

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	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 public¹

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-LP-004
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	ABO Antibody Titre	Plasma	BioRad IH500 Automated Technique	CE Marked	N/A	BTD-LP-003
	Blood Grouping (ABO Rh (d) Typing)	Red Blood Cells & Plasma in EDTA	BioRad IH500 Automated Technique	CE Marked	N/A	BTD-LP-003
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen	EDTA Plasma	BioRad IH500 Automated Technique	CE Marked	N/A	BTD-LP-003

		Plasma	Manual/Gel Cards	CE Marked	N/A	BTD-LP-004
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification	EDTA Plasma/ Serum	BioRad IH500 Automated Technique	CE Marked	N/A	BTD-LP-003
		Plasma	Manual/Gel Cards	CE Marked	N/A	BTD-LP-003
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing		IAT Crossmatch Manual	CE Marked	N/A	BTD-LP-002 BTD-LP-004
	Crossmatching	EDTA Plasma	IAT Crossmatch, Automated (Bio Rad IH500) and Electronic Crossmatch	CE Marked	N/A	BTD-LP-002 BTD-LP-003
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping	Red Blood Cells	Manual/Gel Cards/Manual Tube	CE Marked	N/A	BTD-LP-004
		Red Blood Cells in EDTA	BioRad IH500 Automated Technique	CE Marked	N/A	BTD-LP-003
1020 Transfusion science - .08 Antibody titration	ABO Antibody Titre	Plasma	Manual/Gel Cards	CE Marked	N/A	BTD-LP-004
1020 Transfusion science - .09 Direct antiglobulin test	Monospecific Direct Antiglobulin test	Red Blood Cells in EDTA	BioRad IH500 Automated Technique	CE Marked	N/A	BTD-LP-003
	Monospecific Direct Antiglobulin Testing		Manual/Gel Cards	CE Marked	N/A	BTD-LP-004

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.

Head Office

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Alanine 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 mmol/L to 50 mmol/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
eGFR	Li-Heparin/Serum	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	CSF	Colorimetric	Cobas 702/ 0.2 mmol/L to 155.0 mmol/L	CE Marked	CP-LP-0146
Lactate Dehydrogenase (LDH)	Serum/Li-Hep plasma	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
	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		Turbidimetric	Cobas 702/ 0.40 mg/L to 10.2 mg/L	CE Marked	CP-LP-0146
Free Kappa/Free Lambda Ratio	Serum	Calculation	LIS Interface	Based on Standard Method	CP-LP-0160
Interkeukin 6		Immunoassay Sandwich	Cobas 801/ 2.5 pg/ml to 5000 pg/ml	CE Marked	CP-LP-0146
Kappa Free Light Chain		Turbidimetry/Binding Site Optilite	Free Kappa 0.6 mg/L to 127000 mg/L	CE Marked	CP-LP-0161
Lambda Free Light Chain		Turbidimetry/Binding Site Optilite	Free Lambda 1.3 mg/L to 139000 mg/L	CE Marked	CP-LP-0161
Procalcitonin		Immunoassay Sandwich	Cobas 801/ 0.06 ng/ml to 100 ng/ml	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/ g/L to 360 g/L	2 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
	Carbamezapine		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 801/ 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/ 2.4 mg/L to 120 mg/L	CE Marked	CP-LP-0146
	Phenytoin		KIMS	Cobas 702/ 0.8 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	CP-LP-0059
	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/ 3 mg/L to 150mg/L	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 i10 / 138 pmol/mL to 3656 pmol/mL	CE Marked	CP-LP-0132
	Cortisol	Serum/Li-Hep plasma	Immunoassay (Competitive)	Cobas 801 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 801/ 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 i10/ 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 801/ 1 mU/L to 1,000 mU/L	CE Marked	CP-LP-0146
Insulin Like Growth Factor 1 (IGF-1)		Immunoassay	IDS i10/ 10 ng/mL to 1,200 ng/ml	CE Marked	CP-LP-0103
Leutinisig 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 i10 /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 Antigen (Total PSA)		Immunoassay (Sandwich)	Cobas 801/ 0.03 ug/L to 5,000 ug/L	CE Marked	CP-LP-0146
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 (>50manual 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 umol/L (>50manual dilution)	In House Developed	CP-LP-0120
	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	H8190 0 mmol/L to 151 mmol/M	CE Marked	CP-LP-0130
1061 Clinical Chemistry - .81 Qualitative investigation of	Immunoglobulin A (IgA)	Serum	Immunoturbidimetric	Cobas 702/ 0.5 g/L to 64 g/L	CE Marked	CP-LP-0146

