

Schedule of Accreditation



Organisation Name	St Vincent's Healthcare Group (DAC)
Trading As	
INAB Reg No	192MT
Contact Name	Anne Dickinson
Address	Elm Park, Dublin, D4
Contact Phone No	01 2213695
Email	A.Dickinson@st-vincent's.ie
Website	
Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	22/04/2008
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 ¹	Yes

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	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	Blood Grouping (ABO & RhD Typing), Antibody Screening	Whole Blood	IH500 Analyser	CE		LP-BTR-IH500

automated methods						
	Blood Grouping (ABO & RhD Typing), Antibody Screening, Blood Transfusion Service Red Blood Cells; Confirming ABO and RhD group and donor units.	Whole Blood, Red Blood Cells	IH500 Analyser	CE		LP-BTR-IH500
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	Plasma	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		LP-BTR-028, LP-BTR-028A
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
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The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006). It also provides Haemovigilance and Traceability services to another site, further details available in the SLA between the accredited medical testing laboratory and the relevant site.

Head Office

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	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
AST (Aspartate Aminotransferase) **1,2,3,4	Serum/ Plasma	Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
C Reactive Protein (CRP) **1,2,3,4		Particle enhanced immunoturbidimetric 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	Plasma	Photometric	Roche Cobas 8000	CE	LP-CHEM-ROCHE
HDL and LDL Cholesterol **1,2,3,4	Serum/ Plasma	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	Serum	Enzymatic Assay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
Lipid Calculations including: Non-HDL	Blood	Calculation	Roche Cobas 8000/ APEX iLAB	CE	LP-CHEM-CALC

cholesterol (NHDLC) and Total Cholesterol: HDL Cholesterol ratio (TCHDR) **2			(Calculation)		
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	Serum	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
TSH **1,2,3,4	Serum/ Plasma	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)	Serum/ Plasma/ Urine	Enzymatic Colorimetric	Roche Cobas 8000	CE	LP-CHEM-ROCHE/

	**1,2,3,4					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	Immunoturbidimetric	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	Turbidimetric	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	LP-CHEM- OPTILITE
Osteocalcin **1,2,3,4	Serum	Electrochemiluminescent	Roche Cobas 8000	CE	LP-CHEM-ROCHE	

			Immunoassay			
	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 (HCO3) actual **1,2,4		Calculation	GEM5000 Blood Gas Analyser	CE	LP-CHEM-GEM5000
	Bicarbonate (HCO3) 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
	pCO2 **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
	pO2 **1,2,3,4		Potentiometry	GEM5000 Blood	CE	LP-CHEM-

				Gas Analyser		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	Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE
	DHEA Sulphate (DHEAS / Dehydroepiandrosterone Sulphate) **1,2,3,4	Serum/ Plasma	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	Immunoturbidimetric 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	Roche Cobas 8000	CE	LP-CHEM-ROCHE

1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP **1,2,3,4		Immunoassay			
	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)		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	LP-CHEM-ROCHE

	**1,2,3,4					
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- MP96

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

Head Office

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood 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 Reticulocyte Counts			Flow Cytometric	Sysmex XN10/ XN20	CE	LP-HAE-

Automated reticulocyte counts	**1,4			Haematology Analyser		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 **4		Immunochromatographic Test and Microscopy	Test Kit/ Microscope	CE	LP-HAE-M-DIAG
1030 Haematology - .20 Bone marrow examination	Bone marrow staining and examination **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 **4	Peripheral Blood	Clearview kit method	Clearview kit	CE	LP-HAE-IMSCREEN
1030 Haematology - .70 Immunophenotyping	Acute and Chronic Leukaemia screening panel	Peripheral Blood and bone marrow	Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	LP-HAE-CLEARLAB

	**1,2,4					
	Acute Leukaemia Panel and Chronic Leukaemia Panel **1,2,4		Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	LP-HAE-IMMLEUK
	CD34 Quantification cells/microlitre **4	Peripheral Blood	Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	LP-HAE-CD34
	CD34 x 10 ⁶ /kg Harvest yield **4	Peripheral blood apheresis samples	Flow Cytometry and Calculation	Navios EX Flow Cytometer (Beckman Coulter)/ APEX iLAB (Calculation)	CE	LP-HAE-CD34
	Post Thaw Stem Cell Viability **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

Head Office

Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Automated and Manual Haemotoxylin and Eosin Staining, coverslipping **2,4	Human Tissue	Prisma Automated Slide Stainer and G2 Coverslipper	Based on standard method		LP-HIS-INTQC/ LP-HIS-SECTW/ LP-HIS-PRISMA/ LP-HIS-G2COVER/LP-HIS-H&EMAN
	Cut up; Tissue Processing; Embedding; Microtomy **2,4		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-

1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut Up: Frozen Section cryotomy and staining **2,4
1051 Histopathology - .03 Histochemistry	Automated special stains using the ARTISAN: PAS, PASD, Perls, Masson Trichrome, Reticulin, Jones' Methenamine Silver, Grocotts (fungi & pneumocystis), Congo Red, Ziehl Neelson H&E, Gram, Van Gieson, AB/PAS, Miller's Elastin, Alcain Blue, Rubeanic Acid, MSB, Oil Red O, Shikata Orcein and Haematoxylin Shikata
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,

			AMPPROC/ LP-HIS-LIQINT/ LP-HIS-MCLASS1/ LP-HIS-PRFORMAL/ LP-HIS-SECTPAR/ LI-HIS-LEICAMICROTOMES
Leica CM1900 cryostat	Based on standard method		LP-HIS-FRESHFS/ LP-HIS-LIQNIT/ LP-HIS-MCLASS1
Dako Artisan Link Pro Special Stainer	CE marked		LP-HIS-ARTISANPRO/ LP-HIS-EQASP
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
Consultant Microscope			LP-HIS-REPHER-2/ LP-HIS-REPOR/PR

	Neuropathology. Specialist Areas INCLUDED: Medical Renal Pathology, Breast Screening Pathology
1051 Histopathology - .09 Immunohistochemistry	AE1/3 **2,4
	AE1/3-D2-40 Dual Stain **2,4
	ALK (NSCLC) **2,4
	Androgen Receptor **2,4
	BAP1
	BCI2 **2,4
	BCI6 **2,4
	BCL10
	Ber-EP4 **2,4
	Beta-Catenin **2,4
	BRAF V600E **2,4
Calponin **2,4	

Ventana Benchmark Ultra	CE marked		LP-HIS- VENTBENCHMARKULTRA
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Ventana Benchmark Ultra	CE marked		LP-HIS- VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS- VENTBENCHMARKULTRA
Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS- VENTBENCHMARKULTRA
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS- VENTBENCHMARKULTRA
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Ventana Benchmark Ultra	CE marked		LP-HIS- VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS- VENTBENCHMARKULTRA

Calretinin **2,4
CD10 (SP67) **2,4
CD117 **2,4
CD138 **2,4
CD15 (MMA) **2,4
CD15 **2,4
CD20 **2,4
CD23 **2,4
CD246 (ALK1) **2,4
CD3 **2,4
CD30 **2,4
CD31 **2,4
CD34 **2,4
CD4 **2,4
CD45 **2,4
CD5 **2,4

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Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

CD56 (MRQ-42) **2,4
CD68 **2,4
CD79a (SP18) **2,4
CD8 **2,4
CD99 **2,4
CDX2 **2,4
Chromogranin **2,4
CK19 (A53-B/A2.26) **2,4
CK20 **2,4
CK5/6 **2,4
CK7 **2,4
CMV **2,4
C-myc
Cyclin D1 **2,4
D2-40 **2,4
Desmin **2,4

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Ventana Benchmark XT	CE marked		LP-HIS-VENTBENCHMARKXT
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Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
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DOG1 **2,4
Dual Stain Myosin Smooth Muscle and AE1/3 **2,4
EBV (In situ hybridisation, ISH) **2,4
E-Cadherin **2,4
EMA **2,4
ER (SP1) **2,4
ERG **2,4
Gastrin **2,4
GATA-3 **2,4
Glutamine Synthetase **2,4
Glypican 3 **2,4
H. Pylori **2,4
H3K27me3 (C36B11) **2,4
Heat Shock Protein 70 **2,4
Hepar **2,4

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Her2neu (45B) **2,4
HMB45 **2,4
HSV1 **2,4
IgG4 (EP138) **2,4
INSM1 **2,4
Insulin **2,4
Kappa (ISH) **2,4
Ki67 **2,4
Lambda (ISH) **2,4
Melan A **2,4
MLH1 **2,4
MSH2 **2,4
MSH6 **2,4
Muc 4 **2,4
Mum-1 **2,4
Myo D1 **2,4

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Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
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Myogenin **2,4
Myosin Smooth Muscle/ SMMS-1 **2,4
Napsin A **2,4
NKX2.2 (EP336) **2,4
OCT4 **2,4
Oestrogen Receptor **2,4
p-16 **2,4
P5045/ Racemase/ AMACR **2,4
P53 **2,4
P63 **2,4
p63-AE1/3 Dual Stain **2,4
p63-Ker5/6 Dual Stain **2,4
PAX5 **2,4
PAX8 (EP311) **2,4
PD-L1 (22C3)
PD-L1 (SP263) **2,4

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PMS2 **2,4
PRAME (ERP 20330) **2,4
Progesterone Receptor **2,4
PSA **2,4
ROS1 **2,4
S100 **2,4
SMA (IA4) **2,4
SOX-10 **2,4
SSTR2A
Stat 6 **2,4
Succinate Dehydrogenase (SDHB)
Synaptophysin **2,4
TdT (Terminal Deoxynucleotidyl Transferase) **2,4
TTF-1 **2,4
TTF-1-Napsin A Dual Stain **2,4
WT-1 **2,4

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Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
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Ventana Benchmark Ultra	Based on Standard Method		LP-HIS-VENTBENCHMARKULTRA
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Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS-VENTBENCHMARKULTRA
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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 **2,4	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		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
	Ber-EP4 **2,4		Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Beta-Catenin **2,4	Ventana Benchmark Ultra	CE marked		LP-HIS- VENTBENCHMARKULTRA		

BRAF V600E **2,4
Calponin **2,4
Calretinin **2,4
CD10 (SP67) **2,4
CD117 **2,4
CD138 **2,4
CD15 (MMA) **2,4
CD15 **2,4
CD20 **2,4
CD23 **2,4
CD246 (ALK1) **2,4
CD3 **2,4
CD30 **2,4
CD31 **2,4
CD34 **2,4
CD4 **2,4

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Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
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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
CK19 (A53-B/A2.26) **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
Desmin **2,4
DOG1 **2,4
Dual Stain Myosin Smooth Muscle and AE1/3 **2,4
EBV (In Situ hybridisation, ISH) **2,4
E-Cadherin **2,4
EMA **2,4
ER (SP1) **2,4
ERG **2,4
Gastrin **2,4
GATA-3 **2,4
Glutamine Synthetase **2,4
Glypican 3 **2,4
H. Pylori **2,4
H3K27me3 (C36B11) **2,4

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Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOCISH
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
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Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
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
INSM1 **2,4	Urinary Cytology, Serous Fluid Cytology, Respiratory Cytology and FNAs	Ventana Benchmark Ultra	CE marked		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
Mum-1 **2,4
Myo D1 **2,4
Myogenin **2,4
Myosin Smooth Muscle/ SMMS-1 **2,4
Napsin A **2,4
NKX2.2 (EP336) **2,4
OCT4 **2,4
Oestrogen Receptor **2,4
p-16 **2,4
P5045/Racemase/ AMAC **2,4
P53 **2,4
P63 **2,4
p63-AE1/3 dual stain **2,4
p63-Ker5/6 dual stain **2,4
PAX 8 (EP311) **2,4

