

Schedule of Accreditation



Organisation Name	HSE Mid West
Trading As	
INAB Reg No	303MT
Contact Name	Maria Hayes
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Accreditation Standard	EN ISO 15189
Date of award of accreditation	05/06/2012
Scope Classification	Microbiology and Virology
Scope Classification	Haematology
Scope Classification	Histopathology and Cytopathology
Scope Classification	Chemical Pathology
Services available to the public ¹	No

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	University Hospital Limerick	St. Nessian's Road, Dooradoyle, Limerick, Limerick, Ireland, V94 F858
2	Nenagh Pathology Laboratory	Tyone, Nenagh, Tipperary, E45 PT86
3	Ennis Hospital	Gort Road, Ennis, Clare, V95 HN29
4	Raheen Site - Microbiology	HSE Building, Ballycummin Avenue, Raheen Business Park, Limerick, Limerick, V94 D1W9

Scope of Accreditation

Ennis Hospital

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full blood count (FBC), White Cell Count **124 Red Cell Count **124 Haemoglobin **124 Haematocrit **124 MCV **124 MCH **124 MCHC **124 Platelet Count **124	EDTA	Automated	Sysmex XN series (XN10 and XN20)	CE/based on standard method	LP-L-HAE-EQPXN, LP-L-HAE-FBC-XNFBCDR
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination **124	peripheral blood film from EDTA	Manual Method with automated staining	Staining (RAL Stainer)/ Microscopy	CE/based on standard method	LP-E-HAE-FILMPREP, LP-E-HAE_EQP-RALSTAINER, LP-L-HAE-FLM-REPORT

1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte sedimentation rate (ESR)*124	EDTA	Automated	Automated Method- Starrsed ST	CE marked based on standard method	LP-L-HAE-STARRSED_ST, LP-L-HAE-EQP-STARRSED_ST
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential count **124		Automated	Sysmex XN series (XN10 and XN20)	CE/based on standard method	LP-L-HAE-EQPXN, LP-L-HAE-FBC-XNFBCHR
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte count **124		Automated	Sysmex XN series (XN10 and XN20)	CE/based on standard method	LP-L-HAE-EQPXN, LP-L-HAE-FBC-XNFBCHR
1030 Haematology - .41 General haemostasis related tests	APTT **1,2,4	Na Citrate	Clotting assay	Automated method - Stago STA-Compact Max	CE/based on Standard Method	LP-E-HAE-EQP-COMPACTMAX3, LP-E-HAE-APTT_COMPACTMAX
	D-Dimer **1,2,4		Immuno-turbidometric assay	Automated method - Stago STA-Compact Max	CE/based on Standard Method	LP-E-HAE-EQP-COMPACTMAX3, LP-E-HAE-DDIMER_COMPACTMAX
	PT / INR **1,2,4		Clotting assay	Automated method - Stago STA-Compact Max	CE/based on Standard Method	LP-E-HAE-EQP-COMPACTMAX3, LP-E-HAE-DDIMER_COMPACTMAX
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious mononucleosis screen **124	Serum / Plasma	Manual method - immunological	Rapid immunoassay - Clearview IM II kit	CE/based on standard method	LP-L-HAE-MAN-MONOSP

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

Nenagh Pathology Laboratory

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/ ALTPM	Serum/ Plasma (Li Heparin)	Enzymatic, colorimetric with pyridoxal phosphate	Roche Cobas c303/ 5-700 U/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Albumin BCP/ ALBP		Colorimetric	Roche Cobas c303/ 2.0-100 g/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Alkaline Phosphate/ ALP2		Colorimetric	Roche Cobas c303/ 5-1200 U/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Amylase/ AMYL2		Enzymatic, colorimetric	Roche Cobas c303/ 3-1500 U/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Bilirubin Total/ BILT3		Colorimetric diazo	Roche Cobas c303/ 2.5-650 μ mol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Calcium/ CA2		Photometric/NM-BAPTA	Roche Cobas c303/ 0.2-5.0 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Chloride/ Chloride		Indirect ISE	Roche Cobas c303/ 60-140 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
	Creatine Kinase/ CK2		UV, enzymatic reference with hexokinase	Roche Cobas c303/ 7.0-2000 U/L	CE marked	LP-N-BIO-COBAS PURE TESTS

Creatinine/ CREP2		Enzymatic, colorimetric	Roche Cobas c303/ 5.0-2700 µmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Gamma Glutamyl Transferase/ GGT-2 Change to GGT (appropriate test abbreviation)		Enzymatic, colorimetric	Roche Cobas c303/ 3-1200 U/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Glucose/ GLUC3	Plasma (flouride oxalate)	UV, enzymatic reference with hexokinase	Roche Cobas c303/ 0.11-41.6 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Lactate dehydrogenase/ LDHI2	Serum/ Plasma (Li Heparin)	UV	Roche Cobas c303/ 10-1000 U/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Magnesium/ MG2		Colorimetric	Roche Cobas c303/ 0.1-2.0 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Phosphate (Inorganic)/ PHOS2		Molybdate UV	Roche Cobas c303/ 0.10-6.46 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Potassium/ Potassium		Indirect ISE	Roche Cobas c303/ 1.5-10 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Sodium/ Sodium		Indirect ISE	Roche Cobas c303/ 80-180 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Total Protein/ TP2		Colorimetric	Roche Cobas c303/ 2.0-120 g/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Troponin T hs/ TNT-HS	Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas e402/ 3-10000 ng/L	CE marked	LP-N-BIO-COBAS PURE TESTS
Urate/ UA2	Serum/ Plasma (Li Heparin)	Enzymatic, colorimetric	Roche Cobas c303/ 11.9-1487 µmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS

	Urea/ UREAL		Enzymatic	Roche Cobas c303/ 0.5-40 mmol/L	CE marked	LP-N-BIO-COBAS PURE TESTS
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	C-reactive protein/ CRP4		Particle-enhanced immunoturbidimetric	Roche Cobas c303/ 0.6-350 mg/L	CE marked	LP-N-BIO-COBAS PURE TESTS
1061 Clinical Chemistry - .99 Miscellaneous tests	Adjusted calcium		Calculated	Roche Cobas 8000	CE marked	LI-L-BIO- CALCTESTS
	CKD-EPI GFR		Calculated	Roche Cobas 8000	CE marked	LI-L-BIO- CALCTESTS

Nenagh Pathology Laboratory

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count (FBC), White Cell Count **124 Red Cell Count **124 Haemoglobin **124 Haematocrit **124 MCV **124 MCH **124 MCHC **124 Platelet Count **124	EDTA	Automated	Automated method- Sysmex XN-550	CE/based on standard method	LP-N-HAE-XN550FBC LP-N-HAE-XN550
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte sedimentation rate **124		Automated	Automated method- Starrsed ST	CE/based on standard method	LP-L-HAE-STARRSED_ST; LP-L-HAE-EQP-STARRSED_ST;
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential leucocyte count **124		Automated	Automated method- Sysmex XN-550	CE/based on standard method	LP-N-HAE-XN550FBC LP-N-HAE-XN550
1030 Haematology - .06 Automated reticulocyte counts	Automated reticulocyte count **124		Automated	Automated method- Sysmex XN-550	CE/based on standard method	LP-N-HAE-XN550FBC LP-N-HAE-XN550
1030 Haematology - .41 General haemostasis related tests	D-Dimer **124	Sodium Citrate	Automated	AQT90 Flex Analyser	CE/ based on standard method	LP-N-HAE-AQTDD & LP-N-HAE-EQPAQT

