

# Schedule of Accreditation



Organisation Name	St Vincent's Healthcare Group (DAC)
Trading As	
INAB Reg No	192MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	22/04/2008
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
Services available to the public <sup>1</sup>	Yes

<sup>1</sup> 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	SVPH Satellite Laboratory	St Vincent's Private Hospital, Merrion Road, Dublin 4, Dublin, Ireland
2	Head Office	St Vincent's Healthcare Group, Elm Park, Dublin, D4

# 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 & RhD Typing)	Whole Blood	Manual Method in tubes	CE		LP-BTR-008
	Blood Grouping (ABO & RhD Typing), Blood Transfusion Service Red Blood Cells; Confirming ABO and RhD group and donor units	Whole Blood, Red Blood Cells	Manual Method in tubes	CE		LP-BTR-008
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping (ABO & RhD Typing), Antibody Screening	Whole Blood	IH500 Analyser	CE		LP-BTR-IH500
	Blood Grouping (ABO & RhD Typing),	Whole Blood, Red Blood Cells	IH500 Analyser	CE		LP-BTR-IH500

	Antibody Screening, Blood Transfusion Service Red Blood Cells; Confirming ABO and RhD group and donor units.					
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Manual Method using gel IAT cards and tube technique using IAT	CE		LP-BTR-018
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		IH500 Automated Method using gel IAT and enzyme IAT	CE		LP-BTR-IH500, LP-BTR-019
			Manual method using Gel IAT and enzyme IAT, and Tube method using IAT	CE		LP-BTR-019
	LISS Alloadsorption		Antibody Adsorption	CE		LP-BTR-023, LP-BTR-017
1020 Transfusion science - .05 Cross match compatible donor units	Serological crossmatch testing. Compatibility analysis for the release of compatible blood by electronic means			Manual method of crossmatching in tubes and gel technique, Electronic Crossmatching.	CE	
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	Manual method in tubes and cards	CE		LP-BTR-027
1020 Transfusion science - .07 Antibody elution	Antibody Elution Testing of EDTA specimens	EDTA		CE		LP-BTR-024
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Testing	Red Blood Cells	manual method with monospecific gel cards	CE		LP-BTR-015
1020 Transfusion science - .99 Miscellaneous tests	Blood Transfusion Service Red Blood Cells; Confirming ABO and RhD group and donor units		Manual Method using tubes, automated method using gel cards	CE		LP-BTR-009

*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.*



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	24hr Urinary Excretion rates **2 including: Calcium Excretion (UCA24), Chloride Excretion (UCL24), Creatinine Excretion (UCRE24), Magnesium Excretion (UMG24), Nitrogen Excretion (UNIT24), Phosphate Excretion (UPO424), Potassium Excretion (UK24), Sodium Excretion (UNA24), Total Protein Excretion (UTP24), Urate Excretion (UURI24), Urea Excretion (UBUN24)	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC
	Adjusted Calcium **2	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC/ LP-CHEM-INTERP
	Alanine Aminotransferase (ALT) **1,2,3,4		Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE

ALP (Alkaline Phosphatase) **1,2,3,4		Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Amylase **1,2,3,4	Serum/ Plasma / urine	Enzymatic colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
Angiotensin Converting Enzyme (ACE) **1,2,3,4	Serum/ Plasma	Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
AST (Aspartate Aminotransferase) **1,2,3,4		Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
C Reactive Protein (CRP) **1,2,3,4		Particle enhanced immunoturbidometric assay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Caeruloplasmin **1,2,3,4	Serum	Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Calcium **1,2,3,4	Serum/ Plasma/ Urine	Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
Calcium Phosphate Product **2	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLab (Calculation)	CE	LP-CHEM-ROCHE/ LP-CHEM-CALC
Calcium/ Creatinine Ratio (UCa/Creatinine Ratio) **2	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC/ LP-CHEM-U-HP
Calculated Globulin **2	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC/ LP-CHEM-INTERP
Chloride **1,2,3,4	Serum/ Plasma/ Urine	ISE	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
Cholesterol **1,2,3,4	Serum/ Plasma	Enzymatic colorimetric assay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
CK (Creatine Kinase) **1,2,3,4		Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Conjugated Bilirubin (Direct) **1,2,3,4		Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Cortisol **1,2,3,4		Competitive immunoassay using electrochemiluminescence	Roche Cobas 8000	CE	LP-CHEM-ROCHE

Creatinine (Enzymatic) **1,2,3,4	Serum/ Plasma/ Urine	Enzymatic method measured photometrically	Roche Cobas 8000	CE	LP-CHEM-ROCHE	
CSF Glucose **1,2,4	CSF	Photometric	Roche 8000	CE	LP-CHEM-CSF	
Estimated GFR **2	Serum/ Plasma	Calculation (CKD-EPI Formula)	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC/ LP-CHEM-INTERP	
Free T3 (Free Triiodothyronine) **1,2,3,4		Competitive Immunoassay using Electrochemiluminescence	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-INTERP	
Free T4 (Free Thyroxine) **1,2,3,4		Competitive Immunoassay using Electrochemiluminescence	Roche Cobas 8000	CE	LP-CHEM-ROCHE	
Gamma GT (GGT /Gamma Glutamyl Transferase) **1,2,3,4		Enzymatic colorimetric assay	Roche Cobas 8000	CE	LP-CHEM-ROCHE	
Glucose **1,2,3,4		Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE	
HDL and LDL Cholesterol **1,2,3,4		Homogeneous enzymatic colorimetric test	Roche Cobas 8000	CE	LP-CHEM-ROCHE	
Homocysteine **1,2,3,4		EDTA Plasma	Enzymatic	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Iron **1,2,3,4		Serum/ Plasma	Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
LDH (IFCC) (Lactate Dehydrogenase) **1,2,3,4	Enzymatic Assay		Roche Cobas 8000	CE	LP-CHEM-ROCHE	
Lipid Calculations including: Non-HDL cholesterol (NHDLC) and Total Cholesterol: HDL Cholesterol ratio (TCHDR) **2	Blood	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC	
Magnesium **1,2,3,4	Serum/ Plasma/ Urine	Colorimetric end point assay	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP	
NT-ProBNP **1,2,3,4	Serum	Electrochemiluminescent sandwich Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE	
Osmolality **1,3,4	Serum/ Urine	Freezing Point Depression	A20 Automated Osmometer	CE	LP-CHEM-OSMA20	
Phosphate (Inorganic PO4) **1,2,3,4	Serum/ Plasma/ Urine	Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP	



	Potassium **1,2,3,4		ISE	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
	Sodium **1,2,3,4		ISE	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
	Sodium **1,2,3,4	Blood	Direct ISE	Roche Direct ISE Analyser 9180	CE	LP-CHEM-DISE
	Total Bilirubin **1,2,3,4	Serum/ Plasma	Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Total CO2 (Carbon Dioxide) **1,2,3,4		Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Triglyceride **1,2,3,4		enzymatic colorimetric assay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Troponin T (hs) (Troponin T High Sensitivity) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	TSH **1,2,3,4		Electrochemiluminescent sandwich Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Tubular Maximum Resorption of Phosphate TMP/GFR **2	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (calculation)	CE	LP-CHEM-CALC
	Urate (Uric Acid) **1,2,3,4	Serum/ Plasma/ Urine	Enzymatic Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
	Urea **1,2,3,4		Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE/ LP-CHEM-U-HP
	Urea/ Creatinine Ratio **2	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC/ LP-CHEM-U-HP
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	ALB (Albumin) **1,2,3,4	Serum/Plasma/Urine	Colourimetric	Roche Cobas 8000	CE	LP-CHEM- ROCHE/LP-CHEM- U-HP
	Albumin Excretion Rate (AER) **2	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (calculation)	CE	LP-CHEM-CALC
	B2M (Beta 2 Microglobulin) **1,2,3,4	Serum	Immunoturbidometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Complement C3 **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE

	Complement C4 **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	CSF Protein **1,2,4	CSF	Turbidometric	Roche 8000	CE	LP-CHEM-CSF
	IgA (Immunoglobulin A) **1,2,3,4	Serum	Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	IgE (Immunoglobulin E) **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	IgG (Immunoglobulin G) **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	IgM (Immunoglobulin M) **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Interleukin 6 (IL-6) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Kappa: Lambda Ratio KLR **2		Blood	Calculation	Optilite/ APEX iLAB Calculation	CE
	Osteocalcin **1,2,3,4	Serum	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Residual Gamma Concentration RESGAM **2	Blood	Calculation	Capillarys 3 Octa/ APEX iLAB (Calculation)	CE	LP-CHEM- SPECAP3
	Serum Free Light Chains **1,2,4	Serum	Turbidimetric	Optilite	CE	LP-CHEM- OPTILITE
	Total Protein **1,2,3,4	Serum/Plasma/Urine	Colourimetric	Roche Cobas 8000	CE	LP-CHEM- ROCHE/LP-CHEM- U-HP
	Urine Albumin: Creatinine ratio (ACR)**2	Urine	Calculation	Roche Cobas 800/ APEX iLAB (calculation)	CE	LP-CHEM-CALC
1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis	Serum Protein Electrophoresis **1,2,4	Serum	Capillary Electrophoresis	Capillary 3 Octa Electrophoresis analyser	CE	LP-CHEM- SPECAP3
1061 Clinical Chemistry - .05 CO-oximetry	% O2 Saturation **1,2,3,4	Blood	Co-oximetry	GEM5000 Blood Gas Analyser	CE	LP-CHEM- GEM5000
	Base Excess **1,2,4		Calculation	GEM5000 Blood Gas Analyser	CE	LP-CHEM- GEM5000

	Bicarbonate (HCO <sub>3</sub> ) actual **1,2,4		Calculation	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Bicarbonate (HCO <sub>3</sub> ) Std **1,2,4		Calculation	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Carboxyhaemoglobin **1,2,3,4		Co-oximetry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Methaemoglobin **1,2,3,4		Co-oximetry	GEM5000 Blood Gas Analyser		LP-CHEM-GEM5000
	pCO <sub>2</sub> **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	pH **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	pO <sub>2</sub> **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Chloride **1,2,3,4	Serum/ Plasma/ Whole Blood	Direct ISE	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Glucose **1,2,3,4	Blood	Amperometry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Ionised Calcium **1,2,3,4	Serum/ Plasma/ Whole Blood	Potentiometry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Lactate **1,2,3,4	Blood	Amperometry	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Potassium **1,2,3,4	Serum/ Plasma/ Whole Blood	Direct ISE	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Sodium **1,2,3,4		Direct ISE	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin **1,2,3,4	Serum	Immunoassay using absorbance	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Carbamazepine **1,2,3,4		Homogeneous microparticle agglutination immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Digoxin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE

	Gentamicin **1,2,3,4		Kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Lithium **1,2,3,4		Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Phenytoin **1,2,3,4		Kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Theophylline **1,2,3,4		Kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Tobramycin **1,2,3,4		Enzyme Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Valproate **1,2,3,4		Homogeneous enzyme immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Vancomycin **1,2,3,4		Homogeneous enzyme immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol **1,2,3,4	Plasma	Enzymatic	Roche Cobas 8000	CE	LP-CHEM-ROCHE
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol **1,2,3,4	Serum	Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Salicylate **1,2,3,4		Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
1061 Clinical Chemistry - .20 Hormones	25(OH)Vitamin D **1,2,3,4	Serum/ Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	ACTH **1,2,3,4	EDTA Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Androstenedione **1,2,3,4	Serum/ Plasma	Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	DHEA Sulphate (DHEAS / Dehydroepiandrosterone Sulphate) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Follicle Stimulating Hormone (FSH) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE

	Free Testosterone Index (Testosterone: SHBG ratio) **2		Calculation	Roche Cobas 8000/ APEX iLAB (calculation)	CE	LP-CHEM-CALC
	Insulin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Insulin Like Growth Factor 1 (IGF1) **1,2,3,4	Serum	Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Luteinising Hormone (LH) **1,2,3,4	Serum/ Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Oestradiol **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Parathyroid Hormone (PTH) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Procalcitonin **1,2,3,4	Serum	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Progesterone **1,2,3,4	Serum/ Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Sex Hormone Binding Globulin (SHBG) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Testosterone **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Total Prolactin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Ferritin **1,2,3,4		Blood	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE
1061 Clinical Chemistry - .40 Iron studies	Iron **1,2,3,4	Colorimetric		Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Total Iron Binding Capacity (TIBC/C) **2		Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC
	Transferrin **1,2,3,4	Serum/ Plasma	Immunoturbidometric assay using electrochemiluminescence	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Transferrin Saturation (%Transferrin Satn) **2		Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC/ LP-CHEM-INTERP

1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Vitamin B12 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	CA125 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	CA15 -3 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	CA19 -9 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	CEA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	HCG **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Thyroglobulin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Total PSA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c, HPLC (EDTA) **1,2,3,4	Blood	HPLC	Menarini 8180	CE	LP-CHEM-HbA1c
1061 Clinical Chemistry - .99 Miscellaneous tests	Anti -Thyroglobulin **1,2,3,4	Serum	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Anti -Thyroid Peroxidase (Anti-TPO) **1,2,3,4		Electrochemiluminescence Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	Bone Alkaline Phosphatase (BAP) **1,2,3,4	Serum/ Plasma	Monoclonal antibody immunoenzymatic assay	Dynex Agility	CE	LP-CHEM-DYNEX
	CTX-1 (C-Terminal cross-linking Telopeptide of type 1 Collagen)1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	P1NP (Total Procollagen Type 1 N-Propeptide) **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE

1064 Molecular genetics - .02 Assay for identified pathogenic variant(s)	Haemochromatosis Genetic Screen (Hereditary Haemochromatosis HFE gene mutations) (C282Y, H63D, S65C)	Blood	Testing in genomic DNA purified from peripheral blood	Roche MagNA Pure 24 Total Isolation DNA Extractor and Roche Lightcycler 480 II Real Time PCR Analyser	CE	LP-CHEM-OL-HAE- MP24
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*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*

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 including WCC, HB, Platelet Count, RCC, HCT, MCV, MCH, RDW **1,2,4	Blood	Impedance Cell Counting/ Flow Cytometry/ Spectrophotometry	Sysmex XN10/XN20 Haematology Analyser	CE	LP-HAE-SYSMEXXN/ LP-HAE-APXAUTH-H/ LP-HAE-FBC-AUTOC
1030 Haematology - .02 Visual examination of blood films	Blood Films to investigate abnormal white cells, red cells and platelets. This includes manual WCC differentials (neutrophils, lymphocytes, basophils, eosinophils) **4		Microscopy, Slide Preparation and Staining	Microscope, Sysmex SP50 Slide Preparation Unit	CE	LP-HAE-BLDFLMREP/ LP-HAE-BLDFLMMAK/ LP-HAE-SP50/ LP-HAE-SLDSTN
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR **1,4		Sedimentation & Aggregation	Starrsed RS ESR Analyser, Manual Westergren Method	CE	LP-HAE-ESRRS/ LP-HAE-ESRM
1030 Haematology - .05 Automated differential leucocyte counts	Five Part Differential **1,2,4		Flow Cytometric	Sysmex XN10/XN20 Haematology Analyser	CE	LP-HAE-SYSMEXXN/ LP-HAE-APXAUTH-H/ LP-HAE-FBC-AUTOC
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Counts **1,4		Flow Cytometric	Sysmex XN10/ XN20 Haematology Analyser	CE	LP-HAE-SYSMEXXN/ LP-HAE-APXAUTH-H/ LP-HAE-FBC-AUTOC



1030 Haematology - .09 Examination of malarial parasites	Malaria Testing using Antigen and Antibody kits; Thick and thin blood films **2,3,4		Immunochromatographic Test and Microscopy	Test Kit/ Microscope	CE	LP-HAE-M-DIAG
1030 Haematology - .20 Bone marrow examination	Bone marrow staining and examination **2,4	Bone Marrow	Microscopy	Microscope	CE	LP-HAE-BMLABEL
1030 Haematology - .40 Limited haemostasis related tests	Anti Xa-assay **1,2,4	Blood	Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-ANTIXA
	DRVVT Ratio **2		Calculation	IL ACL TOP 550 Coagulation Analyser/ APEX iLAB (calculation)	CE	LP-HAE-LUPUS
	Factor Assays (FII, FV, FVII, FVIII, FIX, FX, FXI, FXII) **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-FA
	Lupus Screen (DRVVT, Silica Clotting Time) **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-LUPUS
	Silica Clotting Time Ratio **2		Calculation	IL ACL TOP 550 Coagulation Analyser/ APEX iLAB (calculation)	CE	LP-HAE-LUPUS
	Thrombin Time **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-TT
	Thrombin Time Ratio **2		Calculation	IL ACL TOP 550 Coagulation Analyser/ APEX iLAB (calculation)	CE	LP-HAE-TT
	Thrombophilia Screen (Protein C, Protein S, Anti-Thrombin, Activated Protein C resistance) **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-SAMPRETS/ LP-HAE-STOREC/ LP-HAE-THROMBOPHILIA
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-COAG

