

Schedule of Accreditation



Organisation Name	Beaumont Hospital
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	07/04/2009
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Immunology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Scope Classification	Genetics
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	Head Office	Clinical Directorate of Laboratory Medicine, Beaumont, Dublin, D9

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 (ABO Rh (d) Typing)	Red Blood cells and Plasma	Manual/Gel Cards	CE Marked	N/A	BTD-P-004
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Automated/IH-1000	CE Marked	N/A	BTD-P-004
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen	Plasma	Automated/IH-1000	CE Marked	N/A	BTD-P-004
			Manual/Gel Cards	CE Marked	N/A	BTD-P-004
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated/IH-1000	CE Marked	N/A	BTD-P-007
			Manual/Gel Cards	CE Marked	N/A	BTD-P-007
1020 Transfusion science - .05 Cross match	Compatibility Testing		IAT Crossmatch Manual	CE Marked	N/A	BTD-P-073 BTD-P-011

compatible donor units						
	Compatibility Testing Automated/ plasma		IAT Crossmatch /Automated (IH1000) and Electronic Crossmatch	CE Marked	N/A	BTD-P-073
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping	Red Blood Cells	Automated (IH-1000)	CE Marked	N/A	BTD-P-008
			Manual/Gel Cards/Manual Tube	CE Marked	N/A	BTD-P-008
1020 Transfusion science - .08 Antibody titration	ABO Antibody Titre	Plasma	Manual/Gel Cards	CE Marked	N/A	BTD-P-014
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Testing	Red Blood Cells	Automated (IH-1000)	CE Marked	N/A	BTD-P-008
			Manual/Gel Cards	CE Marked	N/A	BTD-P-008

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). It also provides Haemovigilance and Traceability services to another site, further details available in the SLA between the accredited medical testing laboratory and the relevant site.

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 Amino Transferase (ALT)	Serum/Li-Hep plasma	IFCC without Pyridoxal Phosphate	Cobas 702/ 5 IU/L to 7000 IU/L	CE Marked	CP-LP-0146
	Albumin Creatinine Ratio	Urine	Calculation	LIS Interface	Based on Standard Method	CP-LP-0160
	Alkaline Phosphatase (ALP)	Serum/Li-Hep plasma	Colorimetric	Cobas 702/ 5 IU/L to 6000 IU/L	CE Marked	CP-LP-0146
	Amylase	Serum/Li-Hep plasma/Urine	Enzymatic/Colorimetric	Cobas 702/ 3 IU/L to 7,500 IU/L	CE Marked	CP-LP-0146
	Aspartate Aminotransferase (AST)	Serum/Li-Hep plasma	IFCC without Pyridoxal Phosphate	Cobas 702/ 5 IU/L to 7000 IU/L	CE Marked	CP-LP-0146
	Bicarbonate		Enzymatic with PEP	Cobas 702/ 2 umol/L to 50 umol/L	CE Marked	CP-LP-0146
	Bilirubin Direct		Diazo method	Cobas 702/ 3 umol/L to 582 umol/L	CE Marked	CP-LP-0146
	Bilirubin Total		Colorimetric	Cobas 702 / 3 umol/L to 1,303.5 umol/L	CE Marked	CP-LP-0146
	Bilirubin Unconjugated		Calculation	LIS Interface	Based on Standard Method	CP-LP-0160
	C Reactive Protein (CRP)		Immunoturbidimetric	Cobas 702/ 1 mg/L to 700 mg/L	CE Marked	CP-LP-0146
	Calcium		NM-BAPTA	Cobas 702/ 0.2 mmol/L to 5 mmol/L	CE Marked	CP-LP-0146
	Calcium Adjusted		Calculation	LIS Interface	In House Developed	CP-LP-0160

Calcium Creatinine Ratio	Urine	Calculation	Manual Calculation	Based on Standard Method	CP-LP-0160	
Calcium Fractional Excretion	Serum/Li-Hep plasma/Urine	Calculation	Manual Calculation	Based on Standard Method	CP-LP-0160	
Calcium Urine	Urine	NM-BAPTA	Cobas 702/ 0.2 mmol/L to 37.5 mmol/L	CE Marked	CP-LP-0146	
Chloride	Serum/Li-Hep plasma/Urine	Ion Selective Electrode (Indirect)	Cobas 702/ 6 mmol/L to 140 mmol/L	CE Marked	CP-LP-0146	
Cholesterol	Serum/Li-Hep plasma	Enzymatic Colorimetric	Cobas 702/ 0.3 mmol/L to 207 mmol/L	CE Marked	CP-LP-0146	
Creatine Kinase (CK)		IFCC UV-test	Cobas 702/ 7 IU/L to 22,000 IU/L	CE Marked	CP-LP-0146	
Creatinine			Enzymatic Colorimetric	Cobas 702/ 5 umol/L to 10,800 umol/L	CE Marked	CP-LP-0146
	Urine	Enzymatic Colorimetric	Cobas 702/ 100 umol/L to 54,000 umol/L	CE Marked	CP-LP-0146	
Creatinine Clearance	Serum/Li-Hep plasma/Urine	Calculation	LIS Interface	Based on Standard Method	CP-LP-0160	
Gamma Glutamyl Transferase (GGT)	Serum/Li-Hep plasma	Enzymatic Colorimetric	Cobas 702 / 3 U/L to 13,200 U/L	CE Marked	CP-LP-0146	
Globulin		Calculation	LIS Interface	Based on Standard Method	CP-LP-0160	
Glucose	Fluoroxalate plasma/Serum/Li-Hep plasma/CSF	Enzymatic reference method with Hexokinase	Cobas 702/ 0.1 mmol/L to 83.2 mmol/L	CE Marked	CP-LP-0146	
High Density Lipoprotein (HDL)	Serum/Li-Hep plasma	Enzymatic	Cobas 702/ 0.08 mmol/L to 6.24 mmol/L	CE Marked	CP-LP-0146	
Lactate Dehydrogenase (LDH)		UV Assay	Cobas 702 / 10 U/L to 1,800 U/L	CE Marked	CP-LP-0146	
Low Density Lipoprotein (LDL)		Calculation	LIS Interface	Based on Standard Method	CP-LP-0160	
Magnesium			Colorimetric	Cobas 702/ 0.1 mmol/L to 4 mmol/L	CE Marked	CP-LP-0146
		Urine	Colorimetric	Cobas 702/ 0.56 mmol/L to 22.0 mmol/L	CE Marked	CP-LP-0146
Non HDL cholesterol	Serum/Li-Hep plasma	Calculation	LIS Interface	Based on Standard Method	CP-LP-0160	

	N-Terminal Pro B-Type Natriuretic Peptide (NT-Pro-BNP)		Immunoassay (Sandwich)	Cobas 801/ 50 pg/mL to 35,000 pg/mL	CE Marked	CP-LP-0146
	Osmolality	Serum/Plasma/Urine	Freezing Point Depression	A20 / 0 mOsm/kg to 3,000 mOsm/kg	CE marked	CP-LP-0156
	Phosphate	Serum/Li-Hep plasma	Molybdate UV	Cobas 702/ 0.1 mmol/L to 12.92 mmol/L	CE Marked	CP-LP-0146
		Urine	Molybdate UV	Cobas 702/ 1.1 mmol/L to 184 mmol/L	CE Marked	CP-LP-0146
	Potassium	Serum/Li-Hep plasma/Urine	Ion Selective Electrode (Indirect)	Cobas 702 / 1.5 mmol/L to 10mmol/L	CE Marked	CP-LP-0146
	Sodium		Ion Selective Electrode (Indirect)	Cobas 702 6 mmol/L to 140 mmol/L	CE Marked	CP-LP-0146
	Sodium Fractional Excretion		Calculation	Manual Calculation	Based on Standard Method	CP-LP-0160
	Triglycerides	Serum/Li-Hep plasma	Enzymatic Colorimetric	Cobas 702/ 0.1 mmol/L to 50 mmol/L	CE Marked	CP-LP-0146
	Urea		Urease	Cobas 702 / 0.5 mmol/L to 120 mmol/L	CE Marked	CP-LP-0146
			Urine	Urease	Cobas 702/ 1 mmol/24 hrs to 3,600 mmol/24 hrs	CE Marked
	Uric Acid	Serum/Li-Hep plasma	Enzymatic Colorimetric	Cobas 702/ 11.9 mmol/L to 3,718 mmol/L	CE Marked	CP-LP-0146
		Urine	Enzymatic Colorimetric	Cobas 702/ 0.13 mmol/24hrs to 40.9 mmol/24hrs	CE Marked	CP-LP-0146
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin	Serum/Li-Hep plasma	Colorimetric (BCG)	Cobas 702 / 8 g/L to 180 g/L	CE Marked	CP-LP-0146
		Urine	Immunoturbidimetric	Cobas 702/ 3 mg/L to 4,400 mg/L	CE Marked	CP-LP-0146
	Alpha 1 Antitrypsin	Serum/Li-Hep plasma	Turbidimetric Method	Cobas 702 / 0.2 g/L to 12 g/L	CE Marked	CP-LP-0146
	B2 Microglobulin		Immunoturbidimetric	Cobas 702/ 0.1 mg/L to 88 mg/L	CE Marked	CP-LP-0146
	Caeruloplasmin		Turbidimetry	Cobas 702/ 0.03 g/L to 4.2g/L	CE Marked	CP-LP-0146