immunoglobulins G, A, M and in body fluids						
	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	CSF B2 Transferrin	CSF	Agarose Gel	Sebia 2 Hydrasys Scan	CE Marked	CP-LP-0168
		Serum	Agarose Gel	Sebia 2 Hydrasys Scan	CE Marked	CP-LP-0168
	CSF Xanthochromia	CSF	Spectrophotometry	Spectrophotometer Libra S32PC	In House Developed	CP-LP-0063
	Electrophoresis	Serum	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

Head Office

Genetics

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
1071 Cytogenetics - .25 Fluorescent in situ hybridisation	ALK Break Apart FISH	Human Tissue	Fluorescent in situ hybridisation	Fluorescent Microscope	Standard method using CE marked kits.	MOL-LP-053
	ROS1 Break Apart FISH		Fluorescent in situ hybridisation	Fluorescent Microscope	Standard method using CE marked kits.	MOL-LP-053
1075 Molecular genetics - .06 Assay for identified pathogenic variant(s)	Factor V Leiden	EDTA Whole Blood	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
	Prothrombin G20210A mutation		DNA Isolation	Magnapure 24	CE Marked	HAEMC-LP-071
1076 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Illumina AmpliSeq Tumour Hotspot Panel v2 Assay	DNA	Next Generation Sequencing	Illumina MiSeq	Based on Standard Method	MOL-LP-041

BRAF Mutation testing
BRCA NGS Assay
DNA Methylation Profiling
DNA Methylation Profiling (V2 kit)
EGFR Mutation testing
IDH Sequencing
Methylation Analysis of MLH1
MGMT Methylation
Microsatellite Instability Testing

Next Generation Sequencing Library Preparation followed by Next Generation Sequencing	Hamilton Microlab STAR and Illumina MiSeq	Non-CE and Based on Standard Method	MOL-LP-108 and MOL-LP-041
PCR	Roche COBAS z480	CE marked	MOL-LP-081
Next Generation Sequencing	Illumina MiSeq	Based on Standard Method	MOL-LP-052
Next Generation Sequencing Library Preparation followed by Next Generation Sequencing	Hamilton Microlab STAR and Illumina MiSeq	Non-CE and Based on Standard Method	MOL-LP-108 and MOL-LP-052
DNA Methylation profiling	Illumina iScan	Based on Standard Method	MOL-LP-070
DNA Methylation profiling	Illumina iScan	Standard method using CE/IVD marked kits.	MOL-LP-070
PCR	Roche COBAS z480	CE marked	MOL-LP-081
Pyrosequencing	Pyromark Q24	Based on Standard Method	MOL-LP-089
Pyrosequencing	Pyromark Q24	Based on Standard Method	MOL-LP-045
Pyrosequencing	Pyromark Q48	Based on Standard Method	MOL-LP-051
Pyrosequencing	Pyromark Q24	Based on Standard Method	MOL-LP-044
Pyrosequencing	Pyromark Q48	Based on Standard Method	MOL-LP-088
MSI Fragment Analysis	Fragment Analyser	Based on Standard Method	MOL-LP-074

1076 Molecular pathology - .04 Assay for somatic variants in gene structure	Array Comparative Genomic Hybridisation		Microarray based comparative genomic hybridisation	Molecular devices- Microarray scanner	Based on Standard Method	MOL-LP-087
	Detection of deletions or duplication in the BRCA1 and BRCA2 genes by Multiplex Ligation-Dependent Probe Amplification		MLPA Fragment Analysis	Fragment Analyser	Non-CE and Based on Standard Method	MOL-LP-103
1076 Molecular pathology - .99 Miscellaneous tests	BRAF Fusion	RNA	PCR	Real time PCR instrument	Based on Standard Method	MOL-LP-090