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

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Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

Raheen Site - Microbiology

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
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: Mycobacteria	Bone marrow, Broncheolar lavage, bronchial aspirate, Bone, Blood, CAPD, CSF, Pleural fluid, Fluid from normally sterile sites, Gastric washing, Pus, Skin/ Tissue Biopsies, Sputum, early morning urine, swabs	Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of mycobacteria	UK Standards for Microbiology Investigations Bacteriology – Staining Procedures TP 39 UK standards for Microbiology SMI B40	Qualitative	LP-L-MIC-TB
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Investigation of specimens for Mycobacterium species/Culture; Instrument monitoring for growth Biomerieux MB Bact Alert ® **34	Bone marrow, Broncheolar lavage, bronchial aspirate, Bone, Blood, CAPD, CSF, Pleural fluid, Sterile body fluid, Gastric washing, Pus, Post-mortem specimens, Skin/ Tissue Biopsies, Sputum, early morning urine, swabs	MB Bact Alert/ semi-automated liquid and solid media culture	UK standards for Microbiology SMI B40	Qualitative	LP-L-MIC-TB
1014 Detection of bacterial, parasite, viral or	MGIT™ TBc Identification test	Acid and alcohol fast (AAFB) smear	Manual/chromatographic immunoassay	CE	Qualitative	LP-L-MIC-TB

fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	qualitative detection of MTBc antigen/MGIT™TBc Identification test **4	positive Liquid cultures				
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University Hospital Limerick

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	Serum/ Plasma (Li Heparin)	Enzymatic, colorimetric with pyridoxal phosphate	Roche Cobas 8000/ 5-700 U/L	CE marked	LP-L-BIO-C8000 Test
	Albumin BCP		Colorimetric	Roche Cobas 8000/ 2.0-100 g/L	CE marked	LP-L-BIO-C8000 Test
	Alkaline Phosphate		Colorimetric	Roche Cobas 8000/ 5-1200 U/L	CE marked	LP-L-BIO-C8000 Test
	Ammonia	Plasma (EDTA)	Enzymatic	Roche Cobas 8000/ 10-1000 µmol/L	CE marked	LP-L-BIO-C8000 Test
	Amylase	Serum/ Plasma (Li Heparin)	Enzymatic, colorimetric	Roche Cobas 8000/ 3-1500 U/L	CE marked	LP-L-BIO-C8000 Test
	Aspartate Amino Transferase		Enzymatic, colorimetric with pyridoxal phosphate	Roche Cobas 8000/ 5-700 U/L	CE marked	LP-L-BIO-C8000 Test
	Bicarbonate		Enzymatic	Roche Cobas 8000/ 2.0-50 mmol/L	CE marked	LP-L-BIO-C8000 Test
	Bilirubin Direct		Diazo	Roche Cobas 8000/ 1.2-236 µmol/L	CE marked	LP-L-BIO-C8000 Test

Bilirubin Total		Colorimetric diazo	Roche Cobas 8000/ 2.5-550 µmol/L	CE marked	LP-L-BIO-C8000 Test
Calcium		Photometric/NM-BAPTA	Roche Cobas 8000/ 0.2-5.0 mmol/L	CE marked	LP-L-BIO-C8000 Test
Chloride/ Chloride		Indirect ISE	Roche Cobas 8000/ 60-140 mmol/L	CE marked	LP-L-BIO-C8000 Test
Cholesterol		Enzymatic, colorimetric	Roche Cobas 8000/ 0.1-20.7 mmol/L	CE marked	LP-L-BIO-C8000 Test
Creatine Kinase		UV, enzymatic reference with hexokinase	Roche Cobas 8000/ 7.0-2000 U/L	CE marked	LP-L-BIO-C8000 Test
Creatinine		Enzymatic, colorimetric	Roche Cobas 8000/ 5.0-2700 µmol/L	CE marked	LP-L-BIO-C8000 Test
Gamma Glutamyl Transferase		Enzymatic, colorimetric	Roche Cobas 8000/ 3-1200 U/L	CE marked	LP-L-BIO-C8000 Test
Glucose	Plasma (fluoride oxalate)	UV, enzymatic reference with hexokinase	Roche Cobas 8000/ 0.11-41.6 mmol/L	CE marked	LP-L-BIO-C8000 Test
High Density Lipoprotein (HDL)	Serum/ Plasma (Li Heparin)	Enzymatic, colorimetric	Roche Cobas 8000/ 0.08-3.88 mmol/L	CE marked	LP-L-BIO-C8000 Test
Lactate	Plasma (fluoride oxalate)	Colorimetric	Roche Cobas 8000/ 0.2-15.5 mmol/L	CE marked	LP-L-BIO-C8000 Test
Lactate dehydrogenase	Serum/ Plasma (Li Heparin)	UV	Roche Cobas 8000/ 10-1000 U/L	CE marked	LP-L-BIO-C8000 Test
Low Density Lipoprotein (LDL)		Enzymatic, colorimetric	Roche Cobas 8000/ 0.1-14.2 mmol/L	CE marked	LP-L-BIO-C8000 Test

	Magnesium		Colorimetric	Roche Cobas 8000/ 0.1-2.0 mmol/L	CE marked	LP-L-BIO-C8000 Test
	NT pro BNP		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 5.0-35000 ng/L	CE marked	LP-L-BIO-C8000 Test
	Phosphate (Inorganic)		Molybdate UV	Roche Cobas 8000/ 0.1-6.46 mmol/L	CE marked	LP-L-BIO-C8000 Test
	Potassium/ Potassium		Indirect ISE	Roche Cobas 8000/ 1.5-10 mmol/L	CE marked	LP-L-BIO-C8000 Test
	Sodium/ Sodium		Indirect ISE	Roche Cobas 8000/ 80-180 mmol/L	CE marked	LP-L-BIO-C8000 Test
	Total Protein		Colorimetric	Roche Cobas 8000/ 2.0-120 g/L	CE marked	LP-L-BIO-C8000 Test
	Triglycerides		Enzymatic, colorimetric	Roche Cobas 8000/ 0.1-10.0 mmol/L	CE marked	LP-L-BIO-C8000 Test
	Troponin T hs	Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 3-10000 ng/L	CE marked	LP-L-BIO-C8000 Test
	Urate	Serum/ Plasma (Li Heparin)	Enzymatic, colorimetric	Roche Cobas 8000/ 11.9-1487 µmol/L	CE marked	LP-L-BIO-C8000 Test
	Urea		Enzymatic	Roche Cobas 8000/ 0.5-40 mmol/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Alpha 1 Antitrypsin		Immunoturbidimetric	Roche Cobas 8000/ 0.2-6.0 g/L	CE marked	LP-L-BIO-C8000 Test
	Caeruloplasmin		Immunoturbidimetric	Roche Cobas 8000/ 0.03-1.4 g/L	CE marked	LP-L-BIO-C8000 Test