	Cystatin C	Serum	Turbidimetric	Cobas 702/ 0.40 mg/L to 10.2 mg/L	CE Marked	CP-LP-0146
	Protein Creatinine Ratio	Urine	Calculation	LIS Interface	Based on Standard Method	CP-LP-0160
	Protein Total	CSF	Turbidimetric Method	Cobas 702 4 mg/dL to 600 mg/dL	CE Marked	CP-LP-0146
		Serum/Li-Hep plasma	Colorimetric	Cobas 702/ 2 g/L to 360 g/L	CE Marked	CP-LP-0146
		Urine	Turbidimetric Method	Cobas 702 / 0.04 g/24hr to 6 g/24hr	CE Marked	CP-LP-0146
	Transferrin	Serum/Li-Hep plasma	Immunoturbidimetric	Cobas 702/ 10 mg/dL to 780 mg/dL	CE Marked	CP-LP-0146
	Transferrin Saturation		Calculation	LIS Interface	Based on Standard Method	CP-LP-0160
	Troponin T (hs)	Li-Hep plasma	Immunoassay (Sandwich)	Cobas 801/ 13 ng/L to 100,000ng/L	CE Marked	CP-LP-0146
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Acetaminophen (Paracetamol)	Serum	Enzymatic	Cobas 702/ 5 mg/L to 1,500 mg/L	CE Marked	CP-LP-0146
	Carbamazepine		KIMS	Cobas 702/ 2 mg/L to 40 mg/L	CE Marked	CP-LP-0146
	Cyclosporin A	EDTA Whole Blood	LC-MS-MS	Aquity TQD 25 ng/mL to 1,200 ng/mL	In House Developed	CP-LP-0052
	Digoxin	Serum	Immunoassay (Electrochemiluminescence)	Cobas 802/ 0.4 ug/L to 10ug/L	CE Marked	CP-LP-0146
	Gentamicin		KIMS	Cobas 702/ 0.3 ug/mL to 10 ug/mL	CE Marked	CP-LP-0146
	Lithium		Colorimetric	Cobas 702 0.05 mmol/L to 6 mmol/L	CE Marked	CP-LP-0146
	Phenobarbitol		KIMS	Cobas 702/ mg/L to 120 mg/L	CE Marked	CP-LP-0146
	Phenytoin		KIMS	Cobas 702/ mg/L to 80 mg/L	CE Marked	CP-LP-0146
	Salicylate		Enzymatic	Cobas 702/ 10 mg/L to 1,400 mg/L	CE Marked	CP-LP-0146
	Tacrolimus		EDTA Whole Blood	LC-MS-MS	Aquity TQD / 1 ng/mL to 30 ng/mL	CE Marked
Theophylline	Serum	KIMS	Cobas 702/ 0.8 mg/L to 80 mg/L	CE Marked	CP-LP-0146	

	Valproic Acid		Homogeneous Enzyme Immunoassay Technique	Cobas 702/ mg/L to 150mg/L	3	CE Marked	CP-LP-0146
	Vancomycin		KIMS	Cobas 702 / 4 ug/mL to 80 ug/mL		CE Marked	CP-LP-0146
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol	Fluoroxalate plasma	Enzymatic Method with Alcohol Dehydrogenase	Cobas 702 / 10 mg/dL to 498 mg/dL		CE Marked	CP-LP-0146
1061 Clinical Chemistry - .20 Hormones	Adrenocorticotrophic Hormone (ACTH)	EDTA Plasma	Immunoassay (Sandwich)	Cobas 801/ 3.0 pg/mL to 2000 pg/mL		CE Marked	CP-LP-0146
	Aldosterone		Immunoassay (Chemiluminescence)	IDS ISYS / 138 pmol/mL to 3656 pmol/mL		CE Marked	CP-LP-0132
	Cortisol	Serum/Li-Hep plasma	Immunoassay (Competitive)	Cobas 802 3-17,500 nmol/L		CE Marked	CP-LP-0146
	C-Peptide	Serum	Immunoassay (Sandwich)	Cobas 801 / 0.05 nmol/L to 133.0 nmol/L		CE Marked	CP-LP-0146
	Dehydroepiandrosterone Sulfate (DHEAS)		Immunoassay (Competitive)	Cobas 802/ 0.081 umol/L to 135.5 umol/L		CE Marked	CP-LP-0146
	Estradiol	Serum/Li-Hep plasma	Immunoassay (Competitive)	Cobas 801 / 92 pmol/L to 110,100 pmol/L		CE Marked	CP-LP-0146
	Follicle Stimulating Hormone (FSH)		Immunoassay (Sandwich)	Cobas 801/ 1 IU/L to 200 IU/L		CE Marked	CP-LP-0146
	Growth Hormone (GH)	Serum	Immunoassay	IDS ISYS/ 0.05 ng/mL to 100 ng/mL		CE Marked	CP-LP-0103
	Human Chorionic Gonadotropin (hCG)	Serum/Li-Hep plasma	Immunoassay (Sandwich)	Cobas 801/ 0.3 IU/L to 1,000,000 IU/L		CE Marked	CP-LP-0146
	Insulin	Serum	Immunoassay (Sandwich)	Cobas 802/ 1 mU/L to 1,000 mU/L		CE Marked	CP-LP-0146
	Insulin Like Growth Factor 1 (IGF1)		Immunoassay	IDS ISYS/ 10 ng/mL to 1,200 ng/mL		CE Marked	CP-LP-0103
	Leutinising Hormone (LH)	Serum/Li-Hep plasma	Immunoassay (Sandwich)	Cobas 801/ 1 U/L to 200 U/L		CE Marked	CP-LP-0146
	Parathyroid Hormone (PTH)	EDTA Plasma	Immunoassay (Sandwich)	Cobas 801/ 6 pg/mL to 5,000 pg/mL		CE Marked	CP-LP-0146
	Progesterone	Serum/Li-Hep plasma	Immunoassay (Competitive)	Cobas 801/ 1 nmol/L to 1,910nmol/L		CE Marked	CP-LP-0146
Prolactin Bioactive	Immunoassay (Sandwich)		Cobas 801/ 20 mIU/ml to 100000mIU/ml		CE Marked	CP-LP-0159	

	Prolactin Total		Immunoassay (Sandwich)	Cobas 801 / 20 mIU/ml to 100000mIU/ml	CE Marked	CP-LP-0146
	Renin Direct	EDTA Plasma	Immunoassay (Chemiluminescence)	IDS ISYS / 5 mIU/L to 550 mIU/L	CE Marked	CP-LP-0132
	Sex Hormone Binding Globulin (SHBG)	Serum	Immunoassay (Sandwich)	Cobas 801/ 2 nmol/L to 200 nmol/L	CE Marked	CP-LP-0146
	T3 Free	Serum/Li-Hep plasma	Immunoassay (Competitive)	Cobas 801/ 2.0 pmol/L to 50.0 pmol/L	CE Marked	CP-LP-0146
	T4 Free		Immunoassay (Competitive)	Cobas 801/ 1.3 pmol/L to 100 pmol/L	CE Marked	CP-LP-0146
	T4 Total		Immunoassay (Competitive)	Cobas 801 / 15 nmol/L to 320 nmol/L	CE Marked	CP-LP-0146
	Testosterone	Serum	Immunoassay (Competitive)	Cobas 801/ 0.4 nmol/L to 52.0 nmol/L	CE Marked	CP-LP-0146
	Thyroid Stimulating Hormone (TSH)	Serum/Li-Hep plasma	Immunoassay (Sandwich)	Cobas 801/ 0.01 mU/L to 1,000mU/L	CE Marked	CP-LP-0146
1061 Clinical Chemistry - .40 Iron studies	Ferritin		Immunoassay (Sandwich)	Cobas 801/ 2 ng/ml to 100,000ng/ml	CE Marked	CP-LP-0146
	Iron		Colorimetric	Cobas 702/ 0.9 umol/L to 375.9 umol/L	CE Marked	CP-LP-0146
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate		Immunoassay (Competitive)	Cobas 801/ 2 ug/L to 40ug/L	CE Marked	CP-LP-0146
	Vitamin B12		Immunoassay (Competitive)	Cobas 801/ 150 ng/L to 4000 ng/L	CE Marked	CP-LP-0146
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D	Serum	LC-MS-MS	AB Sciex 4500 / 10 nmol/L to 600 nmol/L	CE Marked	CP-LP-0149
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein (AFP)	Serum/Li-Hep plasma	Immunoassay (Sandwich)	Cobas 801/ 2.7 KU/L to 60,050 KU/L	CE Marked	CP-LP-0146
	Cancer Antigen 125 (CA125)		Immunoassay (Sandwich)	Cobas 801/ 2 KU/L to 25,000 KU/L	CE Marked	CP-LP-0146
	Cancer Antigen 15-3 (CA15.3)		Immunoassay (Sandwich)	Cobas 801 / 3 KU/L to 3,000 KU/L	CE Marked	CP-LP-0146
	Carbohydrate Antigen 19-9 (CA19.9)		Immunoassay (Sandwich)	Cobas 801 / 9 KU/L to 10,000 KU/L	CE Marked	CP-LP-0146
	Carcinoembryonic Antigen (CEA)		Immunoassay (Sandwich)	Cobas 801/ 1.8 ng/mL to 50,000 ng/mL	CE Marked	CP-LP-0146
	Total Prostate Specific		Immunoassay (Sandwich)	Cobas 801/ 0.03	CE Marked	CP-LP-0146