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
	Platelet count F		Fluorescence Flow Cytometry	1-5000 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 Sysmex sp50	CE Marked	HAEMG-LP-009 , 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	MGG	Bone Marrow Aspirate	Staining	N/A Multi Stainer/ or Aerospray Haematology Pro. Elitechgroup	CE Marked	HAEMG-LP-027 HAEMG-LP-017, HAEMG-LP-069. HAEMG-LP-019
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		Chromogenic	0.6 IU/mL to 2.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-056

Low Molecular Weight Heparin (LMWH)
Anti-Xa Rivaroxaban
D-Dimer
Factor II
Factor IX
Factor V
Factor VII
Factor VIII
Factor X
Factor XI
Factor XII
Fibrinogen
Free Protein S
International Normalised Ratio (INR)
Lupus Anticoagulants

Chromogenic	15 ng/mL to 1100 ng/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-056
Immuno-turbidimetric	0.22 ug/mL to 128 ug/mL, IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-006
Coagulometric(turbidimetric)	0.008 IU/mL to 1.5 IU/mL IL-Haemostasis ACL TOP	CE Marked	HAEMC-LP-014
Coagulometric(turbidimetric)	0.001 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
Coagulometric(turbidimetric)	0.005 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-014
Coagulometric(turbidimetric)	0.003 IU/mL - 1.5 IU/mL IL Haenostasis, ACL TOP	CE Marked	HAEMC-LP-014
Coagulometric(turbidimetric)	0.001 IU/mL-1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
Coagulometric(turbidimetric)	0.008 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-014
Coagulometric(turbidimetric)	0.001 IU/ml to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
Coagulometric(turbidimetric)	0.01 IU/mL to 1.5 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-017
Clotting (Clauss)	0.35 g/L to 10.0 g/L IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-066
Immuno-turbidimetric	0.073 IU/mL to 3.0 IU/mL IL-Haemostasis, ACL TOP	CE Marked	HAEMC-LP-055
Coagulometric(turbidimetric)	0.67 ISI to 26 ISI Dependent, IL- Haemostasis, ACL TOP	CE Marked	HAEMC-LP-068
Coagulometric(turbidimetric)	DRVVS = 16 to 240 secs, DRVVC = 16 to 121secs,	CE Marked	HAEMC-LP-070

				SCT: 10 to 400secs IL-Haemostasis, ACL TOP		
	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	Immune-Monitoring (T-helper cells & T, B, NK)		Flow Cytometry	0 - 100% BD FACSLytic & BD FACSDuet Premium	CE Marked	HAEMF-LP-007, HAEMF-LP-008
	Lymphoid Screening Tube (Lymphproliferative Screen)	Bone Marrow Aspirate/EDTA Whole Blood/ Lymph node Aspirate	Flow Cytometry	0 - 100% BD FACSLytic & BD FACSDuet Premium	CE Marked	HAEMF-LP-023
	T-cell panel	Bone Marrow Aspirate/EDTA Whole Blood	Flow Cytometry	0 to 100% BD FACSCanto II	CE Marked	HAEMF-LP-022

Head Office

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
	Embedding		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
			Automated/Tissue Tek VIP6	CE Marked	N/A	LP-HIS-VIPProc, LI-HIS-VIPProcProg
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cryotomy	Fresh section	Manual/Leica Cryotomy	Based on standard method	N/A	LP-HIS-Cryostat , LP-NEU-CryostatCM1900
	Cut Up	Human Tissue	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-FSUrgeant LP-HIS-FSProc LP-HIS-RapHE
	Frozen section cutting		Cryostat	Based on standard method	N/A	LP-HIS-Cryostat, LP-NEU-CryostatCM1900
1051 Histopathology - .03 Histochemistry	Alcian Blue Technique for Acid Mucins		Manual	Based on Standard Method	N/A	LP-HIS-SpAb
	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