	C-reactive protein		Particle-enhanced immunoturbidimetric	Roche Cobas 8000/ 0.6-350 mg/L	CE marked	LP-L-BIO-C8000 Test
	Interleukin 6		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 1.5-5000 ng/L	CE marked	LP-L-BIO-C8000 Test
	Procalcitonin		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.02-100 µg/L	CE marked	LP-L-BIO-C8000 Test
	Thyroid specific peroxidase		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 9.0-600 kU/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Glycohaemoglobins	EDTA	Automated	Automated Methof-Tosoh G11	CE marked/based on standard method	LP-L-BS-HBA1C, LP-L-BS-EQP-G11
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Carbamazepine	Serum/ Plasma (Li Heparin)	Kinetic interaction of microparticles Immunoassay	Roche Cobas 8000/ 2-20 mg/L	CE marked	LP-L-BIO-C8000 Test
	Digoxin		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.2-5.0 µg/L	CE marked	LP-L-BIO-C8000 Test
	Lithium	Serum	Colorimetric	Roche Cobas 8000/ 0.05-3.0 mmol/L	CE marked	LP-L-BIO-C8000 Test
	Phenobarbital	Serum/ Plasma (Li Heparin)	Kinetic interaction of microparticles Immunoassay	Roche Cobas 8000/ 2.4-60 mg/L	CE marked	LP-L-BIO-C8000 Test
	Phenytoin		Kinetic interaction of microparticles Immunoassay	Roche Cobas 8000/ 0.8-40 mg/L	CE marked	LP-L-BIO-C8000 Test
	Theophylline		Kinetic interaction of microparticles Immunoassay	Roche Cobas 8000/ 0.8-40 mg/L	CE marked	LP-L-BIO-C8000 Test

	Valproate		Homogeneous Enzyme Immunoassay	Roche Cobas 8000/ 2.8-150 mg/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol		Enzymatic	Roche Cobas 8000/ 10.1-498 mg/dL	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol		Enzymatic, colorimetric	Roche Cobas 8000/ 1.2-500 mg/L	CE marked	LP-L-BIO-C8000 Test
	Salicylate		Enzymatic, colorimetric	Roche Cobas 8000/ 3.0-700 mg/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .20 Hormones	C Peptide/CPEPTID	Serum	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.007-13.3nmol/L	CE marked	LP-L-BIO-C8000 Test
	Cortisol	Serum/ Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 1.5-1750 nmol/L	CE marked	LP-L-BIO-C8000 Test
	DHEAS		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.005-27.1 µmol/L	CE marked	LP-L-BIO-C8000 Test
	Follicle Stimulating Hormone		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.3-200 U/L	CE marked	LP-L-BIO-C8000 Test
	Free T3		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.6-50 pmol/L	CE marked	LP-L-BIO-C8000 Test
	Free T4		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.5-100 pmol/L	CE marked	LP-L-BIO-C8000 Test
	HCG/ HCG-BETA		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.2-10000 U/L	CE marked	LP-L-BIO-C8000 Test

1061 Clinical Chemistry - .40 Iron studies	Insulin/INSULIN	Serum	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 2.78-6945 pmol/L	CE marked	LP-L-BIO-C8000 Test
	Luteinizing Hormone	Serum/ Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.3-200 U/L	CE marked	LP-L-BIO-C8000 Test
	Oestradiol		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 18.4-11010 pmol/L	CE marked	LP-L-BIO-C8000 Test
	Parathyroid Hormone	Plasma (EDTA)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 1.2-5000 ng/L	CE marked	LP-L-BIO-C8000 Test
	Parathyroid Hormone/ PTH		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 2.4-5000 ng/L	CE marked	LP-L-BIO-C8000 Test
	Progesterone	Serum/ Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.159-191 nmol/L	CE marked	LP-L-BIO-C8000 Test
	Prolactin		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 2.0-10000 mU/L	CE marked	LP-L-BIO-C8000 Test
	Sex Hormone Binding Globulin (SHBG)		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.8-200 nmol/L	CE marked	LP-L-BIO-C8000 Test
	Testosterone		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.087-52 nmol/L	CE marked	LP-L-BIO-C8000 Test
	Thyroid stimulating Hormone		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.005-100 mU/L	CE marked	LP-L-BIO-C8000 Test
	Ferritin		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.5 - 2000 ng/mL	CE marked	LP-L-BIO-C8000 Test

	Iron		Colorimetric	Roche Cobas 8000/ 0.9-179 µmol/L	CE marked	LP-L-BIO-C8000 Test
	Transferrin		Immunturbidimetric	Roche Cobas 8000/ 0.1-5.2 g/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate/FOL	Serum/ Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.6-20 ng/mL	CE marked	LP-L-BIO-C8000 Test
	Vitamin B12	Serum/ Plasma (Li Heparin)	Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 100 - 2000 pg/mL	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .47 Vitamin assays	Folate		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.6 - 20 ng/mL	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.9-1210 ng/mL	CE marked	LP-L-BIO-C8000 Test
	CA 15-3		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 1.5-300 kU/L	CE marked	LP-L-BIO-C8000 Test
	CA 19-9		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 2-1000 kU/L	CE marked	LP-L-BIO-C8000 Test
	CA-125		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.6-5000 kU/L	CE marked	LP-L-BIO-C8000 Test
	Carcinoembryonic antigen		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.3-1000 ug/L	CE marked	LP-L-BIO-C8000 Test
	Total PSA		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.006-100 µg/L	CE marked	LP-L-BIO-C8000 Test
	Vitamin D total III		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 7.5-300 nmol/L	CE marked	LP-L-BIO-C8000 Test

1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin IgA		Immunoturbidimetric	Roche Cobas 8000/ 0.5-8 g/L	CE marked	LP-L-BIO-C8000 Test
	Immunoglobulin IgG		Immunoturbidimetric	Roche Cobas 8000/ 3.0-50 g/L	CE marked	LP-L-BIO-C8000 Test
	Immunoglobulin IgM		Immunoturbidimetric	Roche Cobas 8000/ 0.25-6.5 g/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .82 Total IgE	Total Immunoglobulin IgE		Electrochemiluminescence Immunoassay	Roche Cobas 8000/ 0.2-2500 kUA/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .86 C3 and C4	Complement C3		Immunoturbidimetric	Roche Cobas 8000/ 0.04-5 g/L	CE marked	LP-L-BIO-C8000 Test
	Complement C4		Immunoturbidimetric	Roche Cobas 8000/ 0.02-1.0 g/L	CE marked	LP-L-BIO-C8000 Test
1061 Clinical Chemistry - .99 Miscellaneous tests	Adjusted calcium		Calculated	Roche Cobas 8000. Calculated in APEX/ILAB	CE marked	LI-L-BIO-CALCTESTS
	Calculated Free Testosterone		Calculated	Roche Cobas 8000. Calculated in APEX/ILAB	CE marked	LI-L-BIO-CALCTESTS
	CKD-EPI GFR		Calculated	Roche Cobas 8000. Calculated in APEX/ILAB	CE marked	LI-L-BIO-CALCTESTS
	FIB-4 Score	Serum/ Plasma (Li Heparin)/ Plasma EDTA (Platelet)	Calculated	Roche Cobas 8000. Calculated in APEX/ILAB	CE marked	LI-L-BIO-CALCTESTS
	Non-HDL Cholesterol	Serum/ Plasma (Li Heparin)	Calculated	Roche Cobas 8000.	CE marked	LI-L-BIO-CALCTESTS

			Calculated in APEX/ILAB		
Osmolality	Serum/ Plasma (Li Heparin) and urine	Freezing point depression	Advanced Instruments OsmoPro Micro- osmometer/ 0 - 2000 mOsm/kg H2O	CE marked	LP-L-BIO-OSMOPRO
Total iron-binding capacity	Serum/ Plasma (Li Heparin)	Calculated	Roche Cobas 8000. Calculated in APEX/ILAB	CE marked	LI-L-BIO- CALCTESTS
Transferrin Saturation		Calculated	Roche Cobas 8000. Calculated in APEX/ILAB	CE marked	LI-L-BIO- CALCTESTS

University Hospital Limerick

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count (FBC), White Cell Count **124 Red Cell Count **124 Haemoglobin **124 Haematocrit **124 MCV **124 MCH **124 MCHC **124 Platelet Count **124	EDTA	Automated	Automated Method – Sysmex XN-9100	CE / based on standard method	LP-L-HAE-FBC-XNFBCDR, LP-L-HAE-EQPXN
1030 Haematology - .02 Visual examination of blood films	Blood film **124	Peripheral Blood Film	Staining / microscopy	Automated method – Sysmex SP50	CE/based on standard method	LI-L-HAE-FLM-MAN, LP-L-HAE-FLM-REPORT, LP-L-HAE-FLM-STAIN, LP-L-HAE-EQP-SP50
		Peripheral Blood Film	Staining / microscopy	Manual method	CE/based on standard method	LI-L-HAE-FLM-MAN LP-L-HAE-FLM-REPORT LP-L-HAE-FLM-STAIN LP-L-HAE-EQP-HEMATEK
	Manual differentials **124		Staining / microscopy	Manual method	CE/based on standard method	LI-L-HAE-FLM-DIFFM

1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate **124	EDTA	Westergen method	Automated method – Interliner RL	CE/based on standard method	LP-L-HAE-EQPSTARRSEDRLRS, LP-L-HAE-STARRSED_RLRS.
	Erythrocyte Sedimentation Rate **124		Westergen method	Automated method – Starrsed RS	CE/based on standard method	LP-L-HAE-EQPSTARRSEDRLRS, LP-L-HAE-STARRSED_RLRS.
1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential count **124		Automated	Automated Method – Sysmex XN-9100	CE / based on standard method	LP-L-HAE-FBC-XNFBCCR, LP-L-HAE-EQPXN
1030 Haematology - .06 Automated reticulocyte counts	Automated reticulocyte count **124		Automated	Automated Method – Sysmex XN-9100	CE / based on standard method	LP-L-HAE-FBC-XNFBCCR, LP-L-HAE-EQPXN
1030 Haematology - .08 Blood film examinations involving special staining procedures	Perls prussian blue stain **1234	EDTA	Staining / microscopy	Manual method	CE/based on standard method	LP-L-HAE-FLM-PPB
1030 Haematology - .09 Examination of malarial parasites	Malaria and DNA Amplification Assay **4	Whole Blood	Molecular Assay based on Loop-Mediated Amplification(LAMP) technology	Automated - Meridian ILLUMIPRO-10	CE/based on standard method	LP-L-HAE-FLM-ILLUMIGENE & LP-L-HAE-EQP-ILLUMIPRO
	Malaria antigen **124	Plasma	Immunochromatographic test	Manual method	CE/based on standard method	LP-L-HAE-FLM-MALAB
	Malaria film **124	EDTA	Staining / microscopy	Manual method	CE/based on standard method	LP-L-HAE-FLM-MALST
1030 Haematology - .20 Bone marrow examination	Bone marrow aspirates **124	Blood	Staining / microscopy	Manual method	CE/based on standard method	LP-L-HAE-FLM-BM
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle screening **124	EDTA	Qualitative solubility test	Manual method	CE/based on standard method	LP-L-HAE-MAN-SICKLP

1030 Haematology - .40 Limited haemostasis related tests	Activated Protein C Resistance assay **124	Citratd Plasma	Clotting assay	Automated method - Stago STA-R Max	CE/Based on standard method	LP-L-HAE-COA-APC- R, LI-L-HAE-COA- SPIN, LP-L-HAE-COA- SPEC, LP-L-HAE- EQP-STA-R
	Antithrombin III assay **124		Colorimetric/Chromogenic assay	Automated method - Stago STA-R Max	CE/Based on Standard method	LP-L-HAE-COA-ATIII, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-COA-TPHIL, LP-L-HAE-EQP-STA-R
	Anti-Xa assay **124		Colorimetric/Chromogenic assay	Automated method - Stago STA-R Max	CE/Based on Standard Method	LP-L-HAE-COA-XA, LI- L-HAE-COA-SPIN, LP- L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
	Apixaban **124		Colorimetric/ Chromogenic assay	Automated method - Stago STA-R Max	CE marked based on standard method	LP-L-HAE-COA-DOAC, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
	APTT **124		Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method	LP-L-HAE-COA-APTT, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
	Ddimer **124		Immunoturbidometric assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA- DDIMER, LI-L-HAE- COA-SPIN, LP-L-HAE- COA-SPEC, LP-L- HAE-EQP-STA-R
	Factor II assay **124		Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA- EXFACT, LI-L-HAE- COA-SPIN, LP-L-HAE- COA-SPEC, LP-L- HAE-EQP-STA-R
	Factor IX assay **124		Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method	LP-L-HAE-COA- INFACT, LI-L-HAE- COA-SPIN, LP-L-HAE-

Factor V assay **124
Factor VII assay **124
Factor VIII assay **124
Factor X assay **124
Factor XI assay **124
Factor XII assay **124
Fibrinogen **124

			COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-EXFACT, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method	LP-L-HAE-COA-EXFACT, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-INFAC, LP-L-HAE-COA-LOVIII, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-EXFACT, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method	LP-L-HAE-COA-INFAC, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-FXII, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-FIB, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R

Free Protein S assay **124
Lupus Like Anticoagulant **124
Mixing studies **124
Protein C **124
Protein S **124
PT/INR **124
Reptilase **124

Immunoturbidometric assay	Automated method - Stago STA-R Max	CE/based on standard method	LP-L-HAE-COA-FREEPS, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-COA-TPHIL, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-LLA, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard methods.	LP-L-HAE-COA-MIX, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Colorimetric/Chromogenic assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-PROTC, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-COA-TPHIL, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-PROTS, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-COA-TPHIL, LP-L-HAE-EQP-STA-R
Clotting assay / ratio calculation	Automated method - Stago STA-R Max	CE/based on standard method	LP-L-HAE-COA-PTINR, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
Clotting assay	Automated method - Stago STA-R Max	CE/based on standard method.	LP-L-HAE-COA-TTREET, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R

	Rivaroxaban **124		Colorimetric/Chromogenic assay	Automated method - Stago STA-R Max	CE marked based on standard method	LP-L-HAE-COA-DOAC, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
	Thrombin Time **124		Clotting assay	Automated method - Stago STA-R Max		LP-L-HAE-COA-TTREPT, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
	Vwf Antigen Assay **124		Immunoturbidometric assay	Automated method - Stago STA-R Max		LP-L-HAE-COA-VWF, LI-L-HAE-COA-SPIN, LP-L-HAE-COA-SPEC, LP-L-HAE-EQP-STA-R
1030 Haematology - .45 Tests of platelet function	Ristocetin cofactor assay **124		Platelet aggregation	Automated - Sysmex	CE/based on standard method	LP-L-HAE-COA-RI_COF
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious mononucleosis screen **124	Serum / plasma	Manual method - immunological	Rapid immunoassay - Clearview IM II kit	CE/based on standard method	LP-L-HAE-MAN-MONOSP
1030 Haematology - .62 Plasma viscosity	Plasma viscosity **124	EDTA / plasma	Capillary method	Benson Viscometer BV1	CE/based on standard method	LP-L-HAE-MAN-PVISC LP-L-HAE-EQP-BENSON
1030 Haematology - .70 Immunophenotyping	Immune monitoring Antigens Tested: CD3, CD4, CD8, CD19, CD56/16 **1234	EDTA	Immunophenotyping	Automated method BD FacsLyric Flow Cytometer	CE / based on standard method	LP-L-HAE-FLO-IMMUNEMON LP-L-HAE-EQPFACSLyric LP-L-HAE-EQP-Integrated BDFACSLyric BD FACS Duet system

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.



University Hospital Limerick

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	Coverslipping	Stained slides Human Breast Tissue and Human Lung Tissue	Ventana-HE 600 (automated)	CE Marked	Qualitative test	LP-L-HIS-HE600
	Cut-Up	Human Breast Tissue Human Lung Tissue	Manual (Knives, scalpels, dyes etc)	CE Marked	Qualitative test	LP-L-HIS-RECEPT, LP-L-HIS-LABCASS, LP-L-HIS-MSCUTUP, LP-L-HIS-CUTUP, LP-L-HIS-DAYLIST, ,LP-L-HIS-APEX, LP-L-HIS-HDBREAST
	Embedding	Paraffin infiltrated Human Breast and Human Lung Tissue	Sakura Tissuetek Tec 6 Manual embedding centre & Cold Plate Automated Sakura A120 autoembedder	CE Marked	Qualitative test	LP-L-HIS-EMBEDD, LP-L-HIS-A120AUTOEMBED
	H+E staining	Paraffin wax tissue sections Human Breast Tissue and Human Lung Tissue	Ventana-HE 600 (automated)	CE Marked	Qualitative test	LP-L-HIS-HE600
	Microtomy	Paraffin wax blocks Human Breast and Human Lung Tissue	Sakura Autosection & Leica Histocut	CE Marked	Qualitative test	LP-L-HIS-MICROTOMY

	Tissue Processing	Formalin fixed Human Breast and Human Lung Tissue	Sakura VIPA1 Automated Vacuum Infiltration Processor	CE Marked	Qualitative test	LP-L-HIS-TISTEKVIP6AI
1051 Histopathology - .03 Histochemistry	AFB / ZN	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	Alcian Blue		Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	Alcian Blue / PAS		Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	Congo Red		Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	Fe (Iron) Perls Prussian Blue	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	Grocotts Methenamine Silver	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	Massons Trichrome	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	PAS		Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
	PASD (Diastase)	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN

	Reticulin		Ventana Benchmark (automated) Special Stains	CE Marked	Qualitative test	LP-L-HIS-BMSPECSTAIN
1051 Histopathology - .035 Histological Interpretation	Human Breast Tissue and Human Lung Tissue	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Microscopic Examination	Based on standard methods	Qualitative test	LP-L-HIS-SORTING, LP-L-HIS-G2DDVR, LP-L-LOF-REPTYP, MP-L-HIS-REPORT
1051 Histopathology - .09 Immunohistochemistry	Immunohistochemistry Optiview DAB Detection Kit: AE1/3, ALK-1, BCL2, BCL6, Calretenin, CA125, CAM5.2, Calcitonin, CD2, CD3, CD4, CD5, CD8, CD10, CD15, CD20, CD21, CD23, CD30, CD31, CD34, CD56 (NCAM), CD68, CD79A, CD99, CD138, CDX2, CEA, Chromogranin, CLA, CK5/6, CK7, CK19, CK20, CK903, C-KIT (CD117), Cyclin D1, c-MYC, dESMIN, dog1, d2-40, E-Cadherin, EMA, Epithelial Antigen, GATA-3, HBME, HCG, Ki-67, Mammaglobin, MUM1, Napsin, NSE, Oct-4, PAX-8, p16, p40, p53, p57, p63, p504s (AMACR), PLAP, PSA, PSAP, SATB2, SMA, SOX-10, Synaptophysin,	Glass slides – Human Breast Tissue and Human Lung Tissue	Immunohistochemistry Staining - Ventana Benchmark Ultra	CE Marked	Qualitative test	LP-L-HIS-BMKULTRA

	Thyroglobulin, TTF-1, Vimentin, WT-1.					
	Immunohistochemistry Ultraview Phosphatase Red Detection Kit: HMB45, MART-1, PRAME, S100, SOX-10	Glass slides – tissue sections Human Breast Tissue and Human Lung Tissue	Immunohistochemistry Staining - Ventana Benchmark Ultra	CE Marked	Qualitative test	LP-L-HIS-BMKULTRA
	Immunohistochemistry Ultraview Universal DAB Detection Kit: HER2/neu IHC, Oestrogen Receptor, Progesterone Reception.	Glass slides – tissue sections Human Breast Tissue	Immunohistochemistry Staining - Ventana Benchmark Ultra	CE Marked	Qualitative test	LP-L-HIS-BMKULTRA
	Immunohistochemistry: Ventana Red ISH DIG Detection Kit (DDISH)	Glass slides – tissue sections Human Breast Tissue	Immunohistochemistry Staining - Ventana Benchmark Ultra	CE Marked	Qualitative test	LP-L-HIS-BMKULTRA, LP-L-HIS-HER2DUALISH
	Immunohistochemistry: Ventana Silver ISH DNP Detection Kit (DDISH)	Glass slides – tissue sections Human Breast Tissue	Immunohistochemistry Staining - Ventana Benchmark Ultra	CE Marked	Qualitative test	LP-L-HIS-BMKULTRA, LP-L-HIS-HER2DUALISH

University Hospital Limerick

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: Sputum CSF Fluids **3	CAPD Fluid CSF Other body fluids Pleural fluid Sputum	Manual observation	UK standards for Microbiology SMI B25 ; SMI B26; SMI B27; SMI B57	Qualitative	LP-L-MIC-CAPD LP-L-MIC-FLUID LP-L-MIC- PLEURALFL LP-L-MIC-CSF LP-L-MIC-SPUTA
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)	Automated Urine Microscopy **234	Human Urine	Sysmex UF5000/Automated particle counting	CE/ UK standards for Microbiology SMI B 41	semi-quantitative	LP-L-MIC-URINE LP-L-MIC- EQP-UF5000
	Manual Microscopy/KOVA standardized microscopic analysis **34	Fluids from normally sterile Sites	CE/KOVA ® slide Glasstic™ Slide 10	UK standards for Microbiology SMI B25 ; SMI B26; SMI B27; SMI B57	semi-quantitative	LP-L-MIC-CAPD LP-L-MIC-FLUID LP-L-MIC- PLEURALFL LP-L-MIC-CSF LP-L-MIC-SPUTA

