

Schedule of Accreditation



Organisation Name	RCSI Hospital Group Our Lady's of Lourdes Hospital Drogheda
Trading As	
INAB Reg No	295MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	25/10/2011
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology
Services available to the public ¹	Yes

¹ 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	Our Lady of Lourdes Hospital	Pathology Laboratory, Drogheda, Louth, Ireland

Scope of Accreditation

Our Lady of Lourdes Hospital

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	Blood Grouping (ABO & RhD) Typing	4.5ml EDTA	Manual Cassette	Based on Standard Method	N/A	LP-BB-0004
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods		4.5ml EDTA/2.7ml/1.6ml/7.5 ml EDTA	Ortho Vision / Automated / Tube	Based on standard method	N/A	LP-BB-0004
1020 Transfusion science - .03 Blood group antibody screen	Blood Group Antibody screen	Plasma	Ortho Vision-Automated Ortho Biovue manual method	Based on Standard Method	N/A	LP-BB-0011
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated and Manual Column Agglutination Technique (Ortho BioVue)	Based on Standard Method	N/A	LP-BB-0014

1020 Transfusion science - .05 Cross match compatible donor units	Compatibility testing	Whole Blood 4.5ml EDTA	Serological (Manual & Automated) and Electronic Crossmatching	Based on standard method	n/a	LP-BB-0028
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping		Manual cassette / Automated / Tube	Based on standard method	N/A	LP-BB-0025
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test	Whole Blood 4.5 ml EDTA	Ortho Vision / Automated; Ortho Biovue Manual Cassette & Tube technique	Based on standard method	N/A	LP-BB-0019

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)

Haematology

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	White Blood Cell Count Red Blood Cell Count Haemoglobin (Hb) Mean Cell Volume (MCV) Mean Cell Volume Haemoglobin (MCH) Mean Cell Volume Haemoglobin Concentration (MCHC) Haemocrit (HCT) Platelets Nucleated Red Blood Cells (NRBCs)	Whole Blood	Automated Method using Sysmex XN-1000 and XN-3000 Full Blood Count Testing, Authorisation, Reporting of Results (Critical Values) and Criteria for Blood Films	Sysmex XN-1000 and XN-2000 The Linearity Limits for the Sysmex XN series are: WBC: 0 - 440 x10 ⁹ /L Hb: 0 - 260g/L HCT: 0 - 75% RBC: 0 - 12 x 10 ¹² /L PLT: 0 - 5000 x10 ⁹ /L NRBC: 0 - 20 x10 ⁹ /L RET: 0 - 30%	Based on Standard Method	LP-HAEM-0032 Operation and Maintenance of Sysmex XN-1000 and XN-3000 LP-HAEM-0005 Full Blood Count Testing, Authorisation, Reporting of Results (Critical Values) and Criteria for Blood Films LP-HAEM-0039 Validation and Release of FBC Results in EPU
1030 Haematology - .02 Visual examination of blood films	Visual Examination of Red Blood Cell, White Blood Cell and Platelet Morphology in Peripheral Blood and Bone Marrow Aspirates	Whole Blood and Bone Marrow Aspirates	Automated Preparation, staining and visual examination of blood films	Sysmex SP-10, WESCOR 7120 Aerospray Stainer, Micron BM3 Double Head Microscope, Nikon Eclipse 50i Microscope	Based on Standard Method	LP-HAEM-0006 Preparation, Staining and Examination of Blood Films and Bone Marrow Aspirates LP-HAEM-0007 Operation and Maintenance of the

						WESCOR 7120 Aerospray Stainer LP-HAEM-0008 Operation and Maintenance of the Nikon Eclipse 50i Microscope LP-HAEM-0035 Operation and Maintenance of the Sysmex SP-10 Automated Slide Preparation Unit LP-HAEM-0040 Operation and Maintenance of the Micron BM3 Double Head Microscope
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate	Whole Blood	Photometrical Capillary stopped flow kinetic analysis	Alifax Test 1 ESR Analyser Linear Range of Measurement is: 0 -120 mm/min	Based on Standard Method	LP-HAEM-0004 Operation and Maintenance of the Alifax Test 1 ESR Analyser
1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential Count on Neutrophils Lymphocytes Monocytes Eosinophils Basophils		Automated Method using Sysmex XN-1000 and XN-3000 Full Blood Count Testing, Authorisation, Reporting of Results (Critical Values) and Criteria for Blood Films	Sysmex XN-1000 and XN-3000 The Linearity Limits for the Sysmex XN series are: WBC: 0 - 440 x10 ⁹ /L	Based on Standard Method	LP-HAEM-0032 Operation and Maintenance of Sysmex XN-1000 and XN-3000 LP-HAEM-0005 Full Blood Count Testing, Authorisation, Reporting of Results (Critical Values) and Criteria for Blood Films LP-HAEM-0032 Validation and