	Antigen (Total PSA)			ug/L to 5,000 ug/L		
1061 Clinical Chemistry - .56 Biogenic amines	4-Hydroxy 3-Methoxymandelic Acid (HMMA)	Urine	LC-MS-MS	AB Sciex 5500/ 1.5 umol/L to 757 umol/L (>757 manual dilution)	CE Marked	CP-LP-0136
	4-Hydroxy-3-Methoxyphenylacetic Acid (HVA)		LC-MS-MS	AB Sciex 5500/ 1.0 umol/L to 1,372 umol/L (>1,372 manual dilution)	CE Marked	CP-LP-0136
	5 Hydroxyindole Acetic Acid (5HIAA)		LC-MS-MS	AB Sciex 5500/ 2.6 umol/L to 785 umol/L (>785 manual dilution)	CE Marked	CP-LP-0136
	Adrenaline		LC-MS-MS	AB Sciex 5500/ 0.005 umol/L to 10 umol/L (>10 manual dilution)	In House Developed	CP-LP-0120
	Dopamine		LC-MS-MS	AB Sciex 5500/ 0.005 umol/L to 4.5 umol/L (>4.5 manual dilution)	In House Developed	CP-LP-0120
	Metanephrine	EDTA Plasma	LC-MS-MS	AB Sciex 5500 / 100 pmol/L to 28646 pmol/L	CE Marked	CP-LP-0129
		Urine	LC-MS-MS	AB Sciex 5500/ 0.005 umol/L to 50 umol/L (>50 manual dilution)	In House Developed	CP-LP-0120
		Metanephrine Free	LC-MS-MS	AB Sciex 5500/ 0.005 umol/L to 10 umol/L (>10 manual dilution)	In House Developed	CP-LP-0120
	Methoxytyramine	EDTA Plasma	LC-MS-MS	AB Sciex 5500/ 100 pmol/L to 34686 pmol/L	CE Marked	CP-LP-0129
	Noradrenaline	Urine	LC-MS-MS	AB Sciex 5500 / 0.005 umol/L to 10 umol/L (>10 manual dilution)	In House Developed	CP-LP-0120
	Normetanephrine	EDTA Plasma	LC-MS-MS	AB Sciex 5500/ 100 pmol/L to 46397 pmol/L	CE Marked	CP-LP-0129
		Urine	LC-MS-MS	AB Sciex 5500/ 0.005 umol/L to 50	In House Developed	CP-LP-0120

				umol/L (>50 manual dilution)		
	Normetanephrine Free		LC-MS-MS	AB Sciex 5500/ 0.005 umol/L to 10 umol/L (>10 manual dilution)	In House Developed	CP-LP-0120
1061 Clinical Chemistry - .60 Glycohaemoglobins	Haemoglobin A1c (HbA1c)	EDTA Whole Blood	HPLC	H8180/ 0 mmol/M to 151 mmol/M	CE Marked	CP-LP-0130
1061 Clinical Chemistry - .81 Qualitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin A (IgA)	Serum	Immunoturbidimetric	Cobas 702/ 0.5 g/L to 64 g/L	CE Marked	CP-LP-0146
	Immunoglobulin G (IgG)		Immunoturbidimetric	Cobas 702/ 3 g/L to 275 g/L	CE Marked	CP-LP-0146
	Immunoglobulin M (IgM)		Immunoturbidimetric	Cobas 702/ 0.25 g/L to 58.5 g/L	CE Marked	CP-LP-0146
1061 Clinical Chemistry - .99 Miscellaneous tests	Angiotension Converting Enzyme (ACE)		Enzymatic	Cobas 702 / 5 IU/L to 166 IU/L	CE Marked	CP-LP-0146
	Electrophoresis		Capillary Zone Electrophoresis	Sebia CAP 3	CE Marked	CP-LP-0147
	Human Chorionic Gonadotropin (hCG)	Urine	Manual/Rapid Immunochromatographic Assay	Alere HCG/ N/A	CE Marked	LP-MIC-Urines
	Immunofixation	Serum	Agarose Gel	Sebia Hydrasys 2 Scan	CE Marked	CP-LP-0061
	Xanthochromia	CSF	Spectrophotometry	Spectrophotometer Libra S32PC	In House Developed	CP-LP-0063

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1075 Molecular genetics - .05 Screening for unidentified pathogenic variant(s)	JAK2 V617F	EDTA Whole Blood	Real-Time PCR	0 to 100% /ABI 7500	In house developed	HAEMC-LP-057
1075 Molecular genetics - .06 Assay for identified pathogenic variant(s)	Factor V Leiden		Real-Time PCR	Roche Cobas z480	CE Marked	HAEMP-LP-001
	HFE		Real-Time PCR	Roche Lightcycler 480 II	CE Marked	MOL-LP-027
	Prothrombin G20210A mutation		Real-Time PCR	Roche Cobas z480	CE Marked	HAEMP-LP-001
			Real-Time PCR	Roche COBAS z480	CE Marked	HAEMP-LP-001
1075 Molecular genetics - .11 DNA extraction	Factor V Leiden		DNA Isolation	Magnapure 24	CE Marked	HAEMC-LP-071
	HFE		DNA Isolation	Magnapure 24	CE Marked	HAEMC-LP-071
	JAK2 V617F		DNA Isolation	Magnapure 24	CE Marked	HAEMC-LP-071
	Prothrombin G20210A mutation		DNA Isolation	Magnapure 24	CE Marked	HAEMC-LP-071
1075 Molecular genetics - .99 Miscellaneous tests	Detection of PrPsc By Western Blotting in Query CJD Cases		Human Tissue or Fluid	Western blotting	Electrophoresis equipment	Non-CE/Based on standard method

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	Haematocrit	EDTA Whole Blood	Measured as a function of the numeric integration of FBC	0.1% to 75.0% Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
	Haemoglobin		Sodium Lauryl Sulphate (SLS) Haemoglobin Method	0.1g/dL to 26.0g/dL Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
	Mean Cell Haemoglobin		Calculated Parameter	N/A Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
	Mean Cell Haemoglobin Concentration		Calculated Parameter	N/A Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
	Mean Cell Volume		Calculated Parameter	N/A Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
	NRBC		Fluorescence Flow Cytometry	0.03 x 10 ⁹ /l to 20 x 10 ⁹ /l /Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
	Platelet Count		Impedance Technology	2 x 10 ⁹ /l to 5000 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064 HAEMG-LP-014
	Red Cell Count		Impedance Technology	0.01 x 10 ⁹ /l to 8.6 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050, HAEMG-LP-064
1030 Haematology - .02 Visual examination of blood films	Basophils		Staining/Microscopy	N/A Sysmex sp50	CE Marked	HAEMG-LP-009 , HAEMG-LP-068
	Eosinophils		Staining/Microscopy	N/A Sysmex sp50	CE Marked	HAEMG-LP-009 , HAEMG-LP-068
	Lymphocytes		Staining/Microscopy	N/A Sysmex sp50	CE Marked	HAEMG-LP-009 , HAEMG-LP-068
	Monocytes		Staining/Microscopy	N/A	CE Marked	HAEMG-LP-009 ,

				Sysmex sp50		HAEMG-LP-068
	Neutrophils		Staining/Microscopy	N/A Sysmex sp50	CE Marked	HAEMG-LP-009 , HAEMG-LP-068
	Red cell morphology		Staining/Microscopy	N/A Sysmex sp50	CE Marked	HAEMG-LP-009 , HAEMG-LP-068
	White cell precursor morphology		Staining/Microscopy	N/A Sysmex sp50	CE Marked	HAEMG-LP-009 , HAEMG-LP-068
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR (automated ESR instrument)	Citrated Whole Blood	Sedimentation of RBC's	Measuring range: 0mm to 70 mm, equating to a sedimentation value range of 0mm to 147 mm Sarstedt Desaga S2000	CE Marked	HAEMG-LP-013
1030 Haematology - .05 Automated differential leucocyte counts	Basophil count	EDTA Whole Blood	Fluorescence Flow Cytometry	0.03 x 10 ⁹ /l to 440 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
	Eosinophil count		Fluorescence Flow Cytometry	0.03-440 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
	Lymphocyte count		Fluorescence Flow Cytometry	0.03 x 10 ⁹ /l to 440 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
	Monocyte count		Fluorescence Flow Cytometry	0.03 to 440 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
	Neutrophil count		Fluorescence Flow Cytometry	0.03 x 10 ⁹ /l to 440 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
	White Cell Count		Fluorescence Flow Cytometry	0.03 to 440 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Fluorescence Flow Cytometry	1 x 10 ⁹ /l to 720 x 10 ⁹ /l Sysmex XN	CE Marked	HAEMG-LP-050 , HAEMG-LP-064
1030 Haematology - .08 Blood film examinations involving special staining procedures	MGG Staining		Staining	N/A Sysmex sp50 Stainer	CE Marked	HAEMG-LP-068
1030 Haematology - .09 Examination of malarial parasites	Malaria Screen/CareUS Malaria kit		Manual/ Immuno-chromatographic test	N/A	CE Marked	HAEMG-LP-033
	Malaria/Blood Film Examination		Manual Staining	N/A	CE Marked	HAEMG-LP-033

