

Schedule of Accreditation



Organisation Name Saolta University Healthcare Group Letterkenny University Hospital
 Trading As
 INAB Reg No 210MT
 Contact Name Mary McDaid
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 Website
 Accreditation Standard ISO 15189
 Date Initially Awarded 09/12/2008
 Scope Classification Microbiology and virology
 Scope Classification Blood Transfusion Science
 Scope Classification Haematology

Services available to the public¹

¹ Refer to document on interpreting INAB Scopes of Accreditation

Name		Address
Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
1	Pathology Department	Blood Transfusion Department, Letterkenny University Hospital, Letterkenny, Donegal

Scope of Accreditation

Pathology Department

Blood Transfusion Science

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
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO & Rh (D) typing	Red Blood Cells and Plasma	Manual Tube Method Automated Gel Station Manual Gel System Automated BIO-RAD IH-1000			LP-BT-017 (Manual Tube Method) LP-BT-0014 (Automated Gel Station) LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO-RAD IH-1000)
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Automated Gel Station Manual Gel System Automated BIO-RAD IH-1000			LP-BT-0014 (Automated Gel Station) LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO-RAD IH-1000)
1020 Transfusion science - .04 Identification of blood group antibodies	Identification of Antibodies		Automated Gel Station Manual Gel System Automated BIO-RAD IH-1000			LP-BT-0014 (Automated Gel Station) LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO-RAD IH-1000)
1020 Transfusion science - .05 Cross match compatible donor units	Red Cell Compatibility Testing			Computer assisted compatibility testing (electronic issue)		
	Red Cell Compatibility Testing	Plasma	Manual Gel System			LP-BT-0015 (Manual Gel System)
1020 Transfusion science - .06 Red cell phenotyping	Phenotyping	Red Cells	Manual Gel System Automated Gel Station Automated BIO-RAD IH-1000			LP-BT-0015 (Manual Gel System) LP-BT-0014 (Automated Gel Station) LP-BT-0035 (BIO-RAD IH-1000)
1020 Transfusion science	Direct Coombs Test		Automated Gel Station			LP-BT-0014

- .99 Miscellaneous tests	(DCT)		Manual Gel System Automated BIO-RAD IH-1000		(Automated Gel Station) LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO-RAD IH-1000)
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a The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

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	Blood		Sysmex XN-9000	Calculation from Area of Curve	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Haemoglobin			Sysmex XN-9000	Spectrophotometric Analysis	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	MCH			Sysmex XN-9000	Calculation with RBC and HgB	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	MCHC			Sysmex XN-9000	Calculation with HCT and HgB	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Mean Cell Volume			Sysmex XN-9000	Calculation with RBC and HCT	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Platelet Count			Sysmex XN-9000	Aperture Impedance Counting	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Red Cell Count			Sysmex XN-9000	Aperture Impedance Counting	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	White Cell Count			Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000

					LP-HAEM-0053 Authorisation on the EPU
1030 Haematology - .02 Visual examination of blood films	Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils		Sysmex SP-10 Slide unit/ Manual Stain/ Microscope	Staining/ Microscopy	LP-HAEM-0054 Operation of the SP-10 Slide Preparation Unit LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides LP-HAEM-0001 Blood Film Preparation LP-HAEM-0003 Blood Film Examination and Manual Differential
	Red Cell Morphology		Sysmex SP-10 Slide unit/ Manual Stain/ Microscope	Staining/ Microscopy	LP-HAEM-0054 Operation of the SP-10 Slide Preparation Unit LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides LP-HAEM-0001 Blood Film Preparation LP-HAEM-0003 Blood Film Examination and Manual Differential
	White Cell Morphology		Sysmex SP-10 Slide unit/ Manual Stain/ Microscope	Staining/ Microscopy	LP-HAEM-0054 Operation of the SP-10 Slide Preparation Unit LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides LP-HAEM-0001 Blood Film Preparation LP-HAEM-0003 Blood Film Examination and Manual Differential

					Examination and Manual Differential
1030 Haematology - .03 Erthrocyte sedimentation rate	ESR (Automated)		Interliner ESR analyser		LP-HAEM-0056 Operataion of the Interliner ESR
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count		Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Eosinophil Count		Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Lymphocyte Count		Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Monocyte Count		Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Neutrophil Count		Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Analysis		Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
1030 Haematology - .09 Examination of malarial parasites	Binax NOW Screening Test, CARESTART Screening Test		Binax NOW Screening Test/ CARESTART Screening Test	Immuno-Qualitative Assay	LP-HAEM-0004 Identification of Malarial Parasites LP-HAEM-0014 Binax NOW Malaria
	Blood film examination		Microscope	Staining/ Microscopy	LP-HAEM-0004 Identification of Malarial Parasites LP-HAEM-0006 Manual