					Release of FBC Results in EPU
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte Count	Automated Method using Sysmex XN-1000 and XN-3000 Full Blood Count Testing, Authorisation, Reporting of Results (Critical Values) and Criteria for Blood Films	Sysmex XN-1000 and XN-3000 The Linearity Limits for the Sysmex XN series are: RET: 0 - 30%	Based on Standard Method	LP-HAEM-0032 Operation and Maintenance of Sysmex XN-1000 and XN-3000 LP-HAEM-0005 Full Blood Count Testing, Authorisation, Reporting of Results (Critical Values) and Criteria for Blood Films LP-HAEM-0032 Validation and Release of FBC Results in EPU
1030 Haematology - .09 Examination of malarial parasites	Immunochromatographic test for qualitative detection of malarial antigens	Manual Serological Test (immunochromatographic test) for Malarial Antigens and Manual Blood Film Preparation, Staining and Morphological Examination	CareUs Malaria Test Kit and Malarial Parasitic Morphology by thick blood film (ProLab diagnostics staining) and thin blood film (Wescor staining). Range of Measurement is Positive for P. Falciparum, P. Ovale, P. Vivax, P. Malariae or P. Knowlesi and related parasitaemia	Based on Standard Method	LP-HAEM-0012 Serological Testing and Blood Film Staining and Examination for Malarial Parasites
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Manual Method for HbS Solubility Screening Kit	Sickledex (HbS) test uses the principle that Sodium Hydrosulphite present in the working solubility buffer reduces haemoglobin. Reduced HbS is insoluble in the buffer and forms a cloudy, turbid suspension.	HbS Solubility Screening Kit Range of Measurement is: Positive or Negative	Based on Standard Method	LP-HAEM-0013 Preparation of Reagent and Performance of Sickledex Test

1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Manual Method Guest Kit for Fetal Red Cell Detection Kit) of Film Preparation, Staining and examination for fetal red cells in maternal circulation		Acid elution test whereby fetal haemoglobin (HbF) is more resistant than adult haemoglobin (HbA) to both alkali denaturation and acid elution	Micron BM3 or Nikon Eclipse 50i Microscope Range of Measurement is an estimation of the number of fetal cells present using the formula: fetal cells/adult cells x 2400	Based on Standard Method	LP-HAEM-0014 Performance of a Kleihauer Test (Acid Elution Test)
1030 Haematology - .41 General haemostasis related tests	anti-Xa (Heparin) anti-Xa (Apixaban) anti-Xa (Rivaroxaban) Lupus Screen	Plasma	Automated Testing of Coagulation Testing, Authorisation and Reporting of Coagulation Results	ACL TOP 550 CTS The linearity limits for the ACL TOP 550 CTS are: anti-Xa Hep: -0.6 - 2.5 IU/mL anti-Xa Apix: - 15.0 - 1100 ng/mL anti- Xa Riv: -15.0 - 1100 ng/mL dRVVT Screen: 16 -240 secs dRVVT Confirm: 6.0 - 121 secs SCT Screen: 10 - 400 secs SCT Confirm: 10 - 400secs	Based on Standard Method	LP-HAEM-0041 Performance and Reporting of anti-Xa for Heparin, Apixaban and Rivaroxaban on ACL TOP 550 CTS LP-HAEM-0042 Performance and Reporting of Lupus Screen on ACL TOP 550 CTS
	D-Dimer	Trisodium Citrate 3.0ml (Adult), 1.4ml paediatric	Automated / ACL TOP 550 CTS	0.215-128 µg/mL	D-Dimer HS500 automated latex enhanced immunoassay for the quantitative determination of D- Dimer. Based on standard method.	LP-HAEM-0036
	Prothrombin Time Internation Normalised Ratio Activated Thromboplastin Time APTT/Ratio Fibrinogen Clotting Assay (Clauss Method) D-Dimer	Plasma	Automated Testing of Coagulation Testing, Authorisation and Reporting of Coagulation Results	ACL TOP 550 CTS The linearity limits for the ACL TOP 550 CTS are: PT: 8.0 - 320 secs APTT: 16.0 - 400 secs Fibrinogen: 0.35 - 10.0 g/L D-Dimer: 0.069 - 5.25 µg/mL	Based on Standard Method	LP-HAEM-0036 PT, APTT, Fibrinogen, derived Fibrinogen and D-Dimer QC and Patient Sample Analysis on ACL TOP 550 CTS LP-HAEM-0037 Maintenance and Troubleshooting of the ACL TOP 550 CTS LP-HAEM-0038