1030 Haematology - .20 Bone marrow examination	Iron stain	Bone Marrow Aspirate	Manual Staining	N/A	CE Marked	HAEMG-LP-027 HAEMG-LP-029
	MGG		Staining	N/A Multi Stainer/ or Aeropspray Haematology Pro. Elitechgroup	CE Marked	HAEMG-LP-027 HAEMG-LP-017, HAEMG-LP-069. HAEMG-LP-019
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen (Clin-Tech Sickle Test)	EDTA Whole Blood	Manual Solubility Test for HbS	N/A	CE Marked	HAEMG-LP-012
1030 Haematology - .40 Limited haemostasis related tests	Activated Partial Thromboplastin Time (APTT)	Blood in Citrated Plasma	Coagulometric(turbidimetric)	16 seconds to 400 seconds IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-068
	Activated Partial Thromboplastin Time Ratio (APTT-R)		Calculation	IL-Haemostasis, ACL TOP	Based on Standard Method	HAEMC-LP-068
	Activated Protein C Resistance		Coagulometric(turbidimetric)	10-250 secs IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-069
	Antithrombin		Chromogenic	0.07 IU/mL to 1.5 IU/mL, IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-065
	Anti-Xa (Unfractionated Heparin UFH and Low Molecular Weight Heparin LMWH)		Chromogenic	0.6 IU/mL to 2.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-056
	Anti-Xa Rivaroxaban		Chromogenic	15 ng/mL to 1100 ng/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-056
	D-Dimer		Immuno-turbidimetric	0.22 ug/mL to 128 ug/mL, IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-006
	Factor II		Coagulometric(turbidimetric)	0.008 IU/mL to 1.5 IU/mL IL-Haemostasis ACL TOP	CE Marked	HAEMC-LP-014
	Factor IX		Coagulometric(turbidimetric)	0.001 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
	Factor V		Coagulometric(turbidimetric)	0.005 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-014
	Factor VII		Coagulometric(turbidimetric)	0.003 IU/mL - 1.5 IU/mL IL Haemostasis, ACL TOP	CE Marked	HAEMC-LP-014
	Factor VIII		Coagulometric(turbidimetric)	0.001 IU/mL-1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017

	Factor X		Coagulometric(turbidimetric)	0.008 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-014
	Factor XI		Coagulometric(turbidimetric)	0.001 IU/ml to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
	Factor XII		Coagulometric(turbidimetric)	0.01 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
	Fibrinogen		Clotting (Clauss)	0.35 g/L to 10.0 g/L IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-066
	Free Protein S		Immuno-turbidimetric	0.073 IU/mL to 3.0 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-055
	International Normalised Ratio (INR)		Coagulometric(turbidimetric)	0.67 ISI to 26 ISI Dependent, IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-068
	Lupus Anticoagulants		Coagulometric(turbidimetric)	DRVVS = 16 to 240 secs, DRVVC = 16 to 121secs, SCT: 10 to 400secs IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-070
	Mixing Study		Coagulometric(turbidimetric)	N/A IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-023
	Protein C		Chromogenic	0.1 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-065
	Prothrombin Time		Coagulometric(turbidimetric)	8 to 320 seconds IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-068
	Von Willebrand Factor Antigen		Immuno-turbidimetric	0.22 IU/ml to 10 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-067
1030 Haematology - .57 Screening test for infectious mononucleosis	Screening test for Infectious Mononucleosis	EDTA Whole Blood	Manual Immunoassay	N/A	CE Marked	HAEMG-LP-010
1030 Haematology - .70 Immunophenotyping	Acute Leukaemia Panel (Acute Screen & Blast Count)	Bone Marrow Aspirate/EDTA Whole Blood	Flow Cytometry	0% to 100% BD FACSCanto II	CE Marked	HAEMF-LP-011
	B-cell Lymphoproliferative panel		Flow Cytometry	0% to 100% BD FACSCanto II	CE Marked	HAEMF-LP-009
	Immune-Monitoring (T-helper cells & T, B, NK)	EDTA Whole Blood	Flow Cytometry	0% to 100% BD FACSCanto II	CE Marked	HAEMF-LP-007, HAEMF-LP-008
	Lymphoid Screening Tube (Lymphoproliferative	Bone Marrow Aspirate/EDTA Whole Blood/	Flow Cytometry	0% to 100% BD FACSCanto II	CE Marked	HAEMF-LP-023

	Screen)	Lymph node Aspirate				
	PNH Testing	EDTA Whole Blood	Flow Cytometry	0 to 100% BD FACSCanto II	CE Marked	HAEMF-LP-013
	T-cell panel	Bone Marrow Aspirate/EDTA Whole Blood	Flow Cytometry	0 to 100% BD FACSCanto II	CE Marked	HAEMF-LP-022

Histopathology and Cytopathology

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	Automated Haematoxylin and Eosin Staining	Human Tissue	Automated/Dako Coverstainer	CE Marked	N/A	LP-HIS-HECoverstainer
	Coverslipping		Automated/Dako Coverstainer	CE Marked	N/A	LP-HIS-HECoverstainer
	Cut Up		Manual	Based on Standard Method	N/A	LP-HIS-SpecRec LP-NEU-SpecReception LP-HIS-TissueTransfer LI-HIS-TissueTransfer
	Decalcification		Manual	Based on Standard Method	N/A	LP-HIS-Decal LP-NEU-SpecDecal
	Dissection by Medical Scientist		Manual	Based on Standard Method	N/A	LP-HIS-SmallSDis
	Embedding		Automated/Embedding Centre	CE Marked	N/A	LP-HIS-EmbBI LP-NEU-EmbBI LP-NCJD-H&E
	Manual Haematoxylin and Eosin Staining		Manual	Based on Standard Method	N/A	LP-NCJD-H&E LP-NEU-RapH&E LP-HIS-RapHE LP-NEU-HEM LP-HIS-SpHE
	Microtomy		Manual/Microtome	Based on Standard Method	N/A	LP-NEU-Microtomy LP-HIS-MicroPB LP-NCJD-H&E LP-EM-SemiThin LP-EM-UltraThin LP-HIS-SpCutPrep

	Tissue Processing		Automated/Tissue Tek VIP	CE Marked	N/A	LP-HIS-VIPProc LP-EM-LeicaEMTP LP-NCJD-Processor LP-HIS-VIPProc LP-HIS-RapHE
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut Up		Manual	Based on Standard Method	N/A	LP-NEU-CutUp LP-HIS-SpecRec
	Frozen Section Cryotomy & Staining		Manual/Cryostat	Based on Standard Method	N/A	LP-NEU-FSUrget LP-HIS-FSProc LP-HIS-RapHE
1051 Histopathology - .03 Histochemistry	Alcian Blue Technique for Acid Mucins		Manual	Based on Standard Method	N/A	LP-HIS-SpAb
	Chloracetate Esterase (CAE)		Manual	Based on Standard Method	N/A	LP-HIS-SpCAE
	Combined Alcian Blue/Periodic Acid Schiffs reaction		Automated/Artisan	CE Marked	N/A	LP-HIS- SpArtisanLink
	Congo Red for Amyloid		Manual	Based on Standard Method	N/A	LP-HIS-SpCR
	Cresyl Violet		Manual	Based on Standard Method	N/A	LP-NEU-CresylViolet
	Diastase Periodic Acid Schiffs Reaction (DPAS)	Human Tissue including Muscle	Automated/Dako Coverstainer	Based on Standard Method	N/A	LP-NEU- DiastasePAS
	Elastic Van Gieson - EVG	Human Tissue	Manual	Based on Standard Method	N/A	LP-HIS-SpEVG
	Giemsa Stain for Helicobacter		Manual	Based on Standard Method	N/A	LP-HIS-SpHLO
	Gomori Trichrome Stain	Human Tissue Including Muscle	Manual	Based on Standard Method	N/A	LP-NEU- GomoriTrichrome
	Gordon & Sweets Method for Reticular Fibres	Human Tissue	Automated/Artisan	CE Marked	N/A	LP-HIS- SpArtisanLink
	Gram Twort Stain for Demonstration of Bacteria		Manual	Based on Standard Method	N/A	LP-HIS-SpGram
	Grocott Technique		Automated/Artisan	CE Marked	N/A	LP-HIS-

