red Cell Distribution Width - CV%		Calculated parameter	Calculated parameter / Sysmex XN	CE	EMSPH021
	Red Cell Distribution Width - SD		Calculated parameter	Calculated parameter / Sysmex XN	CE	EMSPH021
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021

	Eosinophil Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Lymphocyte Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Monocyte Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Neutrophil Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	White Cell Count (WBC)		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Flourescence Flow Cytometry	1x 10 <sup>9</sup> /L to 720x 10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	(1-3)-beta-D-Glucan (BDG)	Serum	Associates of Cape Cod/EIA	CE	Qualitative	EMSPM061
	Aspergillus Galactomannan Antigen	Serum/Bronchoalveolar lavage (BAL)	Dynex Agility/Manual, Enzyme immunoassay (EIA)	CE	Qualitative	EMSPM065
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Altona RNA RealStar SARS-CoV-2 RT-PCR	Nose & throat swabs	Chemagic 360	CE Marked	Qualitative	EMSPM001
	Chlamydia trachomatis	Genital Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT)	CE	Qualitative	EMSPM006
	Chlamydia trachomatis/Neisseria gonorrhoeae Combo	Genital Swab/Pharyngeal Swab/Rectal Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT)	CE	Qualitative	EMSPM005
	Neisseria gonorrhoeae	Genital Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT)	CE	Qualitative	EMSPM007



	Pneumocystis jirovecii PCR	Bronchoalveolar lavage (BAL) and Non directed bronchoalveolar lavage (NBL)	Altona RealStar® PJP/PCR	CE	Qualitative	EMSPM064
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	Rapid Plasma Reagin Test (RPR)	Serum/Plasma/Capillary	Biorad/Manual	CE	Qualitative	EMSPM070
	Treponema Pallidum Haemagglutination (TPHA)	Serum/Plasma	Manual, Partial agglutination	CE	Qualitative	EMSPM071
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Hepatitis B Surface Antigen	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM016
	Hepatitis B Core Antibody		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM019
	Hepatitis B Surface Antibody		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	2.00 mIU/mL to 1000.00 mIU/mL	EMSPM018
	Hepatitis B Surface Antigen (Confirmatory)	Serum/Plasma	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM017
	Hepatitis C IgG Antibody	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM020

	Human Immunodeficiency Virus HIV Ag/Ab Combo		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM013
	Rubella IgG Antibody	Serum/Plasma	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	0.5 to 500.0 IU/mL	EMSPM047
	Syphilis TP	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM023