

Schedule of Accreditation



Organisation Name	St. Vincent's Healthcare Group (DAC)
Trading As	
INAB Reg No	192MT
Contact Name	Anne Dickinson
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Website	
Accreditation Standard	ISO 15189
Date Initially Awarded	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 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
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		ISO15189 5.5, 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		ISO15189 5.5, 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	IH1000 analyser, Diamed ID-Gel Station	CE		ISO15189 5.5, LP-BTR-IH1000, LP-BTR-080

	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	Diamed ID-Gel Station, IH1000 analyser	CE		ISO15189 5.5, LP-BTR-IH1000, LP-BTR-080
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	IAT Manual Method using gel cards and tube technique	CE		ISO15189 5.5, LP-BTR-018
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual method using Gel IAT and enzyme, and Tube method using IAT	CE		ISO15189 5.5, LP-BTR-019
	LISS Alloadsorption		Antibody Adsorption	CE		ISO15189 5.5, LP-BTR-023, LP-BTR-017
1020 Transfusion science - .05 Cross match compatible donor units	Serological crossmatch testing. Compatability analysis for the release of compatible blood by electronic means		Manual method of crossmatching in tubes and gel technique, Electronic Crossmatching	CE		ISO15189 5.5, LP-BTR-028 and LP-BTR-028A
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	Manual method in tubes and cards	CE		ISO15189 5.5, LP-BTR-027
1020 Transfusion science - .07 Antibody elution	Antibody Elution Testing of EDTA specimens	EDTA		CE		ISO15189 5.5, LP-BTR-024
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Testing	Red Blood Cells	manual method with monospecific gel cards	CE		ISO15189 5.5, 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		ISO15189 5.5, LP-BTR-009

Note: St. Vincent's University Hospital has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I.No. 360 of 2005 and S.I. No. 547 of 2006)

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	Adjusted Calcium **1,2,4	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-INTERP
	Alanine Aminotransferase (ALT) **1,2,3,4		colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Alkaline Phosphatase **1,2,3,4		colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Amylase **1,2,3,4	Serum/ Plasma/ fluid/ urine	enzymatic colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
	Angiotensin Converting Enzyme (ACE) **1,2,3,4	Serum/ Plasma	photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Aspartate Aminotransferase (AST) **1,2,3,4		colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Bilirubin - Direct **1,2,3,4	Serum/ Plasma/ fluid	colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Bilirubin - Total **1,2,3,4		colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-FLUIDS

C Reactive Protein **1,2,3,4	Serum/ Plasma	particle enhanced immunoturbidometric assay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Calcium **1,2,3,4	Serum/ Plasma/ Urine	photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
Calcium Phosphate Product **1,2,4	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLab (Calculation)	CE	ISO15189 5.5/ LP-CHEM- ROCHE/ LP- CHEM-CALC
Calcium/ Creatinine Ratio **1,2,4	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-U-HP
Carbon Dioxide **1,2,3,4	Serum/ Plasma	photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Chloride **1,2,3,4	Serum/ Plasma/ Urine / Fluid	ISE	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
Chloride Direct ISE **1,2,3,4	Serum/ Plasma	direct ISE	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Cholesterol **1,2,3,4	Serum/ Plasma/ Fluid	enzymatic colorimetric assay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
CKD-EPI GFR **1,2,4	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CRCE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-INTERP
Cortisol **1,2,3,4		competitive immunoassay using electrochemiluminescence	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Creatine Kinase **1,2,3,4		photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Creatinine (Enzymatic) **1,2,3,4		enzymatic method measured photometrically	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
eGFR **1,2,4		calculated	calculated	Roche Cobas 8000	CE
	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-INTERP

Free T3 **1,2,3,4		competitive immunoassay using electrochemiluminescence	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM/ LP-BIO-INTERP
FT4 **1,2,3,4		competitive immunoassay using electrochemiluminescence	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Gamma Glutamyl Transferase **1,2,3,4		enzymatic colorimetric assay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Glucose **1,2,3,4	Serum/ Plasma/ Fluid/ CSF	photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-CSF
HDL and LDL Cholesterol **1,2,3,4	Serum/ Plasma	homogeneous enzymatic colorimetric test	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Homocysteine **1,2,3,4	EDTA Plasma	enzymatic	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Iron **1,2,3,4	Serum/ Plasma	colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Lactate Dehydrogenase **1,2,3,4	Serum/ Plasma/ Fluid	enzymatic assay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Magnesium **1,2,3,4	Serum/ Plasma/ Urine	colorimetric end point assay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
NT-Pro-BNP **1,2,3,4	Serum	Electrochemiluminescent sandwich Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
Phosphate **1,2,3,4	Serum/ Plasma/ Urine	photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
Potassium **1,2,3,4	Serum/ Plasma/ Urine / Fluid	ISE	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
Potassium Direct ISE **1,2,3,4	Serum/ Plasma	direct ISE	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Serum/ Urine/ Fluid Osmolality Freezing Point Depression	Serum/ Urine	Freezing Point Depression	Advanced Micro-Osmometer	CE	ISO15189 5.5/ LP-SCHEM- OSM/ LP-