						Reagent Management and Calibration of ACL TOP 550 CTS LP-HAEM-0022 Coagulation Testing, Authorisation and Reporting of Coagulation Results (Critical Values)
1030 Haematology - .55 Iron studies	Iron Stain using Perl's Prussian Blue on a bone marrow aspirated film	Bone Marrow Aspirate	Manual Examination of Bone Marrow aspirate film for Iron using Perl's Prussian Blue Staining method	WESCOR 7120 Aerospray Stainer Micron BM3 Double Head Microscope, Nikon Eclipse 50i Microscope	Based on Standard Method	LP-HAEM-0006 Preparation, Staining and Examination of Blood Films and Bone Marrow Aspirates LP-HAEM-0007 Operation and Maintenance of the WESCOR 7120 Aerospray Stainer LP-HAEM-0008 Operation and Maintenance of the Nikon Eclipse 50i Microscope LP-HAEM-0040 Operation and Maintenance of Micron BM3 Double Head Microscope
1030 Haematology - .57 Screening test for infectious mononucleosis	Manual Method of Infectious mononucleosis	Plasma	Qualitative detection of IM-specific heterophile antibodies	Clearview IM II Test Kit Range of Measurement: Positive or Negative	Based on Standard Method	LP-HAEM-0009 Performing the Clearview IM II Test for Infectious Mononucleosis

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
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Cut Up Tissue Processing Embedding Microtomy Automated and Manual Staining Coverslipping	Formalin Fixed Tissue	Microtomes Embedding Centre Tissue-Tek Stainer Coverslipper TissueTek VIP 6 AI Processor Microwriter Waterbaths Microscopes G2 Dictation Cryoconsole	Based on Standard Method	Positive/Negative Controls	LP-HIST-0001,LP-HIST-0002,LP-HIST-0003,LP-HIST-0004,LP-HIST-0007,LP-HIST-0008,LP-HIST-0010,LP-HIST-0015,LP-HIST-0017,LP-HIST-0031,LP-HIST-0034,LP-HIST-0035,LP-HIST-0036,LP-HIST-0055,
1051 Histopathology - .03 Histochemistry	Alcian Blue (Manual), Alcian Blue-Periodic Acid Schiff, Congo Red (Manual), Gram-Twort (Manual), Gordon and Sweet, Grocotts Hexamine Silver, Haematoxylin and Eosin, Haematoxylin Van Gieson (Manual), Martius Scarlet Blue (Manual), Masson Fontana(Manual), Masson Trichrome, Millers Stain (Manual), Periodic Acid Schiff, Perls Prussian Blue,		Microtomes Embedding Centre Waterbaths Tissue-Tek Stainer Coverslipper Artisan	Based on Standard Method	Positive/Negative Controls	LP-HIST-0015; LP-HIST-0055

	Ziehls-Neilson (Manual) Papnicolaou, MGG Diastase Periodic Acid Schiff Warthin Starry, Toluidene Blue (Manual).					
1051 Histopathology - .04 Histological interpretation- medical renal pathology	Diagnostic Interpretation and reporting of Human tissue specimens Specialist areas excluded: - Medical Renal Pathology - Paediatric Pathology - Perinatal Pathology - Neuropathology - Breast screening Pathology (Breast Check designated laboratories only) Specialist areas included: Perinatal (confined to Placenta and products of conception)	Human Tissue	Microscope	N/A	Based on Standard Method	LMn-HIST-0001 LP-HIST-0012; LP- HIST-0005
1051 Histopathology - .05 Histological interpretation- paediatric pathology	Histological interpretation Paediatric interpretation		Ventana Benchmark XT Optiview Detection System	Based on Standard Method	Ventana Benchmark XT Optiview Detection System	LP-HIST-0022 LP-HIST-0024 LP-HIST-0049
1051 Histopathology - .09 Immunohistochemistry	CD23 CDX-2 Oestrogen Receptor (ER) P63 WT-1 BCL2 Calretinin	Formalin Fixed Specimens	Ventana Benchmark XT Optiview Detection System	Based on Standard Method	Positive/Negative Controls	LP-HIST-0022 LP-HIST-0024 LP-HIST-0049