	APTT Ratio **2		Calculation	IL ACL TOP 550 Coagulation Analyser/ APEX iLAB (calculation)	CE	LP-HAE-COAG
	D-Dimers **1,2,4		Latex Immunoassay	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-COAG
	Fibrinogen **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-COAG
	International Normalised Ratio (INR) **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-COAG
	Prothrombin Time (PT) **1,2,4		Optical	IL ACL TOP 550 Coagulation Analyser	CE	LP-HAE-COAG
1030 Haematology - .55 Iron studies	Haemosiderin **4	Urine	Cytochemistry	N/A	CE	LP-HAE-IRONSTN
	Iron Stain **4	Urine, Bone Marrow	Cytochemistry	Tiziano Ultracompact stainer for Iron Stains	CE	LP-HAE-IRONSTN
	Iron Stain for Bone Marrow **4	Bone Marrow	Cytochemistry	N/A	CE	LP-HAE-IRONSTN
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen using Clearview **3,4	Peripheral Blood	Clearview kit method	Clearview kit	CE	LP-HAE-IMSCREEN
1030 Haematology - .70 Immunophenotyping	Acute and Chronic Leukaemia screening panel **1,2,3,4	Peripheral Blood and bone marrow	Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	LP-HAE-CLEARLAB
	Acute Leukaemia Panel and Chronic Leukaemia Panel **1,2,3,4		Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	LP-HAE-IMMLEUK
	CD34 Quantitation **2,4	Peripheral Blood and peripheral blood apheresis samples	Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	LP-HAE-CD34
	CD34 x 10 <sup>6</sup> /kg **2		Calculation	Navios EX Flow Cytometer (Beckman Coulter)/ APEX iLAB (Calculation)	CE	LP-HAE-CD34

	Post Thaw Stem Cell Viability **1,2,4	Peripheral Blood Stem Cells	Flow Cytometry	Navios Ex Flow Cytometer (Beckman Coulter)	CE	LP-HAE-SCTHAW
1030 Haematology - .99 Miscellaneous tests	Sickle Cell Screen **4	Blood	Turbidimetric	N/A	CE	LP-HAE-SCT

*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*

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	Cut up; Tissue Processing; Embedding; Microtomy; Automated and Manual Haematoxylin and Eosin Staining; Coverslipping **2,4	Human Tissue	Leica ASP6025, Peloris 2, Peloris 3, Leica HistoCore Embedding Centre, Leica RM2550 Microtomes, Leica Microtome HistoCore AutoCut, Tissue Tek 5 Embedding Centre, Diamond Pathology Saw.	Based on standard method		LP-HIS-EMBED/ LP-HIS-DICBX/ SVUH Histopathology Manual/ LP-HIS_SPREQMIN/ LP-HIS-SPECREC/ LP-HIS-FRESHINF/ LP-HIS-SPDISSECT/ LP-HIS-FRESHBRE/ LP-HIS-FRESHKID/ LP-HIS-FRESHLN/ LP-HIS-FRESHBMX/ LP-HIS-FRESHNER/ LP-HIS-FRESHSKX/ LP-HIS-FAXITRON/ LP-HIS-DIGFAXITRON/ LP-HIS-GROSPHOTO/ LP-HIS-CLINMCON/ LP-HIS-BMX/ LP-HIS-DECAL/ LP-HIS-BRCHECK/ LP-HIS-POC/ LP-HIS-RADIOACT/ LP-HIS-BIOPAN/ LP-HIS-AMPPROC/ LP-HIS-LIQINT/ LP-HIS-MCLASS1/ LP-HIS-PRFORMAL/ LP-HIS-SECTPAR/ LI-HIS-LEICAMICROTOMES
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut Up; Frozen Section cryotomy and staining **2,4		Leica CM1900 cryostat	Based on standard method		LP-HIS-FRESHFS/ LP-HIS-LIQNIT/ LP-HIS-MCLASS1

1051 Histopathology - .03 Histochemistry	Automated H&E	Prisma Automated Slide Stainer and G2 Coverslipper	Based on Standard method	LP-HIS-INTQC/ LP-HIS-SECTW/ LP-HIS-PRISMA/ LP-HIS-G2COVER
	Automated special stains using the ARTISAN: PAS, PASD, Perls, Masson Trichrome, Reticulin, Jones' Methenamine Silver, Grocotts (fungi & pneumocystis), Congo Red, Ziehl Neelson	Dako Artisan Link Pro Special Stainer	CE marked	LP-HIS-ARTISANPRO/ LP-HIS-EQASP
	H&E, Gram, Van Gieson, AB/PAS, Miller's Elastin, Alcian Blue, Rubeanic Acid, MSB and Oil Red O	Manual	Based on standard method	LP-HIS-H&EMAN/ LP-HIS-SHIKO/ LP-HIS-GRAM/ LP-HIS-VANG/ LP-HIS-AB/PAS/ LP-HIS-MILLER/ LP-HIS-AB/ LP-HIS-RUB/ LP-HIS-MSB/ LP-HIS-ORO
1051 Histopathology - .04 Histological interpretation-medical renal pathology	1051.04.41 Medical Renal Pathology and 1051.04.42 Breast Screening. Diagnostic Interpretation and reporting of human tissue specimens. Specialist areas EXCLUDED: Paediatric Pathology, Perinatal Pathology, Neuropathology. Specialist Areas INCLUDED: Medical Renal Pathology, Breast Screening Pathology	Consultant Microscope		LP-HIS-REPHER-2/ LP-HIS-REPOR/PR
1051 Histopathology - .09 Immunohistochemistry	AE1/3 **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
	AE1/3-D2-40 Dual Stain **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA

ALK (NSCLC) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Androgen Receptor **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
BAP1 **2,4	Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS-VENTBENCHMARKULTRA
BCI2 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
BCI6 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
BCL10	Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS-VENTBENCHMARKULTRA
BEREP4 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Beta-Catenin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
BRAF V600E **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Calponin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Calretinin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD10 (SP67) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD117 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD138 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD15 (MMA) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD15 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD20 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

CD23 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD246 (ALK1) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD3 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD30 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD31 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD34 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD4 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD45 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD5 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD56 (MRQ-42) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD68 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD79a (SP18) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD8 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD99 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CDX2 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Chromogranin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CK20 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CK5/6 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

CK7 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CMV **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
C-myc	Ventana Benchmark XT	CE marked		LP-HIS-VENTBENCHMARKXT
Cyclin D1 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
D2-40 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Desmin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
DOG1 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
EBV (In situ hybridisation, ISH) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
E-Cadherin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
EMA **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
ER (SP1) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
ERG **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Gastrin **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
GATA-3 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Glutamine Synthetase **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Glypican 3 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
H. Pylori **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
H3K27me3 (C36B11) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA



Heat Shock Protein 70 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Hepar **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Her2neu (45B) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
HMB45 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
HSV1 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
IgG4 (EP138) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189/ LP-HIS-VENTBENCHMARKULTRA
Insulin **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Kappa (ISH) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
Ki67 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Lambda (ISH) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
Melan A **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
MLH1 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
MSH2 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
MSH6 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Muc 4 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Mum-1 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Napsin A **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
NKX2.2 (EP336) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

OCT4 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Oestrogen Receptor **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
p-16 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
P5045/ Racemase/ AMACR **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
P53 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
P63 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
p63-AE1/3 Dual Stain **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
p63-Ker5/6 Dual Stain **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PAX5 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PAX8 (EP311) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PD-L1 (22C3) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
PD-L1 (SP263) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PMS2 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PRAME (ERP 20330) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Progesterone Receptor **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
PSA **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
ROS1 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
S100 **2,4	Dako Omnis	CE marked		LP-HIS-DAKOOMNIS

	SMA **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
	SOX-10 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
	SSTR2A		Ventana Benchmark Ultra	Based on Standard Method		LP-HIS-VENTBENCHMARKULTRA
	Stat 6 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
	Succinate Dehydrogenase (SDHB)		Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS-VENTBENCHMARKULTRA
	Synaptophysin **2,4		Dako Omnis	CE marked		LP-HIS-DAKOOMNIS
	TdT (Terminal Deoxynucleotidyl Transferase) **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
	Trypsin		Dako Omnis Immunostainer	Based on standard method, not CE marked		LP-HIS-DAKOOMNIS
	TTF-1 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
	TTF-1-Napsin A Dual Stain **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
	WT-1 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
1051 Histopathology - .10 Fluorescence in situ hybridisation	FISH Her2 **2,4	Human Tissue/ Slide	Dako Omnis Immunostainer	CE		LP-HIS-DAKOOMNIS
1051 Histopathology - .99 Miscellaneous tests	Direct Immunofluorescence DIF	Human Tissue	Manual Technique	CE		LP-HIS-DIFTEC
1052 Cytopathology - .02 Non gynaecological cytology	Exfoliative and FNA cytology	Urinary Cytology, Serous Fluid Cytology, Respiratory Cytology and FNAs	Thin Prep 2000, Leica ST5020			LP-HIS-CYT/ LP-HIS-EBUS/ LP-HIS-PRCTFNA/ LP-HIS-TISSUE/ LP-HIS-PAPAUTO/ LP-HIS-PAPMAN/ LP-HIS-CMGG
1052 Cytopathology - .05 Immunocytochemistry	AE1/3 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

AE1/3-D2-40 dual stain **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
ALK (NSCLC) **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
Androgen Receptor **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
BAP1 **2,4	Ventana Benchmark Ultra	Based on standard method, not CE marked	LP-HIS-VENTBENCHMARKULTRA
BCI2 **2,4	Dako Omnis Immunostainer	CE marked	LP-HIS-DAKOOMNIS
BCI6 **2,4	Dako Omnis Immunostainer	CE marked	LP-HIS-DAKOOMNIS
BCL10	Ventana Benchmark Ultra	Based on standard method, not CE marked	LP-HIS-VENTBENCHMARKULTRA
BEREP4 **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
Beta-Catenin **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
BRAF V600E **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
Calponin **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
Calretinin **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
CD10 (SP67) **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
CD117 **2,4	Dako Omnis Immunostainer	CE marked	LP-HIS-DAKOOMNIS
CD138 **2,4	Dako Omnis Immunostainer	CE marked	LP-HIS-DAKOOMNIS
CD15 (MMA) **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA
CD15 **2,4	Ventana Benchmark Ultra	CE marked	LP-HIS-VENTBENCHMARKULTRA

CD20 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD23 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD246 (ALK1) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD3 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD30 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD31 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD34 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD4 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD45 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD5 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD56 (MRQ-42) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD68 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
CD79a (SP18) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD8 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CD99 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CDX2 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Chromogranin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CK20 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

CK5/6 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CK7 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
CMV **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
C-myc		Ventana Benchmark XT	CE marked		LP-HIS-VENTBENCHMARKXT
Cyclin D1 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
D2-40 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Desmin **2,4		Ventana Benchmark Ultra	CE marked		/LP-HIS-VENTBENCHMARKULTRA
DOG1 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
EBV (In Situ hybridisation, ISH) **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
E-Cadherin **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
EMA **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
ER (SP1) **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
ERG **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Gastrin **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
GATA-3 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Glutamine Synthetase **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-BENCHMARKULTRA
Glypican 3 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
H. Pylori **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

H3K27me3 (C36B11) **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Heat Shock Protein 70 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Hepar **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Her2neu (45B) **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
HMB45 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
HSV1 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
IgG4 (EP138) **2,4	Human Tissue	Ventana Benchmark Ultra	CE marked		ISO15189/ LP-HIS-VENTBENCHMARKULTRA
Insulin **2,4	Urinary Cytology, Serous Fluid Cytology, Respiratory Cytology and FNAs	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Kappa (ISH) **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
Ki67 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Lambda (ISH) **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
Melan A **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
MLH1 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
MSH2 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
MSH6 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Muc 4 **2,4		Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Mum-1 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS

Napsin A **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
NKX2.2 (EP336) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
OCT4 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Oestrogen Receptor **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
p-16 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
P5045/Racemase/AMAC **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
P53 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
P63 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
p63-AE1/3 dual stain **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
p63-Ker5/6 dual stain **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PAX 8 (EP311) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PAX5 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PD-L1 (22C3) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PD-L1 (SP263) **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PMS2 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
PRAME **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Progesterone Receptor **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
PSA **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS



ROS1 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
S100 **2,4	Dako Omnis	CE marked		LP-HIS-DAKOOMNIS
SMA **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
SOX-10 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
SSTR2A	Ventana Benchmark Ultra	Based on standard method		LP-HIS-VENTBENCHMARKULTRA
Stat 6 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Succinate Dehydrogenase (SDHB)	Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS-VENTBENCHMARKULTRA
Synaptophysin **2,4	Dako Omnis	CE marked		LP-HIS-DAKOOMNIS
TdT (Terminal Deoxynucleotidyl Transferase) **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Trypsin	Dako Omnis Immunostainer	Based on standard method, not CE marked		LP-HIS-DAKOOMNIS
TTF-1 **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
TTF-1-Napsin A dual stain **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
WT-1 **2,4	Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS

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*Note 2 – New parameters/tests may be added*

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

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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 - .02 Qualitative investigation of immunoglobulins G,A,M and D in body fluids	Immunofixation electrophoresis	Serum or Urine	Immunofixation electrophoresis on the Sebia Hydrasys 2	CE	Serum detection programme has a limit of detection of 0.06-0.25g/l, BJP programme has a limit of detection of 1-5mg/dl	LP-IMM-IFX
1040 Immunology - .04 Allergen - specific IgE	Allergen Specific IgE	Serum	Allergen – specific IgE: Specific IgE to a range of allergens are measured on the Phadia250	CE	0.0-100kUA/L	LP-IMM-PHADIA
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Rheumatoid Factor (RF)		IgM RF measured by immunoassay on the Phadia250	CE	0.6 to >= 200 IU/ml	LP-IMM-PHADIA
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti GBM antibodies		Detected by ELISA using the DS2 ELISA processor	CE	<20 RU/ml	LP-IMM-DS2
	Anti-Cardiolipin Antibodies (ACA): ACA IgG and ACA IgM		Detected by Immunoassay on the Phadia 250	CE	IgG ACA 0.5 - >=418 GPL-U/ml IgM ACA 0.9 - >=472 MPL-U/ml	LP-IMM-PHADIA
	Anti-CCP antibodies	Detected by immunoassay on the Phadia250	CE	0.4-340 U/ml	LP-IMM-PHADIA	

Anti-dsDNA antibodies	Detected by immunoassay on the Phadia250	CE	0.5-379 IU/ml	LP-IMM-PHADIA
	Screen at 1/10 by IIF on C. luciliae (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
Anti-ENA antibodies	Detected by immunoassay on the Phadia250	CE	0.09-55 (ratio)	LP-IMM-PHADIA
Anti-ENA Profile including: Anti-Ro, Anti-La, Anti-SmDP-S, Anti-U1RNP, Anti-Scl-70S, Anti-Jo-1, Anti-CENP	Detected by immunoassay on the Phadia250	CE	Measuring Ranges: Anti-Ro: 0.3 - >/= 240U/ml, Anti-La: 0.4 - >/= 320U/ml, Anti-SmD: 0.7 - >/= 330U/ml, Anti-U1RNP: 0.3 - >/= 240U/ml, Anti-Scl-70S: 0.6 - >/= 240U/ml, Anti-Jo-1: 0.3 - >/= 240U/ml, Anti-CENP: 0.4 - >/= 240U/ml	LP-IMM-PHADIA
Anti-LKM antibodies	Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
Anti-mitochondrial antibodies	Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		I LP-IMM-QUANTA3000
Anti-MPO antibodies	Detected by immunoassay on the Phadia250	CE	0.2-134 IU/ml	LP-IMM-PHADIA
Anti-neutrophil cytoplasmic antibodies (ANCA)	Screen at 1/20 by indirect immunofluorescence (IIF) on ethanol fixed	CE		LP-IMM-QUANTA3000

		neutrophils (Werfen) using the Quantalyser 3000 (Werfen)			
	Anti-Nuclear Antibody (ANA)	Screen at 1/80 by IIF on HEp2 (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
	Anti-Parietal Cell antibodies	Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
	Anti-PDH antibodies (AMA-M2 subtype)	Detected by ELISA using the DS2 ELISA processor	CE	0-200IU/ml	LP-IMM-DS2
	Anti-PR3 antibodies	Detected by immunoassay on the Phadia250	CE	0.6 to $\geq$ 177 IU/ml	LP-IMM-PHADIA
	Anti-smooth muscle antibodies	Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
	IgA-anti-endomysial antibody (EMA)	Screen at 1/10 by IIF on oesophagus (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
	IgA-anti-tissue transglutaminase (Anti-tTG) antibodies	Detected by immunoassay on the Phadia250	CE	0.2 to $\geq$ 128 U/ml	LP-IMM-PHADIA
1040 Immunology - .54 Tryptase	Tryptase	Measurement of tryptase levels using ThermoFisher ImmunoCAP Tryptase on the Phadia 250 instrument (ThermoFisher)	CE	1.0 - 200ug/l	LP-IMM-PHADIA

1040 Immunology - .99 Miscellaneous tests	Cyclosporine	Whole blood (EDTA)	CMA on Abbott Architect	CE	18-1500 ng/ml	LP-IMM-ARCHITECT
	Tacrolimus		CMA on Abbott Architect	CE	2.0-30 ng/ml	LP-IMM-ARCHITECT