	Manual Urine Microscopy/KOVA standardized microscopic analysis **4	Human Urine	CE/KOVA ® slide Glasstic™ Slide 10	CE/ UK standards for Microbiology SMI B 41	semi-quantitative	LP-L-MIC-URINE
	Microscopic examination of: General Bacteriology **234	Swabs, Blood Cultures, Bone marrow, Bone and associated soft tissue, Peritoneal dialysis fluid (CAPD), Corneal scrapings, CSF, Normally sterile body fluids, Pleural Fluid, Aspirates / Pus/ Exudates, Genitourinary (GUM) specimens, Tissue / biopsies	Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of bacteria and human cells	UK standards for Microbiology TP 39	Qualitative	LI-L-MIC-TISSUE, LI-L-MIC-TISSUORCM, LP-L-MIC-BC, LP-L-MIC-CAPD, LP-L-MIC-CSF, LP-L-MIC-FLUID, LP-L-MIC-GENITAL, LP-L-MIC-PLEURALFL, LI-L-MIC-EYES LP-L-MIC-GRAM
	1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Investigation of Bacterial Eye Infections/ Culture of: General bacteria **34	Eye related samples	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B2; UK SMI S 11	Qualitative LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-EYES
	Carbapenemase Producing Enterobacterales (CPE) Investigation/ Culture of: General bacteria **34	Multidrug Resistant Screening - Faeces/Swab of faeces/Ileostomy swab / Rectal swab / Stool. NB: Local screening policy applies. Microbiological	Manual/ Based on Standard Methods	HPSC Guidelines for the Prevention and Control of Multi-drug resistant organisms (MDRO) excluding MRSA in the healthcare setting UK standards for	Qualitative	LP-L-MC-CPE

	cultures of Enterobacteriaceae		Microbiology SMI B60 EUCAST guidelines for detection of resistance and specific resistances of clinical and/or epidemiological importance		
Extended Spectrum beta lactamase (ESBL) Investigation/Culture of: General bacteria **34	Multidrug Resistant Screening - Faeces, rectal swab, MSU, CSU. NB: Local screening policy applies. Microbiological cultures of enterobacteriaceae	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B59 EUCAST guidelines for detection of resistance and specific resistances of clinical and/or epidemiological importance	Qualitative	LP-L-MIC-ESBL
Investigation deep seated wounds/Culture of: General bacteria **34	Deep Wounds, Pus, exudates, aspirates	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B14	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-WOUND
Investigation of biliary infection/Culture of: General bacteria **4	Bile	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B15	Qualitative	LP-L-MIC-FLUID
Investigation of Bloodstream infections/Culture of: General bacteria **34	Blood Culture	Automated BacTalert 3D/ liquid and solid media Culture	CE/ UK SMI S 12 - Sepsis, and other disseminated infections; Irish Guideline for the Investigation of	Qualitative	LP-L-MIC-BC

			Blood Culture Samples		
Investigation of Bloodstream infections/Culture of: General bacteria **34	Blood	BacTAlert Virtuo	CE Marked	Qualitative	LP-L-MIC-BC
Investigation of Body Fluid/Culture of: General bacteria **4	Breast Milk	Manual/ Based on Standard Methods	N/A	Qualitative	LI-L-MIC-BREAST MILK
Investigation of Body Fluid/Culture of: General bacteria **4	Sterile Fluid	BacTAlert Virtuo	CE Marked	Qualitative	LP-L-MIC-FLUID
Investigation of Bronchoalveolar Lavage, Sputum, and Associated Specimens/Culture of: General bacteria **34	Sputum, Bronchoalveolar Lavage (BAL) & associated specimens	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B57	Qualitative	LP-L-MIC-SPUTA
Investigation of catheter related blood stream infections (CR-BSI)/ Culture of: General bacteria **34	Intravascular Cannulae and associated Specimens	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B20	Semi-quantitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-CANUL
Investigation of Continuous Ambulatory Peritoneal Dialysis (CAPD) Fluid/Culture of: General bacteria **4	CAPD Fluid	Manual & Automated BacTAlert 3D enrichment/ Based on Standard Methods	UK standards for Microbiology B25	Qualitative	LP-L-MIC-CAPD
Investigation of Ear Swabs and Associated Specimens/ Culture of: General bacteria **34	Ear related samples	Manual/ Based on Standard Methods	UK standards for Microbiology SMI S13	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-EARS
Investigation of Fluids from Normally Sterile	Fluids from Sterile Sites	Manual & Automated BacTAlert 3D	UK standards for Microbiology B26	Qualitative	LP-L-MIC-FLUID

SitesCulture of: General bacteria **34		enrichment/ Based on Standard Methods			
Investigation of gastroenteritis/Culture of: General bacteria **34	Human Faeces Rectal Swab	Manual/ Based on Standard Methods	UK standards for Microbiology SMI S7 UK standards for Microbiology SMI B10	Qualitative	LP-L-MIC-FAECES
Investigation of Genital Tract and Associated Specimens including semen and Intrauterine devices/Culture of: General bacteria **34	Human Male/Female Genitourinary Samples	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B28 UK standards for Microbiology SMI B58	Qualitative	LP-L-MIC-GENITAL
Investigation of Nasal Samples/ Culture of: General bacteria **4	Nasal swabs	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B57	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-NASAL
Investigation of orthopaedic implant associated infections/ Culture of: General bacteria **4	Intra-operative Orthopaedic Bone & associated Tissues	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B42	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-TISSORCM
Investigation of Pleural Fluid/Culture of: General bacteria **4	Pleural Fluid	Manual & Automated BacTalert 3D enrichment/ Based on Standard Methods	UK standards for Microbiology SMI B26	Qualitative	LP-L-MIC- PLEURALFL
Investigation of Sinusitis/Culture of: General bacteria **4	Antral washout sinus aspirate /washout	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B5	Qualitative	LP-L-MIC-SINUS
Investigation of superficial mouth samples/ Culture of: General bacteria **34	Mouth swab, saliva and oral rinse	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B4 UK Standards for Microbiology Investigations Bacteriology –	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC- MOUTHTONGUE

			Staining Procedures TP39		
Investigation of Swabs from skin and superficial soft tissue infections/ Culture of: General bacteria **34	Superficial Soft Tissue Wound and body swabs	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B11	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-WOUND
Investigation of Throat related Specimens/ Culture of: General bacteria **34	Throat related samples	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B9	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-THROAT
Investigation of tissues and biopsies from deep-seated sites and organs/ Culture of: General bacteria **4	Bone & associated Tissues	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B42	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-TISSUE
Investigation of tissues and biopsies from deep-seated sites and organs/Culture of: General bacteria **4	Tissues,Biopsies	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B17	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-TISSUE
Investigation of Urine and urinary tract associated specimens/ Culture of: General bacteria **4	Human urine - including mid-stream and clean catch specimens and those collected via bag, ileal conduit, ureter, catheter, urostomy, nephrostomy, cystoscopy, supra pubic aspirate, prostate massage/secretions, and pad urine.	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B41	Qualitative	LP-L-MIC-URINE