DPAS	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
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 for Reticular Fibres	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
Gram Twort Stain for Demonstration of Bacteria	Human Tissue	Manual	Based on Standard Method	N/A	LP-HIS-SpGram
Grocott	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
Grocott Technique for PCP/Fungi	Human Tissue	Automated/Artisan	CE Marked	N/A	LP-HIS-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	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
MGG	Human Tissue	Manual	Based on Standard Method	N/A	LP-CYT-MGG
Mucicarmine	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
Oil Red O	Human Tissue Including Muscle	Manual	Based on Standard Method	N/A	LP-NEU-ORO

	PAS	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
	PASM		ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
	PERLs		ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
	Sirius Red/Congo Red - Amyloid Staining +/- (KMNO4) Pre-Treatment	Human Tissue	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	Human Tissue	ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
	ZN		ArtisanLinkPro	Based on standard method	N/A	LP-HIS-SpArtisanLink
1051 Histopathology - .035 Histological Interpretation	Diagnostic interpretation and reporting	Human Tissue	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
BCOR		Automated/Bond III	Non CE Marked	N/A	LP-NEU-BONDIII LP-NEU-SLIDESIHC
BEP63		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
BER EP4		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
BOB-1 Antibody		Immnohistochemistry Stain	CE Marked	N/A	LP-HIS-ImxBenRun , QF-HIS-ControlTissueDemo, LI-HIS-ImxPosCTRL, VPA-HIS-BOB
BRAF V600E		Automated/Benchmark Ultra	CE Marked	N/A	LP-NEU-BONDIII LP-NEU-SLIDESIHC
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
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

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
EZH1P IHC staining	Brain	Immnohistochemistry	Non-CE Marked	N/A	LP-NEU-BONDIII
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
HER4B5	Breast	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun, MP-HIS- ClinIntrepReporting

	Gastric	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun, MP-HIS- ClinIntrepReporting
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
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

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
NFKP1P65	Brain	Immunohistochemistry	Non-CE Marked	N/A	LP-NEU-BONDIII
NFSH	Human Tissue	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
NKAPIS		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
NL26		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII

NLAMB2
NLAMC
NLAMIS
NLAMP1
NLAMP2
NLH
NMEA
NMELA
NMER
NMHCS
NMSA
NNEST
NNEUN
NNF312
NOCT
NP62
NPL3F4 (CJD)
NPLAP
NPLASY (CJD)
NPLATU (CJD)
NPLBA4 (CJD)
NPLGFA (CJD)
NPRO
NSE

Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondMax	CE Marked	N/A	LP-NEU-BondMax
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Manual	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
Manual	CE Marked	N/A	LP-NEU-BondIII
Manual	CE Marked	N/A	LP-NEU-BondIII
Manual	CE Marked	N/A	LP-NEU-BondIII
Manual	CE Marked	N/A	LP-NEU-BondIII
Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
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
NYAP		Automated/BondIII	CE Marked	N/A	LP-NEU-BondIII
OCT3/4		Automated/Benchmark	CE Marked	N/A	LP-HIS-ImXBenRun
Oestrogen Receptor	Breast	Automated/Benchmark	CE Marked	N/A	LP-HIS-ImxBenRun
	Human Tissue	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- BondIHCDilution
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
Trimethylated	Brain	Immnohistochemistry	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
	Microtomy		Manual/Ultra Microtome	CE Marked	N/A	LP-EM-UltraThin LP- NEU-Microtomy
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	Human Tissue	Manual/Electron Microscope	Based on Standard Method	N/A	LP-HIS-RenPathServ
1051 Histopathology - .13 Molecular testing	Detection of PrPsc By Western Blotting in Query Creutzfeldt- Jakob disease Cases		CDIGIT BLOT Scanner/Western Blotting	Non CE Marked/Based on Standard Method	N/A	LP-NCJD- PRPWESTERN
	RT-QuIC	Cerebrospinal Fluid (CSF)	Real Time Quaking Induced Conversion Assay/BMG Labtech FLUOstar Omega Plate reader	Based on standard method	N/A	LP-NCJD RT-QuIC, VPA-NEU-RT-QuIC
1052 Cytopathology - .02 Non gynaecological cytology	PAP stain	Fluid	Automated/ Tissue Tek Prisma Stainer	Based on Standard Method	N/A	LP-CYT-Cytostainer, LI-CYT-PAPStain , LF-CYT-StainerCytCL
		Human Tissue	Automated/ Tissue Tek Prisma Stainer	Based on Standard Method	N/A	LP-CYT-Cytostainer, LI-HIS-