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 - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Preparation of films; Gram stains Microscopic Examination of clinical specimens; Cell Counts and Gram stains	Gram stains: Wound swabs (of specific type), body fluids, tissues, sputum, BAL, isolates from culture plats, genital swabs. Cell Counts: CSF, body fluids, urine.	Light microscope/ manual	standard method		LP-MIC-GRAM LP-MIC-CSF/ LP-MIC-BOFYFL/ LP-MIC-URINE/ LP-MIC-SPUT/ LP-MIC-BAL
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	Auromine-Rhodamine stain for AFB on Clinical Specimens	Sputum, BAL, Body fluids, CSF, Tissue	Fluorescent microscope/ light microscope/ manual	standard method		LP-MIC-STAIN/ LP-MIC-TB/ LP-MIC-AFB STAIN
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	CPE/ ESBL Screens	Rectal swab	Culture of organisms		N/A	LP-MIC-CRE/ESBL
	CRE/ ESBL screens				N/A	LP-MIC-CRE/ESBL
	Culture of General Bacteria on agar based culture media	Urine, faeces, sputum, BAL, AWO, bone marrow, CSF,	Culture of organisms	standard method		LP-MIC-URINE/ LP-MIC-SVRE/ LP-MIC-FAEC/ LP-MIC-TISS/

		body fluids, wound swabs, tissue, ulcers, genital swabs, throat, eyes, ears, IV tips, MRSA and VRE screens				LP-MIC-BILE/ LP-MIC-SPUT/ LP-MIC-CAPD/ LP-MIC-BAL/ LP-MIC-CORNEA/ LP-MIC-SINUS/ LP-MIC-HPGA/ LP-MIC-GEN/ LP-MIC-MRSA/ LP-MIC-THROAT/ LP-MIC-IVA/ LP-MIC-SKIN/ LP-MIC-BODYFL/ LP-MIC-PUS/ LP-MIC-CSF/ LP-MIC-MOUTH/ LP-MIC-ULCER/ LP-MIC-EAR/ LP-MIC-NOSE/ LP-MIC-EYE/ LP-MIC-PSORE
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 on agar based culture media	Dermatology, BAL, AWO, tissues, ears, devices, mouth, HVS, sputum, throat, urine				LP-MIC-DERM (dermatology)/ LP-MIC-BAL/ LP-MIC-SINUS (AWO)/ LP-MIC-GEN (HVS)/ LP-MIC-THROAT/ LP-MIC-EAR/ LP-MIC-MOUTH/ LP-MIC-TISS (tissue/ devices)/ LP-MIC-SPUT/ LP-MIC-URINE
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of mycobacterium using liquid based and agar based media	Sputum, BAL, Body fluids, CSF, Tissue	Automated liquid culture using Biomerieux MBACT. Manual TB culture using LJ slopes/ BCSA plates	Liquid Culture: CE marked. Solid Culture: Standard method		LP-MIC-TB
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Latex Tests: For Staph aureus and for BHS Lancefield grouping (as identification or partial identification of cultured bacteria)		BioRad Pastorex Strep and BioRad Pastorex Staph Plus	CE marked kits		

1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	C. diff Quik Chek Complete	Faeces	Membrane enzyme immunoassay for the simultaneous detection of C. difficile glutamate dehydrogenase antigen (GDH) and toxins A and B	CE	N/A	LP-MIC-FCD
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	MecA testing to aid in the identification of MRSA	Bacterial isolate	Alere PBP2a SA Culture colony Test	CE marked	N/A	LP-MIC-AST
		Bacterial isolates	Alere PBP2a SA Culture colony Test	CE marked	N/A	LP-MIC-AST
	Resist-5 O.K.N.V.I Detection of Carbapenemase in bacterial culture	Bacterial isolate	RESIST-5 O.K.N.V.I	CE marked	N/A	LP-MIC-AST
	Resist-5 O.K.N.V.I Detection of Carbapenemase in bacterial culture for the identification of query CPE isolates	Bacterial Isolates	RESIST-5 O.K.N.V.I	CE marked	N/A	LP-MIC-AST
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	CPE Identification of query CPE isolates from clinical and screening samples		Cepheid GeneXpert	CE marked	N/A	LP-MIC-AST LP-MIC-GENEXPERT
	Detection of Influenza A, B and RSV	Viral Swab - nose or throat	Cepheid GeneXpert	CE marked	N/A	LP-MIC-FLU LP-MIC-GENEXPERT
	Detection of MTB Complex and Rifampicin resistance	Sputum, BAL	Cepheid GeneXpert	CE	N/A	LI-MIC-XPRTTB, LP-MIC-TB
	Detection of SARS-CoV-2	Nasopharyngeal swabs	Abbott Alinity M	CE	N/A	LP-MIC-ALINITYSARS2



			Cepheid GeneXpert	CE	N/A	LP-MIC-XPERTSARS
			Luminex Aries	CE	N/A	LP-MIC-LUMINEXSARS
			Roche FLOW using Primer Design Genesig SARS-CoV-2 assay	CE	N/A	LP-MIC-FLOWSARS2
	Detection of SARS-CoV2/ Flu A/ Flu B/ RSV - Alinity Four Plex		Abbott Alinity M	CE	N/A	LP-MIC-ALINITYM
	Detection of SARS-Co-V-2/Flu A/ Flu B/ RSV		Cepheid GeneXpert	CE	N/A	LP-MIC-GXSARS/FLU/RSV
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods, CE marked commercial systems	Automated Identification of Gram positive and Gram negative bacteria on Biomerieux Vitek 2 (automated system)		Biomerieux Vitek 2	CE marked		LP-MIC-AST/ LP-MIC-VITEK2
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Microscopic identification of significant moulds		Morphology and Microscopic examination (lactphenol blue)	standard method		LP-MIC-DERM/ LP-MIC-STAIN
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Automated identification of organisms (bacteria and yeast) using Biomerieux Vitek MS		Biomerieux VitekMS	CE marked		LP-MIC-ID/ LP-MIC-VITEK2/ LP-MIC-AST
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Anaerobic bacteria: Gradient MIC strips using EUCAST guidelines		Manual susceptibility testing by MIC strips using Eucast guidelines	standard method		LP-MIC-AST
	General aerobic/CO2/microareophilic		Automated susceptibility testing	Vitek 2: CE marked		LP-MIC-AST/ LP-MIC-VITEK2

	bacteria: Automated susceptibility testing, manual susceptibility testing by disks and MIC strips using EUCAST guidelines		using Vitek 2. Manual sensitivities standard method using Eucast Guidelines			
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Yeasts: Automated susceptibility testing using CLSI guidelines		Automated susceptibility testing for Candida using Vitek 2	Vitek 2: CE marked		LP-MIC-AST
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	mCim (modified carbapenemase inactivation method)	Bacterial Isolate	Modified manual susceptibility testing (non EUCAST guidelines)	Standard method	N/A	LP-MIC-AST/ LI-MIC-CREREP