Investigation of Whooping Cough/Culture of: General bacteria **4	Pernasal swab, nasopharyngeal aspirate, nasopharyngeal swab	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B6	Qualitative	LP-L-MIC-CULTURE LP-L-MIC-READ LI-L-MIC-BORDETELLA
Meningitis Investigation/Culture of: General bacteria **4	Cerebrospinal Fluid (CSF)	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B27	Qualitative	LP-L-MIC-CSF
Methicillin Resistant Staphylococcus aureus (MRSA) Investigation/Culture of: General bacteria **34	Recommended multidrug resistant screening swabs for patient cohort; nose, throat, axilla, groin (or perineum) and rectum Swabs - (Faeces/Swab of faeces/Ileostomy swab / Rectal swab / Stool. NB: Local screening policy applies. Microbiological cultures of staphylococci.	Manual/ Based on Standard Methods	UK standards for Microbiology SMI B29 HPSC: National Clinical (MRSA) Guidelines EUCAST guidelines for detection of resistance and specific resistances of clinical and/or epidemiological importance	Qualitative	LP-L-MIC-MRSA
Vancomycin resistant enterococci (VRE) Investigation/Culture of: General bacteria **34	Multidrug Resistant Screening samples- Faeces/Swab of faeces/ Ileostomy swab / Rectal swab. NB: Local screening policy applies Microbiological cultures of enterococci	Manual/ Based on Standard Methods	HPSC Guidelines for the Prevention and Control of Multi-drug resistant organisms (MDRO) excluding MRSA in the healthcare setting EUCAST guidelines for detection of resistance and specific resistances of	Qualitative	LP-L-MIC-VRE

				clinical and/or epidemiological importance		
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Investigation of fungal infection/Culture of: General Fungi **34	Microbiological samples other than skin scrapings, hair and nails	Manual method or Automated BacTalert 3D/Based on Standard Methods	UK standards for Microbiology Investigations for relevant sample type and UK SMI TP-39	Qualitative	LP-L-MIC-FUNGAL LI-L-MIC-OESOPHAGEAL LP-L-MIC-FLUID LP-L-MIC-CAPD LP-L-MIC-PLEURALFL
	Investigation of fungal infection/Culture of: General Fungi **34	Microbiological samples other than skin scrapings, hair and nails	BacTAlert Virtuo	CE Marked	Qualitative	LP-L-MIC-FUNGAL, LI-L-MIC-OESOPHAGEAL, LP-L-MIC-FLUID, LP-L-MIC-CAPD, LP-L-MICPLEURALFL
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Qualitative detection of H.pylori antigen in stool specimens by Enzyme Immunoassay **4	Faeces	Manual Method / Enzyme Immunoassay (EIA)	CE Marked/based on standard method	Qualitative	LP-L-SER-HPA
	Simultaneous detection of GDH antigen and C.difficile Toxins A&B / TECHLAB® C. DIFF QUIK CHEK COMPLETE® **4		Manual/Enzyme Immunoassay	CE	Qualitative	LP-L-MIC-QUIKCHEKCDIFF
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Cryptococcal Antigen Lateral Flow Assay**4	Cerebral spinal fluid (CSF), Serum	IMMY CrAg Lateral FLOW Assay	CE - IVD UK Standards for Microbiology B27	Qualitative	LP-L-MIC-CRYPAG

	Detection of Legionella pneumophila serogroup 1 Urinary antigen /Binax Now **4	Urine	Alere™ Reader/Binax now Legionella Urinary Antigen Card immunochromatographic assay	CE/ UK Standards for Microbiology B41	Qualitative	LP-L-MIC-UAG
	Detection of Streptococcus pneumoniae Urinary antigen/Binax Now **4	Urine	Alere™ Reader/Binax now Streptococcus pneumoniae Urinary Antigen Card immunochromatographic assay	CE	Qualitative	LP-L-MIC-UAG
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Abbott Alinity m HIV-1 RNA **234	Plasma (EDTA)	Abbott Alinity m Automated real-time PCR	CE-IVD	Quantitative range <1.3 Log Copies/mL - >7 Log Copies /mL	LP-L-SER-ALINITY-HIV-1RNA
	Abbott Alinity M PCR for detection and quantification of HCV RNA **234	Plasma / Serum	Abbott Alinity M automated real time PCR	CE Marked/based on standard method	Qualitative - Not Detected Quantitative range - <1.08 Log IU/mL [Detected <LLOQ] to >9.70 Log IU/mL [Detected >ULOQ]	LP-L-SER-ALINITY-HCVRNA LP-L-SER-EQP-ALINITYM
	Abbott Alinity m Resp-4-Plex assay for detection of SARS-CoV-2, Influenza A, Influenza B & RSV **234	Nasopharyngeal swabs.	Abbott Alinity M automated real time PCR	CE	Qualitative	LP-L-SER-ALINITY-RESP-4-PLEX
	Cobas® CT/NG Automated RT PCR for direct detection of Chlamydia trachomatis (CT) and/or Neisseria	Male and Female urine, clinician-instructed self-collected vaginal swab specimens, clinician-collected	Roche 5800 Automated real-time PCR	CE-IVD	N/A Qualitative	LP-L-MIC-STD MOLECULAR

gonorrhoeae (NG) DNA **234	vaginal swab specimens, endocervical swab specimens, oropharyngeal (throat) swab specimens, and anorectal swab specimens, all collected in cobas® PCR Media				
Detection of: Toxigenic Clostridium difficile, Salmonella, Shigella, Campylobacter, Verotoxigenic E.coli, Cryptosporidium spp and Giardia spp/EntericBio® Gastro Panel 2 **24	Faeces	EntericBio Epimotion/Roche light cycler 481/Real-time PCR	CE	Qualitative	LP-L-MIC-ENTBIO2, LP-L-MIC-CDIFFENTBIO
EntericBio Viral Panel 3 for the detection of Norovirus GI & GII, Rotavirus A, Adenovirus F 40 & 41, Astrovirus and Sapovirus **24		SeroSep EntericBio Viral Panel 3 Real Time PCR	CE Marked/based on standard method	Qualitative	LP-L-SER-EBVP3 LP-L-GEN-ECYCLER480
GeneXpert Express SARS-CoV-2/Flu/RSV Plus **234	Nasopharyngeal Swabs	Cepheid GeneXpert automated real time PCR	CE Marked/based on standard method	Qualitative	LP-L-SER-XPRT-RESP LP-L-GEN-EQP-GENEXPERT
Meningitis-Encephalitis bacterial/ viral/ yeast nucleic acid screen/ FilmArray® ME Panel **234	Cerebrospinal Fluid (CSF)	Biofire FilmArray®system/ multiplex PCR	CE	Qualitative	LP-L-MIC-FILMARRAY