					H&ECytoStainer , LF-CYT-StainerCytCL, LF-CYT-MusCytoStainer
Liquid cytology PAP staining	Non-Gynaecological samples	Genesis Thin Prep Processor	Based on standard method	N/A	LP-CYT-TPPREP
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 Agar, MGG, H&E)	Fluid	Manual & Automated/Thin Prep	Based on Standard Method	N/A	LP-CYT-TPPrep LP-NEU-Agar LP-NEU-CSFCytology
Preparation of Specimens (ThinPrep, Agar, Cytopsin MGG, H&E)		Manual & Automated/ Tissue Tek Prisma Stainer	Based on Standard Method	N/A	LP-NEU-CSFCytology ,LF-CYT-CSFCytoStain
		Human Tissue	Manual & Automated/ Tissue Tek Prisma Stainer	Based on Standard Method	N/A
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 Interperation and Reporting of Non- Gycnaecological 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

Head Office

Immunology

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
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
	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 ≥480 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	1.7 MPLU/ml to ≥472 MPLU/ml	LP-IMM-ICAP0011
	Anti-Cyclic Citruinated Peptide Antibody (CCP)		Phadia 250/FEIA	CE	0.5 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	0.2 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 ≥240 U/ml	LP-IMM-ICAP0015

Anti-La Antibodies (La)		Phadia 250/FEIA	CE	0.4 U/mL to ≥ 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
Anti-Myeloperoxidase Antibodies (MPO)		PHADIA 250/FEIA	CE	0.2 IU/ml to ≥ 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-Proteinase-3 Antibodies (PR3)		Phadia 250/FEIA	CE	0.6 IU/ml to ≥ 177 IU/ml	LP-IMM-ICAP0004
Anti-Ribosomal P Antibodies		EUROBLOT ONE/Manual/Immunoblot	CE	N/A	LP-IMM-BLOT0001

Anti-RNP Antibodies(RNP)
Anti-Ro (RO) Antibodies
Anti-Scl-70 Antibodies (Scl-70)
Anti-Sm antibodies (Sm)
Anti-Thyroid Peroxidase Antibodies (TPO)
Anti-Tissue Transglutaminase Antibodies (TTG)
Connective Tissue Disease Screen (CTD)
Myositis Screen 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, cN-1A and HMGCR Antibodies
Scleroderma Panel including Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR and Ro-52

