

Schedule of Accreditation



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Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	09/09/2008
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Chemical Pathology
Services available to the public ¹	No

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	Head Office	Pathology Department, University Hospital Kerry, Tralee, Kerry

Scope of Accreditation

Head Office

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 including ABO (Rh)D	Red Cells Plasma	Automated Grifols Erytra Eflexis system	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFOLS] Procedure for Grifols Analyser
			Manual Method Grifols	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFABO] Procedure for manual Grifols screen
1020 Transfusion science - .03 Blood group antibody screen	Blood Group antibody screen		Automated Grifols Erytra Eflexis system	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFOLS] Procedure for Grifols Analyser
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated Grifols Erytra Eflexis system	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFOLS] Procedure for Grifols Analyser
			Manual Method Grifols	CE based on	Refer to associated	[LP-BLO-GRIFMID]

				standard methods	procedure	Grifols Manual Antibody ID
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing		Automated Grifols Erytra Eflexis system	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFOLS] Procedure for Grifols Analyser
			Manual Method Grifols	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFMCOM] Procedure on Manual Compatibility Testing
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Cells	Automated Grifols Erytra Eflexis system	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFOLS] Procedure for Grifols Analyser
			Manual Method Grifols	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFMRHP] Procedure for Grifols Rh Phenotyping Manual Method
1020 Transfusion science - .99 Miscellaneous tests	Direct Coombs Test		Automated Grifols Erytra Eflexis system	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFOLS] Procedure for Grifols Analyser
			Manual Method Grifols	CE based on standard methods	Refer to associated procedure	[LP-BLO-GRIFMDCT] Grifols Manual Direct Coombs Test
	Kleihauer Testing		Manual Stain	Kleihauer Blake		LP-BLO-KLEIHOU
<i>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).</i>						

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	24 hour creatinine clearance	Urine	Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary amylase		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary calcium		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary chloride		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary creatinine		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary magnesium		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary phosphate		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary potassium		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary sodium		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	24 hour urinary urate		Calculation	Beckman Coulter	CE	LP-BIO-AU5812

			AU5812		
24 hour urinary urea		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Albumin	Serum	Colorimetric - BCG	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Alkaline Phosphatase		Enzymatic AMP optimised to IFCC	Beckman Coulter AU5812	CE	LP-BIO-AU5812
ALT		Enzymatic - IFCC without PSP	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Amylase	Serum and Urine	Enzymatic - blocked pNPG7	Beckman Coulter AU5812	CE	LP-BIO-AU5812
AST	Serum	Enzymatic - Tris buffer without PSP	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Bicarbonate		Enzymatic	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Bilirubin, Direct		Enzymatic - DCP Diazonium	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Bilirubin, Total		Colorimetric - DPD	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Calcium	Serum and Urine	Colorimetric - Arsenazo	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Chloride		Ion Specific Electrode - Indirect	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Cholesterol	Serum	Enzymatic - Cholesterol Oxidase	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Creatine Kinase		Colorimetric - CK- NAC (IFCC)	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Creatinine	Serum and Urine	Enzymatic - PAP	Beckman Coulter AU5812	CE	LP-BIO-AU5812
CSF-Glucose	CSF	Colorimetric - Hexokinase	Beckman Coulter AU5812	CE	LP-BIO-AU5812
GGT	Serum	Enzymatic	Beckman Coulter	CE	LP-BIO-AU5812

			AU5812			
Glucose (Fasting and Random)	Plasma and Urine	Enzymatic - Hexokinase	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
HDL Cholesterol	Serum	Enzymatic - Direct HDL	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Inorganic Phosphate	Serum and Urine	Colorimetric - Phosphomolybdate	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
LDH	Serum	Enzymatic - P to L Scandanavian & Dutch	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
LDL		Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Magnesium	Serum and Urine	Colorimetric - Xylidile Blue	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Microalbumin creatinine ratio	Urine	Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Potassium	Serum and Urine	Ion Specific Electrode - Indirect	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Sodium		Ion Specific Electrode - Indirect	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Total protein		Colorimetric - Biuret	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Triglyceride Total	Serum	Enzymatic - Lipase GK UV no correction	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Urea	Serum and Urine	Enzymatic - Urease	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Uric Acid		Enzymatic - Uricase Perox with ascorb. Ox.	Beckman Coulter AU5812	CE	LP-BIO-AU5812	
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	24 hour urinary total protein	Urine	Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812