	for PCP/Fungi					SpArtisanLink
	Haematoxylin & Eosin		Automated/Dako Coverstainer	Based on Standard Method	N/A	LP-HIS-HECoverStainer
	Luxol Fast Blue		Manual	Based on Standard Method	N/A	LP-NEU-LFB
	Martius Scarlet Blue for Fibrin (MSB)		Manual	Based on Standard Method	N/A	LP-HIS-SpMSB
	Masson Fontana		Manual	Based on Standard Method	N/A	LP-HIS-SpMF
	Masson Trichrome		Automated/Artisan	CE Marked	N/A	LP-HIS-SpArtisanLink
	MGG		Manual	Based on Standard Method	N/A	LP-CYT-MGG
	Oil Red O	Human Tissue Including Muscle	Manual	Based on Standard Method	N/A	LP-NEU-ORO
	Periodic Acid Methemaline Silver (PASM)	Human Tissue	Automated/Artisan	Based on Standard Method	N/A	LP-HIS-SpArtisanLink
	Periodic Acid Schiffs Reaction (PAS)		Automated/Artisan	CE Marked	N/A	LP-HIS-SpArtisanLink
	Perls Prussian Blue Method for Ferric Iron		Automated/Artisan	CE Marked	N/A	LP-HIS-SpArtisanLink
	Sirius Red for Amyloid		Manual	Based on Standard Method	N/A	LP-HIS-SpSRAmy
	Sirius Red/Congo Red - Amyloid Staining +/- (KMNO4) Pre-Treatment		Manual	Based on Standard Method	N/A	LP-HIS-SpSR/CRPP+/-
	Von Kossa to Detect Calcium		Manual	Based on Standard Method	N/A	LP-HIS-SpVonK
	Warthin & Starry Method		Automated/Artisan	CE Marked	N/A	LP-HIS-SpArtisanLink
	Ziehl-Neelsen (ZN)		Automated/Artisan	Based on Standard Method	N/A	LP-HIS-SpArtisanLink
1051 Histopathology - .035 Histological Interpretation	Diagnostic interpretation and reporting		Manual/Microscope	Based on Standard Method	N/A	LP-HIS-RepCons

1051 Histopathology - .04 Histological interpretation- medical renal pathology	Diagnostic interpretation and reporting of human tissue specimens. Medical Renal Pathology		Manual/Microscope	Based on Standard Method	N/A	LP-HIS-RepCons
1051 Histopathology - .07 Histological interpretation- neuropathology	Diagnostic interpretation and reporting		Manual/Microscope	Based on Standard Method	N/A	LP-HIS-RepCons
1051 Histopathology - .09 Immunohistochemistry	NKX3.1	Prostate	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	34BE12	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	AE1AE3		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	ALK (D5F3) (Lung)		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	Alk Protein (Lymphoma)		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	Alpha Fetpprotein		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	BCAT (Catenin-Beta)		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	BCL2		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	BCL6		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	BEP63		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	BER EP4		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	C4d	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun	
	C5B9	Frozen muscle	Bond III	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU- BondIHCDilution
	Calbindin	Brain tumour/Brain	Automated/Bond III	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU- BondIHCDilution
	Calcitonin	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	Calretinin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	CAM 5.2		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
CD10	Automated/Benchmark		CE Marked	N/A	LP-HIS-ImxBenRun	
CD138	Automated/Benchmark		CE Marked	N/A	LP-HIS-ImxBenRun	
CD15	Automated/Benchmark		CE Marked	N/A	LP-HIS-ImxBenRun	

CD1a	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD2	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD20	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD21	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD23	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD3	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD30	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD31	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD34	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD4	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD45 (CLA)	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD5	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD57	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD68 (KP-1)	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD7	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD79a	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD8	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CD99	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CDX2	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CEA	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Chromogranin	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CK20	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CK5/6	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CK7	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Ckit	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CMV	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
CMYC	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
COSD	Manual	Based on Standard Method	N/A	LP-NEU-COXSHD

CRX		Automated/BOND III	CE	N/A	LP-NEU-BONDIII LI-NEU-BondIHCDilution
Cyclin-D1		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Desmin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
DOG-1		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
E-Cadherin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
EMA		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
ERG	Prostate	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
F8 RE AG	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
GATA3		Benchmark Ultra	CE Marked	N/A	LP-HIS-ImXBenRun LI-HIS-ImxAbSpec
GCDFP15		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
GFAP		Automated/Benchmark/BondIII	CE Marked	N/A	LP-HIS-ImXBenRun LP-NEUBondIII
Glycophorin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
HCG		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
HEPAR 1		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
HHV-8	Skin	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
HISTONE H3.3K27M	Brian tumour	Bond III	Non CE Marked	N/A	LP-NEU-Bond111 LI-NEU-IHCDilution
HLO	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
HMB45		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
HSV40		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Inhibin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Kappa		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Lambda		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
LIN28A	Frozen muscle	Bond III	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU-BondIHCDilution
Lysozyme	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MAD		Manual	Based on Standard Method	N/A	LP-NEU-MAD

Mast Cell Tryptase	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Melanin-A	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MIB-1 (Ki-67)	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MLH1	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MNHCF	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
MPH	Manual	Based on Standard Method	N/A	LP-NEU-MPH
MSA	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MSH2	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MSH6	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
MUM-1	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Myeloperoxidase	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
NACTH	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NADH-TR	Manual	Based on Standard Method	N/A	LP-NEU-NADH-TR
NAE1/3	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NAPPA4	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NAPSIN-A	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
NASRC	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NBA4	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NBCL2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NBCL6	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NBDG	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NBSRC	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCAV	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD10	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD117	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD138	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD15	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII

NCD1a	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD21	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD23	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD3	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD30	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD31	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD34	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD56	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD68 (KP-1)	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD79a	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCD99	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCDX2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCEA	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCHROM	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCK20	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCK5/6	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCK7	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCLA	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCM5.2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCMV	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NCOLL6	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NDES	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NDFERL	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NDSRC	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NDYS1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NDYS2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NDYS3	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NEBVIS	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NEMER	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII

Neurofilament	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
NFILA	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NFSH	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NGAB1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NGFAP	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NGH	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NGSRC	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NHLA1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NHMB45	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NHSV1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NHSV2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NIDH1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NIN1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NINTER	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NKAPIS	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NL26	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NLAMB2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NLAMC	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NLAMIS	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NLAMP1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NLAMP2	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NLH	Automated/BondMax	CE Marked	N/A	LP-NEU-BondMax
NMEA	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NMELA	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NMER	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NMHCS	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NMIB1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NMSA	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NMUM1	Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII

NNEST		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NNEUN		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NNF312		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NNK52		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NNSE		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NOCT		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NP62		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPL3F4 (CJD)		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPLAP		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPLASY (CJD)		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPLATU (CJD)		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPLBA4 (CJD)		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPLGFA (CJD)		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NPRO		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NSE		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
NSPEC		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NSYN38		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NSYNUC		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NTAU		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NTSH		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
		Automated/BondMax	CE Marked	N/A	LP-NEU-BondMax
NTTF1		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NUBUQ		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NWT1		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NYAP		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
OCT3/4		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Oestrogen Receptor		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
OLIG-2	Brain tumour/Brain	Automated/Bond III	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU- BondIHC Dilution

P16	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
P504S		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
P53		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
P63		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
PAX-5		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
PAX-8		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
PDL-1 (Lung)		Automated/Benchmark	CE Marked	N/A	LI-HIS-ImxAbSpec
PFK		Manual	Based on Standard Method	N/A	LP-NEU-PFK
PIT 1	Pituitary	Immunohistochemistry/ Dako Coverstainer	Non CE marked	N/A	LP-NEU-SLIDESIHC
PLAP	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
PMS2		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Progesterone Receptor		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
PSA		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
PSMA		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
S100 Protein		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
SF1	Pituitary	Autoamted/BondIII	Non-CE Marked,	N/A	LP-NEU-BondIII
SMMYO	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
SMSA		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
SOX10		Automated/Benchmark	CE Marked	N/A	QP-HIS-QAImxSt
SOX11		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun LI-HIS-ImxAbSpec
Synactophysin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
TARDBP		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Tau 3r	Brain	Automated/BondIII	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU-BondIHCDilution
TAU 4R		Automated/Bond III	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU-BondIHCDilution
TdT	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun

	Thyroglobulin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
	TPIT	Pituitary	Automated/BondIII	Non-CE Marked	N/A	LP-NEU-BONDIII
	TTF-1	Human Tissue	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
	Vimentin		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
	Zinc 3 Transporter	Brain tumour/Brain	Automated/Bond III	Non CE Marked	N/A	LP-NEU-BondIII LI-NEU- BondIHC Dilution
1051 Histopathology - .10 Fluorescence in situ hybridisation	HER2 ISH	Human Tissue	Automated/Bond III	Based on Standard Method	N/A	MOL-LP-053
1051 Histopathology - .12 Electron microscopy	Electron Microscopy		Manual/Electron Microscopy	CE Marked with Processing Based on Standard Method	N/A	LP-EM-LoadR LP-EM-EMSETUP unLeica
	Reporting of EM Findings	Fluid	Manual/Microscope	Based on Standard Method	N/A	LP-HIS-RenPathServ
		Human Tissue	Manual/Microscope	Based on Standard Method	N/A	LP-HIS-RenPathServ
	Reporting of EM findings by Consultant Renal Pathologist		Manual/Electron Microscope	Based on Standard Method	N/A	LP-HIS-RenPathServ
1052 Cytopathology - .02 Non gynaecological cytology	MGG Stain	Fluid	Manual	Based on Standard Method	N/A	LP-CYT-MGG
		Human Tissue	Manual	Based on Standard Method	N/A	LP-CYT-MGG
	PAP Stain	Fluid	Automated/DRS Stainer	Based on Standard Method	N/A	LP-CYT-PAPDRS
		Human Tissue	Automated/DRS Stainer	Based on Standard Method	N/A	LP-CYT-PAPDRS
	Preparation of Specimens (ThinPrep, Agar, MGG, H&E)	Fluid	Manual & Automated/Thin Prep	Based on Standard Method	N/A	LP-CYT-TPPrep LP-NEU-Agar LP-NEU- CSFCytology
		Human Tissue	Manual & Automated/Thin Prep	Based on Standard Method	N/A	LP-CYT-TPPrep LP-NEU-Agar LP-NEU- CSFCytology