	CA125 CD5 CD10 CD15 CD20 CD30 CD31 CD34 CD45 CD56 CD68 CD79a CD117 CD138 Chromogranin A Cyclin D1 Cytokeratin AE1/3 Cytokeratin CAM 5.2 Cytokeratin 5/6 Cytokeratin 7 Cytokeratin 20 Cytokeratin 34BE12 CEA					
CD3 Desmin EMA BerEP4 HMB45 Ki67 Mart1/Tyrosinase PSA P16 P53 Synaptophysin S100 TTF Vimentin	Formalin Fixed Tissue	Ventana Benchmark XT Optiview Detection System	Based on Standard Method	Positive/Negative Controls	LP-HIST-0022 LP-HIST-0024 LP-HIST-0050 LP-HIST-0049	
Moc-31	Formalin Fixed Specimens	Immunohistochemistry	Ventana Benchmark XT Optiview Detection System. Pos/Neg	Based on Standard Method. CE marked	LP-HIST-0022, LP-HIST-0024, LP-HIST-0049	

	Napsin-A	Formalin Fixed Tissue	Ventana Benchmark XT Optiview Detection Kit	Based on Standard Method	Positive/Negative	LP-HIST-0024
	Optiview Detection System			Detection of Antibodies Ventana Benchmark XT	Based on Standard Method	Positive/Negative Controls
1052 Cytopathology - .02 Non gynaecological cytology	Preparation of slides from cytology samples	Non Gynaecological Samples	Thin Prep 2000 Cytospin Centrifuge Tissue Tek Stainer Coverslipper Wescor TI20 Aerospray stainer	Based on Standard Method	Positive/Negative Controls	LP-HIST-0016 Cytology Sample Preparation LP-HIST-0038 Operation and Maintenance of the Thin Prep Machine Cytology Sample Preparation LM-HIST-0033 Serous Effusions LM-HIST-0034 Bronchial Lavage LM-HIST-0035 Sputum LM-HIST-0036 Fine Needle Aspiration LM-HIST-0037 Bronchial Brush LM-HIST-0038 Urine for Cytology LM-HIST-0039 CSF Sample Preparation LP-HAEM-0007

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
1011 Macroscopic examination and description	Healthcare Screening (MRSA, VRE, CPE)	Various Sample Types	Microscopy Vitek 2 Maldi ToF Manual AMS Culture Gene Xpert	Based on Standard Method	Isolated/Not Isolated	LP-MIC-0007 - Investigation of specimens for Infection Control Screening
	Identification and Susceptability Testing	Genital Tract Specimens	Microscopy Vitek 2 Maldi ToF Manual AMS Culture	Based on Standard Method	Isolated/Not Isolated	LP-MIC-0006 Investigation of Genital Tract and Associated Specimens
	Investigation of Cerebrospinal Fluid Specimens	Cerebrospinal Fluid	Microscopy Vitek 2 Maldi ToF Manual AMS Culture	Based on Standard Method	Isolated/Not Isolated	LP-MIC-0002 Investgation of Cerebrospinal Fluid (CSF) and CSF Shunts
	Investigation of Fluids	Various Fluid Types Bile	Microscopy Vitek 2 Maldi ToF Manual AMS Culture	Based on Standard Method	Isolated/Not Isolated	LP-MIC-0011 Investigation of Fluids and Bile from normally sterile sites, intravascular cannulae and associated specimens.
	Investigation of Urines	Urine Samples	Microscopy Vitek 2 Maldi ToF Manual AMS Culture	Based on Standard Method	Isolated/Not Isolated	LP-MIC-0003 Investigation of Urines

	Investigation of Wounds/Abscesses	Various Wound Sites	Microscopy Vitek 2 Maldi ToF Manual AMS Culture	Based on Standard Method	Isolated/Not Isolated	LP-MIC-0009 Investigation of Skin, Superficial and Non Surgical Wound Swabs LP-MIC-0010 Investigation of Abscesses and Deep Seated Wound Infections
	Legionella & Pneumococcal Antigen Testing	Urine Samples	Immunochromatographic	Based on Standard Method	Detected/Not Detected	LP-MIC-0019 Detection of Legionella and Pneumococcal Antigens