1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Anti Thyroid Peroxidase Ab's	Serum	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	CRP		Immunoturbidimetric	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	CSF-Total Protein	CSF and Urine	Colorimetric - Pyrogallol Red	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Ferritin	Serum	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	hs Troponin I		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Microalbumin	Urine	Turbidimetric measure of Albumin	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	NT proBNP	Serum	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Protein creatinine ratio	Urine	Calculation	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Rheumatoid Factor	Serum	Immunoturbidimetric - Non IFCC	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Carbamazepine		Enzymatic EMIT	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Digoxin		Enzymatic EMIT	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Gentamycin		Enzymatic EMIT	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Lithium		Colorimetric	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Paracetamol		Enzymatic - Emit Tox Assay	Beckman Coulter AU5812	CE	LP-BIO-AU5812
Valproic Acid	Enzymatic EMIT		Beckman Coulter AU5812	CE	LP-BIO-AU5812	
Vancomycin	Enzymatic EMIT		Beckman Coulter AU5812	CE	LP-BIO-AU5812	

1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Alcohol		Enzymatic - Dri ethyl alcohol	Beckman Coulter AU5812	CE	LP-BIO-AU5812
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Salicylate		Enzymatic - Emit Tox Assay	Beckman Coulter AU5812	CE	LP-BIO-AU5812
1061 Clinical Chemistry - .20 Hormones	Cortisol		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Follicle stimulating hormone (FSH)		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Free T3		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Free T4		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Luteinizing hormone (LH)		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Oestradiol		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Parathyroid Hormone (PTH)	EDTA Plasma	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Progesterone	Serum	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Prolactin		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Testosterone		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
Thyroid stimulating hormone (TSH)		CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000	
1061 Clinical Chemistry - .40 Iron studies	Iron		Colorimetric without ppt	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	Transferrin		Immunoturbidimetric	Beckman Coulter AU5812	CE	LP-BIO-AU5812

1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alphafeta protein (AFP)	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	beta-HCG	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	CA125	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	CA15-3	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	CA19-9	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	Carcinoembryonic Antigen (CEA)	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
	PSA (Total)	CMIA	Beckman Coulter DXI9000	CE	LP-BIO-DXI9000
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	IgA	Immunoturbidimetric	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	IgG	Immunoturbidimetric	Beckman Coulter AU5812	CE	LP-BIO-AU5812
	IgM	Immunoturbidimetric	Beckman Coulter AU5812	CE	LP-BIO-AU5812

Head Office

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	Full Blood Counts	EDTA Whole Blood	Automated Sysmex	XN Series	CE	LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER
			Optimal flow cytometry	XN Series	CE	LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER
1030 Haematology - .02 Visual examination of blood films	Visual Examination of Blood Film		Automated Sysmex	SP-50 stainer	CE	LP-HAEM-SP50, LP-HAEM-BLDFLM
			Staining microscopy	SP-50 Stainer	CE	LP-HAEM-SP50, LP-HAEM-BLDFILM
1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential		Automated Sysmex	XN Series	CE	LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER
			Fluorescence Flow cytometry	XN Series	CE	LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER

1030 Haematology - .06 Automated reticulocyte counts	Automated reticulocyte count		Automated Sysmex	XN Series	CE	LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER
			Fluorescence Flow cytometry	XN Series	CE	LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER
1030 Haematology - .09 Examination of malarial parasites	Examination of malarial parasites		Manual Method & Automated	SP-50 stainer, Field Stain Microscopy	CE	LP-HAEM-MALARIA, LP-HAEM-SP50,
			Staining microscopy	SP-50 Stainer, field stain	CE	LP-HAEM-SP50, LP-HAEM-MALARIA
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Cell Screening		Manual Method	Clintech Kit	CE	LP-HAEM-SICKLE
1030 Haematology - .41 General haemostasis related tests	Activated Partial Prothrombin Time (A.P.T.T.)	Sodium Citrate Plasma	Automated and Semi Automated	CN Series, KC4	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL, LP-HAEM-OPERKC4
			Coagulation	CN Series	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL
	D-Dimer		Automated and Semi Automated	CN Series	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL
			Turbidity	CN Series	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL

	Fibrinogen		Automated and Semi Automated	CN Series, KC4	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL, LP-HAEM-OPERKC4
			Coagulation	CN Series	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL
	International Normalised Ratio (INR)		Calculation	CN Series Calculated from PT	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL
	Prothrombin Time (P.T.)		Coagulation	CN Series	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL
	Prothrombin Time (P.T.)/INR		Automated and Semi Automated	CN Series and KC4	CE	LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL, LP-HAEM-OPERKC4
1030 Haematology - .57 Screening test for infectious mononucleosis	Screening test for infectious mononucleosis	Serum or Sodium Citrate Plasma or EDTA Whole Blood	Manual Method	Clear View IM II	CE	LP-HAEM-IMSCREN