						Staining of Blood Films and Bone Marrow Slides
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen (Sickledex)			Kit	Qualitative Solubility Test	LP-HAEM-0011 Sickledex Screening Test
1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Kleihauer Test			Kit	Acid Elution/ Microscopy	LP-HAEM-0008 Kleihauer Test for detection of Foetal Hb
1030 Haematology - .40 Limited haemostasis related tests	Anti Factor 10a Assay	Plasma		Sysmex CS2500	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0025 Biophen Heparin Anti Xa Assay
	FIX			Sysmex CS2500	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0035 Intrinsic Factor Assay
	FVIII			Sysmex CS2500	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0035 Intrinsic Factor Assay
	FX			Sysmex CS2500	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0036 Extrinsic Factor Assay
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT)			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0058 Operation of the CS5100
	D-Dimer			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0058 Operation of the CS5100
	Fibrinogen (Clauss)			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0058 Operation of the CS5100
	International Normalised Ratio (INR)			Sysmex CS2500 Sysmex CS5100	Ratio Calculation	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0058 Operation of the CS5100
	Prothrombin Time (PT)			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0057 Operation

						of the CS2500 LP-HAEM-0058 Operation of the CS5100
	Thrombin Time			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0057 Operation of the CS2500 LP-HAEM-0058 Operation of the CS5100
1030 Haematology - .55 Iron studies	Urinary Haemosiderin	Urine			Staining	LP-HAEM-0016 Iron Stain LP-HAEM-0016 Urinary Haemosiderin
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screening	Plasma or serum			Qualitative detection of Heterophile antibodies	LP-HAEM-0042 Clearview IM

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
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Microscopic examination of General bacteriology	Swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CRE)	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells. Based on National Standard Methods, Health Protection Agency, UK		LP-MICRO-0009, LP-MICRO-0018, LP-MICRO-0010, LP-MICRO-0014, LP-MICRO-0012, LP-MICRO-0001, LP-MICRO-0002, LP-MICRO-0004, LP-MICRO-0007, LP-MICRO-0008, LP-MICRO-0019, LP-MICRO-0016, LP-MICRO-0022, LP-MICRO-0030, LP-MICRO-0006, LP-MICRO-0020, LP-MICRO-0066, LP-MICRO-0029, LP-MICRO-0036, LP-MICRO-0037
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of general bacteria		Culture Media	Culture, sensitivity testing as required		LP-MICRO-0009, LP-MICRO-0018, LP-MICRO-0010, LP-MICRO-0014, LP-MICRO-0012, LP-MICRO-0001, LP-MICRO-0002, LP-MICRO-0004,

						LP-MICRO-0007, LP-MICRO-0008, LP-MICRO-0019, LP-MICRO-0016, LP-MICRO-0022, LP-MICRO-0030, LP-MICRO-0006, LP-MICRO-0020, LP-MICRO-0066, LP-MICRO-0029, LP-MICRO-0036, LP-MICRO-0037
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immuno chromatographic methods,	Clostridium Difficile GDH and Toxin	Faeces	Kit	Immuno chromatographic.		LP-MICRO-0099
	Legionella Urine Antigen	Urine	Kit	Immuno chromatographic.		LP-MICRO-0062
	Rotavirus/ Adenovirus	Faeces	Kit	Immuno chromatographic.		LP-MICRO-0036
	RSV	Nasopharyngeal aspirate/sputum	Kit	Immuno chromatographic.		
	Urinary Pneumococcal antigens	Urine	Kit	Immuno chromatographic.		LP-MICRO-0063
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Clostridium Difficile Toxin	Faeces	Kit	NAAT		LP-MICRO-0099
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Commercial Biochemical Identification	Isolates from swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CRE)	Vitek 2	Vitek ID Cards		LP-MICRO-0038-44 LP-MICRO-0046, LP-MICRO-0048-58, LP-MICRO-0064-66, LP-MICRO-0068-70,

1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	ID using MALDI-TOF		MALDI-TOF	Mass Spectrophotometry		LP-MICRO-0038-44 LP-MICRO-0046, LP-MICRO-0048-58, LP-MICRO-0064-66, LP-MICRO-0068-70,
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Antifungal Susceptibility	Yeast isolates	Manual	Sensititre		MP-MICRO-0015
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Antibiotic Susceptibility	Isolates from Swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CRE)	Manual	MIC Strips		MP-MICRO-0015
			Vitek 2	Vitek Susceptibility Cards		EQ-Micro-0002, MP-MICRO-0015
			Zone Reader	Disc Diffusion		EQ-Micro-0015, MP-MICRO-0015
1024 Preservation of microbial cultures	Preservation of microbial cultures	Isolates	Frozen	Storage Beads		LP-MICRO-0026
1029 Miscellaneous - .01 Semen analysis (Screening Test)	Semen Analysis	Semen	Phase Microscopy	Manual		LP-MICRO-0031