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Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
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Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA

PAX5 **2,4
PD-L1 (22C3) **2,4
PD-L1 (SP263) **2,4
PMS2 **2,4
PRAME **2,4
Progesterone Receptor **2,4
PSA **2,4
ROS1 **2,4
S100 **2,4
SMA (IA4) **2,4
SOX-10 **2,4
SSTR2A
Stat 6 **2,4
Succinate Dehydrogenase (SDHB)
Synaptophysin **2,4
TdT (Terminal Deoxynucleotidyl Transferase) **2,4

Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Dako Omnis	CE marked		LP-HIS-DAKOOMNIS
Dako Omnis Immunostainer	CE marked		LP-HIS-DAKOOMNIS
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	Based on standard method		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	CE marked		LP-HIS-VENTBENCHMARKULTRA
Ventana Benchmark Ultra	Based on standard method, not CE marked		LP-HIS-VENTBENCHMARKULTRA
Dako Omnis	CE marked		LP-HIS-DAKOOMNIS
Dako Omnis Immunostainer	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
1054 Molecular genetics - .06 DNA extraction	Nucleic Acid Extraction from FFPE - Formapure Nucleic Acid kit	FFPE scrolls (Solid tumour and cytology)		Non CE - Based on standard method		LP-HIS-FORMAPUREEXTRACT
1055 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Thermofisher Oncomine Focus Assay - SNVs/ small indels	DNA	Next generation sequencing Thermofisher Ion Chef system and Ion Genestudio S5 Sequencer. Cobas Z480 lightcycler , VeritiPro 96-well thermal cycler, JSI Seqnext, Ion Reporter	Non CE - Based on standard method		LP-HIS-CHEF-LIBRARYPREP, LP-HIS-CHEFTEMPLATINGSEQ, LP-HIS-NGSANALYSIS, LP-HIS-MOLTRACK
1055 Molecular pathology - .03 Assay for somatic variants in gene structure	Thermofisher Oncomine Focus Assay - fusions and skipping/ splicing	cDNA	Next generation sequencing Thermofisher Ion Chef system and Ion Genestudio S5 Sequencer. Cobas Z480 lightcycler , VeritiPro 96-well thermal cycler, JSI Seqnext, Ion Reporter	Non CE - Based on standard method		LP-HIS-CHEF-LIBRARYPREP, LP-HIS-CHEFTEMPLATINGSEQ, LP-HIS-NGSANALYSIS, LP-HIS-MOLTRACK

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

Head Office

Immunology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. Ref & SOP
1040 Immunology - .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	0-200 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	CE	0.4>=340 U/ml	LP-IMM-PHADIA	

Anti-dsDNA antibodies
Anti-ENA antibodies
Anti-ENA Profile including: Anti-Ro, Anti-La, Anti-SmDP-S, Anti-U1RNP, Anti-Scl-70S, Anti-Jo-1, Anti-CENP
Anti-LKM antibodies
Anti-mitochondrial antibodies

immunoassay on the Phadia250			
Detected by immunoassay on the Phadia250	CE	0.6>/= 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
Detected by immunoassay on the Phadia250	CE	0.09-55 (ratio)	LP-IMM-PHADIA
Detected by immunoassay on the Phadia250	CE	Measuring Ranges: Anti-Ro: 0.4 - >/= 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
Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
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 neutrophils (Werfen) using the Quantalyser 3000 (Werfen)	CE		LP-IMM-QUANTA3000
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-PR3 antibodies	Detected by immunoassay on the Phadia250	CE	0.6 to >= 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	Detected by immunoassay on the	CE	0.2 to >= 128 U/ml	LP-IMM-PHADIA

	(Anti-tTG) antibodies		Phadia250			
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)	CMIA on Abbott Architect	CE	18-1500 ng/ml	LP-IMM-ARCHITECT
	Tacrolimus		CMIA on Abbott Architect	CE	2.0-30 ng/ml	LP-IMM-ARCHITECT