	Sample Preparation & Description	Fluid	Manual	Based on Standard Method	N/A	LP-CYT-SpecRec
		Human Tissue	Manual	Based on Standard Method	N/A	LP-CYT-SpecRec
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic Interpretation and Reporting of Non-Gynaecological Specimens	Fluid	Manual/Microscope	Based on Standard Method	N/A	QP-CYT-QASlidRep
		Human Tissue	Manual/Microscope	Based on Standard Method	N/A	QP-CYT-QASlidRep

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
1040 Immunology - .03 Total IgE	Total IgE	Serum	Phadia 250/FEIA	CE	2 kU/l to 5000 kU/l	LP-IMM-ICAP0003
1040 Immunology - .04 Allergen - specific IgE	Specific IgE		Phadia 250 /FEIA	CE	0 kUA/l to 100 kUA/l	LP-IMM-ICAP0003
1040 Immunology - .06 Investigation of complement	C1 Inhibitor		Binding Site Optilite/Turbidimetry	CE	0.08 g/L to 0.88 g/L	LP-IMM-IC0002
	Complement C3		COBAS 702 /Immunoturbidimetric	CE	0.04 g/L to 5 g/L	LP-IMM-IC0003
	Complement C4		COBAS 702 /Immunoturbidimetric	CE	0.02 g/L to 1 g/L	LP-IMM-IC0003
	Complement Function: Classical and Alternative Pathway Activity		SQII/ELISA	CE	N/A	LP-IMM-ELISA0020
	Mannose Binding Lectin (MBL)	SQII/ELISA	Based on Standard Method invitrogen MBL Oligomer ELISA IFU-0080 v.03 KIT029RUO Issued 1st September 20200	0.0 mg/L to 4.00 mg/L	LP-IMM-ELISA0005	
1040 Immunology - .08 Detection of immune complexes in body fluids and biopsy material	Direct Immunofluorescence of Renal Biopsy	Renal Biopsy	Thermo Scientific HM525 NX Cryostat /Direct Immunofluorescence	Based on Standard Method Manual of Clinical Laboratory Immunology 3rd Edition 1986	N/A	LP-IMM-DIF0004 LP-IMM-DIF0005 LP-IMM-DIF0006

	Direct Immunofluorescence of Skin Biopsy	Skin Biopsy	Thermo Scientific HM525 NX Cryostat /Direct Immunofluorescence	Based on Standard Method Manual of Clinical Laboratory Immunology 3rd Edition 1986	N/A	LP-IMM-DIF0003 LP-IMM-DIF0004 LP-IMM-DIF0005 LP-IMM-DIF0007
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Rheumatoid Factor (RF)	Serum	COBAS 702/Immunturbidimetric	CE	10 IU/mL to 130 IU/mL	LP-IMM-IC0003
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti-Beta-2-Glycoprotein 1 Antibodies (IgG)		Phadia 250/FEIA	CE	0.8 U/ml to ≥532 U/ml	LP-IMM-ICAP0011
	Anti-Beta-2-Glycoprotein 1 Antibodies (IgM)		Phadia 250/FEIA	CE	2.4 U/ml to ≥576 U/ml	LP-IMM-ICAP0011
	Anti-Cardiolipin Antibodies (IgG)		Phadia 250/FEIA	CE	0.5 GPLU/ml to ≥418 GPLU/ml	LP-IMM-ICAP0011
	Anti-Cardiolipin Antibodies (IgM)		Phadia 250/FEIA	CE	0.9 MPLU/ml to ≥472 MPLU/ml	LP-IMM-ICAP0011
	Anti-Cyclic Citrullinated Peptide Antibody (CCP)		Phadia 250/FEIA	CE	0.4 EliA U/ml to ≥340 EliA U/ml	LP-IMM-ICAP0008
	Anti-dsDNA Antibodies (DNA)		Phadia 250/FEIA	CE	0.6 IU/ml to ≥379 IU/ml	LP-IMM-ICAP0002
	Anti-ENA Antibody Screen		Phadia 250/FEIA	CE	0.09 to 55 Ratio	LP-IMM-ICAP0014
	Anti-ENA Blot including Ro, La, Sm, RNP, Jo-1 & Scl-70 Antibodies		EUROBLOT ONE/Manual/Immunoblot	CE	N/A	LP-IMM-BLOT0001
	Anti-Glomerular Basement Membrane Antibodies (GBM)		Phadia 250/FEIA	CE	1.5 U/ml to ≥680 U/ml	LP-IMM-ICAP0009
	Anti-Histone Antibodies		EUROBLOT ONE/Manual/Immunoblot	CE	N/A	LP-IMM-BLOT0001
Anti-Intrinsic Factor Antibodies	Phadia 250/FEIA		CE	0.5 U/mL to 480 U/mL	LP-IMM-ICAP0017	

Anti-Jo-1 Antibodies(Jo1)		Phadia 250/FEIA	CE	0.3 U/ml to \geq 240 U/ml	LP-IMM-ICAP0015
Anti-La Antibodies (La)		Phadia 250/FEIA	CE	0.4 U/mL to \geq 320 U/mL	LP-IMM-ICAP0015
Anti-LC1 Antibodies		EUROBLOT ONE/ Manual/ Immunoblot	CE	N/A	LP-IMM-BLOT0002
Anti-Liver Kidney Microsomal Antibodies (LKM)		EUROBLOT ONE/ Manual/ Immunoblot	CE	N/A	LP-IMM-BLOT0002
Anti-M2 Mitochondrial Antibodies (PDH)		EUROBLOT ONE/Manual/Immunoblot	CE	N/A	LP-IMM-BLOT0002
		SQII /ELISA	CE	N/A	LP-IMM-ELISA0009
Anti-Myeloperoxidase Antibodies (MPO)		PHADIA 250/FEIA	CE	0.2 IU/ml to \geq 134 IU/ml	LP-IMM-ICAP0004
Anti-Neuronal Immunoblot including Amphiphysin, CV2, PNMA2 (Ma/Ta), Ri, Yo, Hu, Recoverin, SOX-1, Titin, Zic4, GAD65 and Tr (DNER) Antibodies	CSF	EUROBLOT ONE/Manual/Immunoblot	CE	N/A	LP-IMM-BLOT0005
Anti-Neuronal Immunoblot including Amphiphysin, CV2, PNMA2 (Ma/Ta), Ri, Yo, Hu, Recoverin, SOX-1, Titin, Zic4, GAD65, Tr (DNER) Antibodies	Serum	EUROBLOT ONE/ Manual/ Immunoblot	CE	N/A	LP-IMM-BLOT0005
Anti-Nucleosome Antibodies		EUROBLOT ONE/ Manual/ Immunoblot	CE	N/A	LP-IMM-BLOT0001
Anti-Phospholipase A2 Receptor Antibodies (PLA2R)		SQII/ELISA	CE	2RU/mL to 1500 RU/mL	LP-IMM-ELISA0018
Anti-Proteinase-3 Antibodies (PR3)		Phadia 250/FEIA	CE	0.6 IU/ml to \geq 177 IU/ml	LP-IMM-ICAP0004
Anti-Ribosomal P Antibodies		EUROBLOT ONE/Manual/Immunoblot	CE	N/A	LP-IMM-BLOT0001

	Anti-RNP Antibodies(RNP)	PHADIA 250/FEIA	CE	0.5 U/ml to ≥ 240 U/ml	LP-IMM-ICAP0015
	Anti-Ro (RO) Antibodies	Phadia 250/FEIA	CE	0.4 U/ml to ≥ 240 U/ml	LP-IMM-ICAP0015
	Anti-Scl-70 Antibodies (Scl-70)	Phadia 250/FEIA	CE	0.6 U/ml to ≥ 240 U/ml	LP-IMM-ICAP0015
	Anti-Thyroid Peroxidase Antibodies (TPO)	COBAS 801 /Immunoassay	CE	9 IU/mL to 600 IU/mL	LP-IMM-IC0003
	Anti-Tissue Transglutaminase Antibodies (TTG)	Phadia 250/FEIA	CE	0.2 EliA U/ml to ≥ 128 EliA U/ml	LP-IMM-ICAP0007
	Connective Tissue Disease Screen (CTD)	Phadia 250/FEIA	CE	0.05 - ≥ 32 ratio	LP-IMM-ICAP0012
	Myositis Panel including Mi-2 Alpha, Mi-2 Beta, T1F1 Gamma, MDA5, NXP2, SAE1, Ku, PM-Scl 100, PM-Scl 75, Jo-1, SRP, PL-7, PL-12, EJ, OJ & Ro-52 Antibodies	EUROBLOT ONE/ Manual/ Immunoblot	CE	N/A	LP-IMM-BLOT0003
	Scleroderma Panel including Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR and Ro-52	EUROBLOT ONE/ Manual/ Immunoblot	CE	N/A	LP-IMM-BLOT0004
1040 Immunology - .54 Tryptase	Tryptase	Phadia 250/FEIA	CE	1 ug/l to 200 ug/l	LP-IMM-ICAP0006
1040 Immunology - .60 Simple slide tests for biochemical and immunological analytes	Anti-Adrenal Antibodies	HELIOS, HELMED/Manual Indirect Immunofluorescence	CE	1/5	LP-IMM-IIF0011
	Anti-ds DNA Chrithidia Antibodies (DNAC)	HELIOS/HELMED/Manual/Indirect Immunofluorescence	CE	1/10 to 1/160	LP-IMM-IIF0006