PHADIA 250/FEIA	CE	1 U/ml to ≥ 240 U/ml	LP-IMM-ICAP0015
Phadia 250/FEIA	CE	0.4 U/ml to ≥ 240 U/ml	LP-IMM-ICAP0015
Phadia 250/FEIA	CE	0.6 U/ml to ≥ 240 U/ml	LP-IMM-ICAP0015
FEIA/Phadia 250	CE	0.7 to ≥ 330 U/mL	LP-IMM-ICAP0015
COBAS 801 /Immunoassay	CE	9 IU/mL to 600 IU/mL	LP-IMM-IC0003
Phadia 250/FEIA	CE	0.2 EliA U/ml to ≥ 128 EliA U/ml	LP-IMM-ICAP0007
Phadia 250/FEIA	CE	0.2 - ≥ 32 ratio	LP-IMM-ICAP0012
Immunoblot Manual/EUROBLOT ONE	CE IVD KIT	N/A	LP-IMM-BLOT0003
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-dsDNA Crithidia 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 to 1/320	LP- IMM-IIF0003	
	Anti-Mitochondrial Antibodies (AMA)		HELIOS/HELMED/ Manual/ Indirect Immunofluorescence	CE	1/40 to 1/320	LP-IMM-IIF0003	
	Anti-Neuronal Antibodies	CSF		HELIOS/HELMED/ Manual/ Indirect Immunofluorescence	In-house developed	N/A	LP-IMM-IIF0008
		Serum		HELIOS/HELMED/ Manual/ Indirect Immunofluorescence	CE	1/50	LP-IMM-IIF0008
	Anti-Neutrophil Cytoplasmic Antibodies (ANCA)			HELIOS/HELMED/ Manual/ Indirect Immunofluorescence	CE	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/ 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 to 1/640	LP-IMM-IIF0007
	Anti-Smooth Muscle Antibodies (SMA)		HELIOS/HELMED/ Manual/ Indirect Immunofluorescence	CE	1/40 to 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 Anti-AMPA 1&2, Anti-GABAb, Anti-CASPR2, Anti-LGI1, Anti-DPPX, Anti-NMDA antibodies	CSF	Manual/Indirect Immunofluorescence	CE	N/A	LP-IMM-IIF0012
1040 Immunology - .99 Miscellaneous tests	Anti-SARS CoV-2 Nucleocapsid Antibodies	Serum	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/Immunoturbidimetric	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

Head Office

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 μL Leucocytes <1 μL to measured cell count per μL Erythrocytes <1 μL to measured cell count / μL	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	Microscopic Examination for Fungi	Nail, Skin, Scalp in sterile screw capped	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	using KOH Calcofluor White stain	container and or 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,	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

		Intravascular Cannulae, CSF Shunts, MRSA Swab, VRE Swab, CPE Swab, Bile, Ulcer Swabs, Environmental Specimens				
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

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 Immunochromatographic methods,	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
	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
	Detection of Streptococcus	Urine in sterile container	Manual/Rapid Immunochromatographic	CE Marked	N/A	LP-MIC-Urines

	pneumoniae Urinary Antigen		method/Alere BinaxNOW®			
	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	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
	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
	Eplex Respiratory Pathogen 2 Panel for the detection of SARS-Co-V-2	BAL (off-label)	Eplex® Instrument/ Automated ePlex® Respiratory Pathogen 2 Panel (GenMark Diagnostics Inc.) assay.	CE marked/In-house	N/A	LP-MIC-Respiratory viruses

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 Enteric Pathogens		Realtime PCR assay Roche LightCycler 480 II EntericBio Gastro 2	CE Marked	N/A	LP-MIC-Faeces
Molecular detection of M.tuberculosis Complex and Rifampicin Resistance in clinical specimens using the MTB/Rif Ultra	Sputum Specimens in sterile screw capped container	PCR/GeneXpert Cepheid GeneXpert DX16 Xpert MTB/RIF Ultra	CE Marked	N/A	LP-MIC-TB
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 Plus	Lysis Swab	PCR/GeneXpert Cepheid GeneXpert DX16	In House Developed	N/A	LP-MIC-Respiratory Viruses

	Xpert Xpress SARS Co-V-2 Plus	Nasopharyngeal swab/Lysis swab	PCR/GeneXpert Cepheid GeneXpert DX16	CE Marked/In House Developed	N/A	LP-MIC-Resp Viruses
	Xpert Xpress SARS Co-V-2/FLU/RSV Plus	Nasopharyngeal swab	PCR/GeneXpert Cepheid GeneXpert DX16	CE Marked	N/A	LP-MIC-RespViruses
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	API20E	Isolate	Fermentation Decarboxylation /Manual Biomérieux API20E	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 MALDI Sirius IVD system	CE Marked	N/A	LP-MIC-MALDI
	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
	Phenotypic confirmation of ESBLs		Manual Disc diffusion	In house developed	N/A	LP-MIC-Susceptibilities
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 Reference Laboratory, EQA Isolates, Other Isolates as Clinically Requested	Cryogenic Beads & Nutrient Agar Slopes/Freezer	CE Marked	N/A	LP-MIC-CSF LP-MIC-Respiratory LP-MIC-Urines 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