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	Adjusted Calcium **1,2,4	Serum	Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	LP-SAT-ROCHE/ LP-CHEM-CALC
	Alanine Aminotransferase (ALT) **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Alkaline Phosphatase **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Amylase **1,2,3,4		Enzymatic Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Aspartate Aminotransferase (AST) **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Bilirubin - Total **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	C Reactive Protein **1,2,3,4		Particle enhanced immunoturbidometric assay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Calcium **1,2,3,4		Photometric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Carbon Dioxide **1,2,3,4		Photometric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Chloride **1,2,3,4		ISE	Roche Cobas 6000	CE	LP-SAT-ROCHE
Cholesterol **1,2,3,4	Enzymatic Colourimetric Assay	Roche Cobas 6000	CE	LP-SAT-ROCHE		

CKD-EPI GFR **1,2,4	Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	LP-SAT-ROCHE/ LP-CHEM-CALC
Creatine Kinase **1,2,3,4	Photometric	Roche Cobas 6000	CE	LP-SAT-ROCHE
Creatinine (Enzymatic) **1,2,3,4	Enzymatic method measured photometrically	Roche Cobas 6000	CE	LP-SAT-ROCHE
eGFR **1,2,4	Calculated	Roche Cobas 6000	CE	LP-SAT-ROCHE
FT3 **1,2,3,4	competitive immunoassay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE
FT4 **1,2,3,4	competitive immunoassay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Enzymatic colourimetric assay	Roche Cobas 6000	CE	LP-SAT-ROCHE
Glucose **1,2,3,4	Photometric	Roche Cobas 6000	CE	LP-SAT-ROCHE
HDL and LDL Cholesterol **1,2,3,4	Homogeneous enzymatic colourimetric test	Roche Cobas 6000	CE	LP-SAT-ROCHE
Iron **1,2,3,4	Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
Lactate Dehydrogenase **1,2,3,4	Enzymatic assay	Roche Cobas 6000	CE	LP-SAT-ROCHE
Lipid Calculations including: Non-HDL cholesterol (NHDLC) and Total Cholesterol: HDL Cholesterol ratio (TCHDR) **2	Calculation	Roche Cobas 6000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC
Lipid Calculations**1,2,4 including: Non-HDL Cholesterol (NHDLC) and Total Cholesterol: HDL Cholesterol Ratio (TCHDR)	Calculation	Roche Cobas 6000/ APEX iLAB (calculation)	CE	LP-CHEM-CALC

	Magnesium **1,2,3,4	Colourimetric end point assay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Phosphate **1,2,3,4	Photometric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Potassium **1,2,3,4	ISE	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Sodium **1,2,3,4	ISE	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Total Iron Binding Capacity (TIBC/C) **1,2,4	Calculation	Roche Cobas 6000/ APEX iLAB (calculation)	CE	LP-CHEM-CALC
	Triglycerides **1,2,3,4	Enzymatic Colourimetric assay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Troponin T high sensitivity **1,2,3,4	Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	TSH **1,2,3,4	Electrochemiluminescent sandwich Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Urea **1,2,3,4	Photometric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Uric Acid **1,2,3,4	Enzymatic Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin **1,2,3,4	Colourimetric	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Calculated Globulin **1,2,4	Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	LP-SAT-ROCHE/ LP-CHEM-CALC
	IgA **1,2,3,4	immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE
	IgE **1,2,3,4	sandwich immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	IgG **1,2,3,4	immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE
	IgM **1,2,3,4	immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Total Protein **1,2,3,4	Immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE

1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamycin **1,2,3,4		kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Vancomycin **1,2,3,4		homogeneous enzyme immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
1061 Clinical Chemistry - .40 Iron studies	Total Iron Binding Capacity (TIBC/C) **2		Calculation	Roche Cobas 6000/ APEX iLAB (Calculation)	CE	LP-CHEM-CALC
	Transferrin **1,2,3,4		immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Transferrin Saturation **1,2,4		Calculation	Roche Cobas 6000/ APEX iLab (Calculation)		LP-SAT-ROCHE/ LP- CHEM-CALC
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	Vitamin B12 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	CA125 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	CA15-3 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	CA19-9 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	CEA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	HCG **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
	PSA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	LP-SAT-ROCHE
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c **1,2,3,4	Blood	Turbidimetric Inhibition Immunoassay with TTAB Haemolyzer	Roche Cobas 6000	CE	LP-SAT-ROCHE

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## 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 including WCC, HB, Platelet Count, RCC, HCT, MCV, MCH, RDW **1,2,4	Blood	Cell counting and Flow Cytometric		CE marked	LP-HAE-SYSMEXXN LP-SAT-SYSMEXXN LF-HAE-APXAUTH
1030 Haematology - .05 Automated differential leucocyte counts	Five Part Differential **1,2,4		Flow Cytometric		CE marked	LP-HAE-SYSMEXXN LP-SAT-SYSMEXXN LF-HAE-APXAUTH
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Counts **1,4		Flow Cytometric		CE marked	LP-HAE-SYSMEXXN LP-SAT-SYSMEXXN LF-HAE-APXAUTH

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