Anti-Endomysial Antibodies IgA & IgG (EMA & EMAG)		HELIOS/HELMED/ Manual/ /Indirect Immunofluorescence	CE	1/5	LP-IMM-IIF0005
Anti-Gastric Parietal Cell Antibodies (GPC)		HELIOS/HELMED/Manual/Indirect Immunofluorescence	CE	1/40	LP-IMM-IIF0003
Anti-LC1 Antibodies		HELIOS/HELMED/ Manual/ /Indirect Immunofluorescence	CE	1/40 to 1/320	LP-IMM-IIF0003
Anti-Liver Kidney Microsomal Antibodies (LKM)		HELIOS/HELMED/Manual/Indirect Immunofluorescence	CE	1/40 - 1/320	LP-IMM-IIF0003
Anti-Mitochondrial Antibodies(AMA)		HELIOS/HELMED/ Manual/ /Indirect Immunofluorescence	CE	1/40 - 1/320	LP-IMM-IIF0003
Anti-Neuronal Antibodies	CSF	HELIOS/HELMED/ Manual/ /Indirect Immunofluorescence	CE	N/A	LP-IMM-IIF0008
	Serum	HELIOS/HELMED/Manual/Immunofluorescence	CE	1/50	LP-IMM-IIF0008
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)		HELIOS, HELMED/Manual/ Indirect Immunofluorescence	CE IVD	1/20	LP-IMM-IIF0004
Anti-NMDA Antibodies (NMDA)	CSF	Manual/Indirect Immunofluorescence	CE	N/A	LP-IMM-IIF0013
	Serum/Plasma	Manual Indirect Immunofluorescence	CE	1/10	LP-IMM-IIF0013
Anti-Nuclear Antibodies (ANA)	Serum	HELIOS, HELMED/Manual Method /Indirect Immunofluorescence	CE	Adults: 1/80 to 1/640 Paediatric: 1/40 to 1/640	LP-IMM-IIF0002
Anti-Skin Autoantibodies		HELIOS/HELMED/Manual/Indirect Immunofluorescence	CE	1/10 - 1/640	LP-IMM-IIF0007
Anti-Smooth Muscle Antibodies (SMA)		HELIOS/HELMED/ Manual/ /Indirect Immunofluorescence	CE	1/40 - 1/320	LP-IMM-IIF0003
Autoimmune Encephalitis Antibodies including Anti-AMPA 1&2, Anti-GABAb, Anti-CASPR2, Anti-LGI1, Anti-DPPX, Anti-NMDA antibodies	Serum/Plasma	Manual/Indirect Immunofluorescence	CE	1/10	LP-IMM-IIF0012
Autoimmune Encephalitis Mosaic Antibodies including	CSF	Manual/Indirect Immunofluorescence	CE	N/A	LP-IMM-IIF0012

	Anti-AMPA 1&2, Anti-GABAb, Anti-CASPR2, Anti-LGI1, Anti-DPPX, Anti-NMDA antibodies					
1040 Immunology - .99 Miscellaneous tests	Anti-Pneumococcal Antibodies (IgG)	Serum	SQII/ELISA	CE Marked	3.3 mg/L to 270mg/L	LP-IMM-ELISA0016
	Anti-SARS CoV-2 Nucleocapsid Antibodies		COBAS 801/Immunoassay	CE	N/A	LP-IMM-IC0003
	Anti-SARS CoV-2 Spike Protein Antibodies		COBAS 801/Immunoassay	CE	0.4 U/mL to 250 U/mL	LP-IMM-IC0003
	Anti-Streptolysin O Titre (ASOT)		COBAS 702/Immunturbidimetric	CE	20 IU/mL to 600 IU/mL	LP-IMM-IC0003
	IgG Subclasses (IgG1, IgG2 & IgG3)		Binding Site Optilite /Turbidimetry	CE	IgG1: 0.15 g/L to 144 g/L IgG2: 0.02 g/L to 28 g/L IgG3: 0.0055 g/L to 8.8 g/L	LP-IMM-IC0002
	Specific IgG Antibodies		Phadia 250/FEIA	CE	2 mgA/l to 200mgA/l	LP-IMM-ICAP0010

Microbiology and Virology

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	Macroscopic Examination and Description of Specimens	Sputum, CSF, Faeces in sterile screw capped container	Manual/Visual	Based on Standard Method	N/A	LP-MIC-Respiratory LP-MIC-CSF LP-MIC-Faeces
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)	Cell Counts and Differential	Urines or CSF in sterile screw capped container Body Fluids in EDTA	Microscope/Staining and Microscopy	Based on Standard Method	PUS, RBC <1 to >10,000 per μ L Leucocytes <1 μ L to measured cell count per μ L Erythrocytes <1 μ L to measured cell count / μ L	LP-MIC-SpecimenPutUp LP-MIC-CSF LP-MIC-Urines LP-MIC-Wounds & Fluids
	Gram Staining	Eye Swab, High Vaginal Swab, Cervical/Urethral Swabs, IUCD, VP Shunts, Fluids, CSF, Tissues/Biopsies, Bone, Pus, Theatre Specimens	Microscope/ Staining & Microscopy	Based on Standard Method	N/A	LP-MIC-STI LP-MIC-OrganismIdentification LP-MIC-TestMethods LP-MIC-Wounds & Fluids LP-MIC-CSF
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Microscopic Examination for Parasites	Faeces, Urine in sterile screw capped container	Microscope/ Concentration and Microscopy	Based on Standard Method	N/A	LP-MIC-OvaandParasites LP-MIC-Urine
1012 Preparation of films on glass slides followed by microscopic examination	Microscopic Examination for Fungi using KOH Calcofluor	Nail, Skin, Scalp in sterile screw capped container and or	Microscope/ Staining & Fluorescent Microscope	Based on Standard Method	N/A	LP-MIC-Fungi

with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	White stain	Dermapak				
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria	Microscopic Examination for Mycobacteria using Auramine O stain and Zn	Sputum, Bronchoalveolar Lavage, Tracheal Aspirate, urine, Body Fluids, CSF, Tissues/ Biopsies, Bone/ Pus, Blood, Swabs, in sterile screw capped container	Microscope /Staining & Fluorescent Microscope	Based on Standard Method	N/A	LP-MIC-TB
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	Blood cultures	BD Bactec FX /Automated	CE Marked	N/A	LP-MIC-Blood Cultures
		Tracheal Aspirate, Sputum, Bronchoalveolar Lavage, Eye Swab, High Vaginal Swab, IUCD, VP Shunts, Urine, Fluids, CSF, Tissues/Biopsies, Bone, Pus, Penile/Urethral Swab, Endocervical Swab, Tips, Drains, Faeces, Mouth Swabs, Wound Swabs, Ear Swabs, Throat Swabs, Theatre Specimens, Sinus Aspirate, Nasal Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, CSF Shunts, MRSA Swab, VRE Swab, CPE Swab, Bile, Ulcer Swabs, Environmental Specimens	Manual/Culture	Based on Standard Method	N/A	LP-MIC-SpecimenPutUp LP-MIC-CSF LP-MIC-Respiratory LP-MIC-Urines LP-MIC-Wounds & Fluids LP-MIC-STI LP-MIC-Faeces LP-MIC-OrganismIdentification LP-MIC-TestMethods

1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of Fungi	Nail, Skin, Scalp in sterile screw capped container and or Dermapak	Manual/Culture	Based on Standard Method	N/A	LP-MIC-Fungi
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of Mycobacteria	Sputum, Bronchoalveolar Lavage, Tracheal Aspirate, Urine, Fluids, CSF, Tissues/Biopsies, Bone/Pus, Blood, Swabs, in sterile screw capped container	Becton Dickinson Bactec MGIT 960 /Automated	CE Marked	N/A	LP-MIC-TB
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Shigella and Salmonella Typing	Isolate	Manual/Slide Agglutination	CE Marked	N/A	LP-MIC-Faeces
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Pastorex Staph Plus Test		Manual/Particle Agglutination Pastorex™ Staph-Plus Kit	CE Marked	N/A	LP-MIC-TestMethods
	Streptococcal Grouping Latex Test		Manual/Particle Agglutination Prolex™ Streptococcal Grouping Latex Kit	CE Marked	N/A	LP-MIC-TestMethods
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	H. Pylori	Faeces in sterile screw capped container	Manual/ Immunoassay Premier Platinum HpSA plus H pylori	CE Marked	N/A	LP-MIC-Faeces-Miscellaneous
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04	Becton Dickinson MGIT TBc Identification Kit	Positive Mycobacterial cultures	Manual/Rapid Immunochromatographic Assay Becton Dickinson MGIT TBc ID	CE Marked	N/A	LP-MIC-TB