	Molecular detection of respiratory viruses - BioFire Torch Respiratory Panel 2.1 Plus **234	Nasopharyngeal Swabs	Biomerieux Biofire TORCH automated real time PCR	CE Marked/based on standard method	Qualitative	LP-L-SER-BIOFIRE-RESP2.1 LP-L-SER-EQP-BIOFIRE
	Norovirus GI & GII	Faeces	Cepheid GeneXpert	CE	Qualitative	LP-L-SER-XPRTNORO
	Qualitative detection of carbapenemase genes in Enterobacteriaceae from human stool specimens/EntericBio® CPE Direct . **234	Human stool samples or rectal swabs Bacterial isolates of Enterobacteriaceae	EntericBio Epimotion, Roche light cycler 480/ Real-time PCR	CE	Qualitative	LP-L-MIC-ENTCPE
	Xpert® CTNG Chlamydia trachomatis and Neisseria gonorrhoea screening / geneXpert assay **234	Vaginal/ Endocervical Swabs, Male Urethral, Female & Male urines and male and female extragenital sites (pharyngeal and rectal swabs)	GeneXpert Instrument Systems/ Real-time PCR	CE	Qualitative	LP-L-MIC-STDMOLECULAR
	Xpert® C. difficile BT /geneXpert assay **24	Unformed (liquid or soft) stool specimens	GeneXpert Instrument Systems/ Real-time PCR	CE	Qualitative	LP-L-MIC-CDIFFGENEXPERT
	Xpert® Carba-R (CPE detection) /geneXpert assay **234	Carbapenem non-susceptible pure colonies of Enterobacteriales, Acinetobacter baumannii or Pseudomonas aeruginosa. Rectal and peri-rectal swab specimens.	GeneXpert Instrument Systems/ Real-time PCR	CE	Qualitative	LP-L-MIC-CPE
1016 Identification of cultured bacteria and fungi using non-nucleic acid	Identification of Enterobacteriaceae and other non-	Microorganism cultures Enterobacteriaceae	Biomerieux api® Standardized	CE	Qualitative	EXTMIC-5

based techniques - .01 Biochemical methods , CE marked commercial systems	fastidious, Gram negative rods using: Biochemical methods/api ® **24		identification strip API 20E ™ / Manual			
	Identification of gram positive and gram negative organisms using: Biochemical methods/ Sensititre Automated Reader Incubator System (ARIS) **24	Microorganism cultures	Trek Sensititre ARIS/Semi-automated	CE	Qualitative	LP-L-MIC-EQPARIS
	Identification of Neisseria, Haemophilus (and related genera) and Moraxella catarrhalis (Branhamella catarrhalis)using: Biochemical methods/api ® Standardized identification strip API NH ™ , **24	Microorganism cultures of Neisseria, Haemophilus (and related genera) and Moraxella catarrhalis (Branhamella catarrhalis)	Biomerieux api ® /Manual	CE	Qualitative	EXTMIC-29
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Fungal Investigation of Microbiological samples (Not skin scrapings, hair and nails) / microscopic identification of fungal isolates **34	Fungal cultures	Light Microscopy examination/ with or without staining with Lactophenol aniline blue	UK standards for Microbiology SMI ID 01	Qualitative	LP-L-MIC-FUNGAL
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04	Identification of microorganisms using: Maldi-Tof Spectroscopy **234	Bacterial and Fungal culture isolates (excluding moulds)	Bruker Madli-Tof / Mass Spectrometry	CE	Qualitative	LP-L-MIC-MALDI

Identification using MALDI-TOF Spectroscopy						
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial resistance testing Anaerobes/antibiotic disc diffusion **234	Bacterial cultures	Manual/disc diffusion-standardised antibiotic concentration disc applied to solid agar inoculations of bacteria under test	CE/based on standard method (EUCAST)	Qualitative	LP-L-MIC-ASTMANUAL LP-L-MIC-ANTIMEDIQC
	Antimicrobial resistance testing Anaerobes/Minimum inhibitory concentration (MIC) **234		Manual /MIC- Graduated standardised antibiotic concentration test strips applied to solid agar inoculations of bacteria under test	CE/based on standard method (EUCAST)	Quantitative	LP-L-MIC-ASTMANUAL LP-L-MIC-ANTIMEDIQC LP-L-MIC-ETESTMICQC
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Antifungal resistance testing Yeasts/ Sensititre Yeast one MIC **234	Yeast cultures	Manual /Minimum inhibitory concentration (MIC) (Sensititre Yeast One)	CE/based on standard method (CLSI)	Quantitative	LI-L-MIC-AST-YEAST REG-202
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Antimicrobial resistance testing - /antibiotic disc diffusion **234	Bacterial cultures	Manual /disc diffusion-standardised antibiotic concentration disc applied to solid agar inoculations of bacteria under test	CE/based on standard method (EUCAST)	Qualitative	LP-L-MIC-ASTMANUAL LP-L-MIC-ANTIMEDIQC
	Antimicrobial resistance testing - /Minimum inhibitory concentration (MIC) **234		Manual / MIC-Graduated standardised antibiotic concentration test strips applied to solid agar inoculations of bacteria under test	CE/based on standard method (EUCAST)	Quantitative	LP-L-MIC-ASTMANUAL LP-L-MIC-ANTIMEDIQC LP-L-MIC-ETESTMICQC

	Antimicrobial resistance testing - /Sensititre ARIS **234		Trek Sensititre ARIS/Semi-automated Breakpoint/minimum inhibitory concentration (MIC)	CE/based on standard method (EUCAST)	Qualitative	LP-L-MIC-EQPARIS,
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	Syphilis- reagin antibodies	Serum	Manual	CE	Semi Quantitative: Negative Positive (titre ratio)	LP-L-SER-SYPH-ASIRPR
	Syphilis TPHA		Manual	CE	Semi Quantitative: Negative <1:80 Positive ≥ 1:80	LP-L-SER-SYPH-BIORAD-TPHA
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Syphilis IgM		Manual	CE	Qualitative	LP-L-SER-SYPH-IGMLAB21
1029 Miscellaneous - .99 Miscellaneous tests	Anti-HAV IgM		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS-TESTS
	Anti-HAV II		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS-TESTS
	Anti-HBc		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS-TESTS
	Anti-HBc IgM		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS-TESTS
	Anti-Hbe		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS-TESTS
	Anti-HBs		Roche Cobas Pure e402 Immunoassay analyser	CE	Quantitative: < 10 IU/L Non	LP-L-SER-COBAS-TESTS

				Immune ≥ 10 IU/ L Immune	
Anti-HCV		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
CMV IgG		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
CMV IgM		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
HBeAg		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
HBsAg		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
HIV Duo Ag/ Ab		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
Pregnancy Testing / Alere [™] hCG ^{**4}	Urine	Alere hCG cassette / Chromatographic immunoassay	CE	Qualitative	LP-L-MIC-hCG
Rubella IgG	Serum	Roche Cobas Pure e402 Immunoassay analyser	CE	Quantitative: < 10 IU/mL Non Immune ≥10 IU/mL Immune	LP-L-SER-COBAS- TESTS
Rubella IgM		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
Syphilis		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
Toxo IgG		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
Toxo IgM		Roche Cobas Pure e402 Immunoassay analyser	CE	Qualitative	LP-L-SER-COBAS- TESTS
<i>The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.</i>					
<i>Note 1 - Range may be extended for the test</i>					
<i>Note 2 – New parameters/tests may be added</i>					

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.