Immunochromatographic methods,						
	C. Difficile Complete (GDH and Toxin)	Faeces in sterile screw capped container	Manual/Rapid Immunochromatographic Assay TechLab C.DIFF Quik Chek Complete	CE Marked	N/A	LP-MIC-Faeces
	Cryptococcal Antigen	CSF, in sterile screw capped container/ Serum	Manual/Rapid Immunochromatographic Assay CrAG LFA	CE Marked	N/A	LP-MIC-CSF
	Detection of Aspergillus Galactomannan antigen	Broncheolar Lavage in sterile screw capped container and Serum	Manual/Rapid Immunochromatographic Assay Immy sona Aspergillus Galactomannan Lateral Flow Assay	CE Marked	N/A	LP-MIC-Fungi
	Detection of Legionella Urinary Antigen	Urine in a sterile screw capped container	Manual/Rapid Immunochromatographic Assay Abbott Legionella Urinary AG Card	CE Marked	N/A	LP-MIC-Urine
	NG TEST CARBA-5 for detection of KPC, NDM, VIM, IMP and OXA-48-like Carbapenemase genes	Isolate	Manual/Rapid Immunochromatographic Assay NG TEST CARBA-5 (Next Generation Biotech)	CE Marked	N/A	LP-MIC-CRE
	PBP2a for detection of penicillin-binding protein 2a		Manual/Rapid Immunochromatographic Assay Alere™ PBP2a	CE Marked	N/A	LP-MIC-BloodCultures
	Rotavirus/ Adenovirus	Faeces	Manual/Rapid Immunochromatographic Assay SD Rota-Adeno Rapid	CE Marked	N/A	LP-MIC-Faeces-Miscellaneous
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Aries SARS-CoV-2	Nasopharyngeal swab / PrimeStore® MTM Lysis Swab	Luminex Aries® System/ Automated Aries® SARS-CoV-2 Assay	CE Marked	N/A	LP-MIC-RespViruses

BCID-GP and BCID-GN	Blood Culture	ePlex ® Nucleic acid detection/PCR ePlex® BCID panel (GenMark Diagnostics Inc.) assay.	CE Marked	N/A	LP-MIC-BloodCultures
Detection of S. aureus (SA) and MRSA from positive blood culture bottles Xpert MRSA/SA BC Real-Time PCR Assay	Blood Cultures	GenXpertPCR/Gene-Xpert Cepheid GeneXpert DX16	CE Marked	N/A	LP-MIC-BloodCultures
Enteric Bacterial Pathogens	Faeces in sterile screw capped container	PCR/Gene-Xpert GeneXpert DX16 Xpert® C. difficile kit PCR/Gene-Xpert	CE Marked	N/A	LP-MIC-Faeces
Eplex Respiratory Pathogen 2 Panel (SARS/FLU/RSV targets)	Nasopharyngeal swab / PrimeStore® MTM Lysis Swab	Eplex ® Instrument /Automated ePlex® Respiratory Pathogen 2 panel (GenMark Diagnostics Inc.) assay.	CE Marked	N/A	LP-MIC-RespViruses
Influenza A&B Xpress/RSV	Nasal Swab, Throat Swab	PCR/Gene-Xpert Cepheid GeneXpert DX16 Xpert® Xpress Flu/RSV Plus	CE Marked	N/A	LP-MIC-RespViruses
LightMix Carbapenemase	Copan Eswab	Roche Flow Flex/Automated Roche MagNa Pure 96 Roche LightCycler 480 II	CE Marked	N/A	LP-MIC-MolecularCPE
Molecular detection of C. difficile	Faeces in sterile screw capped container	PCR/Gene-Xpert GeneXpert DX16 Xpert® C. difficile kit PCR/Gene-Xpert	CE Marked	N/A	LP-MIC-C.difficile
		Realtime PCR/ assay Roche LightCycler 480 II EntericBio Realtime C. Diff panel	CE Marked	N/A	LP-MIC-C.difficile
Molecular detection of M.tuberculosis Complex and	Sputum Specimens in sterile screw capped container	PCR/GeneXpert Cepheid GeneXpert DX16	CE Marked	N/A	LP-MIC-TB

	Rifampicin Resistance in clinical specimens using the MTB/Rif Ultra		Xpert MTB/RIF Ultra			
	VIASURE SARS-CoV-2 ,FLU A/B and RSV Realtime PCR Detection Kit	Bronchoalveolar lavage/ PrimeStore® MTM Lysis Swab	Roche Flow Flex /Automated Roche MagNa Pure 96 Roche LightCycler 480 II	CE Marked	N/A	LP-MIC-RespViruses
		Nasopharyngeal swab / PrimeStore® MTM Lysis Swab	Roche Flow Flex /Automated Roche MagNa Pure 96 Roche LightCycler 480 II	CE Marked	N/A	LP-MIC-RespViruses
	VIASURE SARS-CoV-2(N1 +N2) Realtime PCR Detection Kit	Broncheolar Lavage/PrimeStore® MTM swabs	Roche Flow Flex /Automated Roche MagNa Pure 96 Roche LightCycler 480 II	CE Marked	N/A	LP-MIC-Resp Viruses
		Nasopharyngeal swab/PrimeStore® MTM swabs	Roche Flow Flex /Automated Roche MagNa Pure 96 Roche LightCycler 480 II	CE Marked	N/A	LP-MIC-Resp Viruses
	Viral Lysis Swabs	Nasopharyngeal and Broncheolar Lavage	Eplex and FlowFLex	CE Marked	N/A	LP-MIC-Respiratory Viruses
	XPERT Carba-R	Copan Eswab	PCR/Gene-Xpert Cepheid GeneXpert DX16 Xpert®CarbaR	CE Marked	N/A	LP-MIC-MolecularCPE
	Xpert CarbaR-CRE	Isolates	PCR/Gene-Xpert Cepheid GeneXpert DX16 Xpert®CarbaR	Non CE Marked	N/A	LP-MIC-CRE
	Xpert Xpress FLU A/B/RSV Xpert SARS-CoV-2	Lysis Swab	PCR/GeneXpert Cepheid GeneXpert DX16	In House Developed	N/A	LP-MIC-Respiratory Viruses
	Xpert Xpress SARS Co-V-2	Nasopharyngeal swab	PCR/GeneXpert Cepheid GeneXpert DX16	CE Marked	N/A	LP-MIC-Resp Viruses
	Xpert Xpress SARS Co-V-2/FLU/RSV		PCR/GeneXpert Cepheid GeneXpert DX16	CE Marked	N/A	LP-MIC-RespViruses
1016 Identification of cultured bacteria and fungi using non-nucleic acid	API20E	Isolate	Fermentation Decarboxylation /Manual Biomérieux API20E	CE Marked	N/A	LP-MIC-TestMethods

based techniques - .01 Biochemical methods , CE marked commercial systems						
	Rapid NH		Fermentation Decarboxylation /Manual Remel RapIDTMNH	CE Marked	N/A	LP-MIC-TestMethods
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Lactofuschin		Staining & Microscopy/Manual PRO-LAB Lactofuchsin stain	CE Marked	N/A	LP-MIC-Fungi
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI- TOF Spectroscopy	Identification using MALDI-TOF Spectroscopy	Bacterial Isolates and Candida spp.	Mass Spectrophotometry/ Bruker MALDI- TOF BioTyper	CE Marked	N/A	LP-MIC-MALDI-TOF
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial Susceptibility Testing	Isolate	Automated Broth Microdilution/Phoenix Becton Dickinson Phoenix M50	CE Marked	N/A	LP-MIC-Phoenix LP-MIC-Susceptibility
	Antimicrobial Susceptibility Testing & Phenotypic confirmation of ESBLs		Disc Diffusion/Manual MASTDISCS® Combi	Based on Standard Method	N/A	LP-MIC-Susceptibility
	Minimum Inhibitory Concentration		Gradient MICs/Manual	Based on Standard Method	N/A	LP-MIC-Susceptibility
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Broth Microdilution		Broth MIC/Manual Sensititre Yeast ONE kit Y10	Based on Standard Method	N/A	LP-MIC-Susceptibility
1024 Preservation of microbial cultures	Microorganism Storage	New MRSAs, New VREs, CPEs, ESBLs, Isolates Referred to	Cryogenic Beads & Nutrient Agar Slopes/Freezer	CE Marked	N/A	LP-MIC-CSF LP-MIC-Respiratory LP-MIC-Urines

		Reference Laboratory, EQA Isolates, Other Isolates as Clinically Requested				LP-MIC- WoundsandFluids LP-MIC-STI LP-MIC-Faeces
1029 Miscellaneous - .99 Miscellaneous tests	hCG	Urine	Manual/Rapid Immunochromatographic Assay	CE Marked	N/A	LP-MIC-Urine