	(50-850mOsm/kg) **1,2,3,4					SCHEM-OSM3320
	Sodium **1,2,3,4	Serum/ Plasma/ Urine/ Fluid	ISE	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP/ LP-BIO-FLUIDS
	Sodium Direct ISE **1,2,3,4	Serum/ Plasma	direct ISE	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM-ROCHEIMM
	T3 **1,2,3,4		competitive immunoassay using electrochemiluminescence	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM-ROCHEIMM
	Triglycerides **1,2,3,4	Serum/ Plasma/ Fluid	enzymatic colorimetric assay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Troponin T High Sensitivity **1,2,3,4	Serum/ Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM-ROCHEIMM
	TSH **1,2,3,4		electrochemiluminescent sandwich Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM-ROCHEIMM
	Urea **1,2,3,4	Serum/ Plasma/ Urine/ Fluid	photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP
	Urea/ Creatinine Ratio **1,2,4	Urine	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-U-HP
	Uric Acid **1,2,3,4	Serum/ Plasma/ Urine/ Fluid	enymatic colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE/ LP-BIO-U-HP/ LP-BIO-FLUIDS
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin **1,2,3,4	Serum/Plasma/Urine	Colourimetric	Roche Cobas 8000	CE	ISO15189.5/LP-BIO-ROCHE/LP-BIO-U-HP
	Beta 2 Microglobulin **1,2,3,4	Serum	immunoturbidometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Caeruloplasmin **1,2,3,4		Immunturbidimetric	Roche Cobas 8000	CE	ISO15189.5/LP-BIO-ROCHE

	Calculated Globulin **1,2,4	Serum/ Plasma	Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-INTERP
	Complement C3 **1,2,3,4	Serum	Immunoturbidimetric	Roche Cobas 8000	CE	ISO151895.5/LP- BIO-ROCHE
	Complement C4 **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	ISO151895.5/LP- BIO-ROCHE
	CSF Total Protein **1,2,4	CSF	turbidometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-CSF
	Immunoglobulin A **1,2,3,4	Serum	Immunoturbidimetric	Roche Cobas 8000	CE	ISO151895.5/LP- BIO-ROCHE
	Immunoglobulin E **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	ISO151895.5/LP- BIO-ROCHE
	Immunoglobulin G **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	ISO151895.5/LP- BIO-ROCHE
	Immunoglobulin M **1,2,3,4		Immunoturbidimetric	Roche Cobas 8000	CE	ISO151895.5/LP- BIO-ROCHE
	Osteocalcin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Serum Protein Electrophoresis **1,2,4		Electrophoresis	Sebia Hydrasys	CE	ISO15189 5.5/LP-CHEM- SPE
			Electrophoresis	Sebia Hydrasys	CE	ISO15189 5.5/LP-CHEM- SPE
	Total Protein **1,2,3,4		Serum/Plasma/Urine/CSF	Colourimetric	Roche Cobas 8000	CE
1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis	Protein Electrophoresis **1,2,4	Urine	Electrophoresis	Sebia Hydrasys	CE	ISO15189 5.5/ LP-BIO-SPE
1061 Clinical Chemistry - .05 CO- oximetry	Carboxyhaemoglobin **1,2,3,4	Blood	Co-oximetry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000

	Methaemoglobin **1,2,3,4		Co-oximetry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Base Excess **1,2,4		calculation	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	HCO3 actual **1,2,4		calculation	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	HCO3 Std **1,2,4		calculation	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	O2 Saturation **1,2,3,4		Co-oximetry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	pCO2 **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	pH **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	pO2 **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Chloride **1,2,3,4	Serum/ Plasma/ Whole Blood	Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	Glucose **1,2,3,4	Blood	Amperometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	Ionised Calcium **1,2,3,4	Serum/ Plasma/ Whole Blood	Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	Lactate **1,2,3,4	Blood	Amperometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000

	Potassium **1,2,3,4	Serum/ Plasma/ Whole Blood	Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
	Sodium **1,2,3,4		Potentiometry	GEM5000 Blood Gas Analyser	CE	ISO15189 5.5/ LP-CHEM- GEM5000
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin **1,2,3,4	Serum	immunoassay using absorbance	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Carbamazepine **1,2,3,4		homogeneous microparticle agglutination immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Digoxin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Gentamicin **1,2,3,4		kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Lithium **1,2,3,4		colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Phenytoin **1,2,3,4		KIMS	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Theophylline **1,2,3,4		KIMS	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Tobramycin **1,2,3,4		enzyme immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Vancomycin **1,2,3,4	homogeneous enzyme immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE	
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol **1,2,3,4	Plasma	enzymatic	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Acetaminophen **1,2,3,4	Serum	Photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHE

	Paracetamol **1,2,3,4		Enzymatic	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
	Salicylate **1,2,3,4		photometric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO-ROCHE
1061 Clinical Chemistry - .20 Hormones	ACTH, clinically relevant levels **1,2,3,4	EDTA Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Androstenedione **1,2,3,4	Serum/ Plasma	RIA	Wallac Wizard Gamma Counter	CE	ISO15189 5.5/ LP-SCHEM- ANDRO/ LP- SCHEM- GAMMAOP
	Chromogranin A **1,2,3,4	Plasma	RIA	Wallac Wizard Gamma Counter	CE	ISO15189 5.5/ LP-SCHEM- CGA/ LP- SCHEM- GAMMAOP
	DHEAS, clinically relevant levels **1,2,3,4	Serum/ Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	FSH, clinically relevant levels **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Insulin Like Growth Factor 1 (IGF1) **1,2,3,4	Serum	IRMA	Wallac Wizard Gamma Counter	CE	ISO15189 5.5/ LP-SCHEM-IGF/ LP-SCHEM- GAMMAOP
	Insulin, clinically relevant levels **1,2,3,4	Serum/ Plasma	Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	LH, clinically relevant levels **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Oestradiol, clinically relevant levels **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Parathyroid Hormone **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM

	Progesterone, clinically relevant levels **1,2,3,4
	Prolactin, clinically relevant levels **1,2,3,4
	SHBG, clinically relevant levels **1,2,3,4
	Testosterone, clinically relevant levels **1,2,3,4
	Vitamin D **1,2,3,4
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4
	Iron **1,2,3,4
	Transferrin **1,2,3,4
	Transferrin Saturation **1,2,4
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4
	Vitamin B12 **1,2,3,4
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP **1,2,3,4
	CA125 **1,2,3,4

Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
colorimetric	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO- ROCHE
immunospectrometric assay using electrochemiluminescence	Roche Cobas 8000	CE	ISO15189 5.5/ LP-BIO- ROCHE
Calculation	Roche Cobas 8000/ APEX iLAB (Calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC/ LP-BIO-INTERP
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM

	CA15-3 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	CA19-9 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	CEA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	HCG **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	PSA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Thyroglobulin, clinically relevant levels **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-SCHEM- ROCHE
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c, clinically relevant levels **1,2,3,4	Blood	HPLC	Menarini 8180	CE	ISO15189 5.5/ LP-SCHEM- HbA1c
1061 Clinical Chemistry - .62 pH of urine and fluids by electrode	pH **1,2,3,4	Urine	pH Meter	Jenway pH/ mV Temperature Meter Model 3510	CE	ISO15189 5.5/ LP-CHEM- PHMETER
1061 Clinical Chemistry - .99 Miscellaneous tests	Anti-TPO **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Bone Alkaline Phosphatase **1,2,3,4	Serum/ Plasma	monoclonal antibody immunoenzymatic assay	Grifols Triturus	CE	ISO15189 5.5/ LP-SCHEM-BAP
	C-Terminal Propeptide of Type 1 Collagen **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Procollagen Type 1 amino-terminal propeptide **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 8000	CE	ISO15189 5.5/ LP-CHEM- ROCHEIMM
	Urine N-Terminal Telopeptide of Type 1 Collagen **1,2,3,4	Urine	competitive-inhibition enzyme-linked immunosorbent assay	Grifols Triturus	CE	ISO15189 5.5/ LP-SCHEM-NTX

1064 Molecular genetics - .02 Assay for identified pathogenic variant(s)	Hereditary Haemochromatosis HFE gene mutations (C282Y, H63D, S65C)	Blood	testing in genomic DNA purified from peripheral blood	Roche Magna Pure Compact automated DNA extractor and Roche Lightcycler 480 11 Real Time PCR Analyser	CE	Iso15189 5.5/ LP-BIO-HFE1
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The laboratory is accredited for a flexible scope of testing in the following categories

- 1 Range of measurement may be extended*
- 2 Parameters may be added*
- 3 Test matrices may be added*
- 4 Equipment/kit*

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	Blood	Cell counting and Flow Cytometric	Sysmex XE5000	CE	ISO15189 5.5/ LP-HAE-SYSMEX/ 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)		Microscopy	Microscope	CE	ISO15189 5.5/ LP-HAE-BLDFLMREP/ LP-HAE-BLDFLMMAK/ LP-HAE-SXSP100-M/ LP-HAE-SLDSTN
1030 Haematology - .03 Erthrocyte sedimentation rate	ESR		Sedimentation & Aggregation	Alifax Test 1 THL ESR Analyser	CE	ISO15189 5.5/ LP-HAE-ESR
1030 Haematology - .05 Automated differential leucocyte counts	Five Part Differential		Flow Cytometric	Sysmex XE5000	CE	ISO15189 5.5/ LP-HAE-SYSMEX
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Counts		Flow Cytometric	Sysmex XE5000	CE	ISO15189 5.5/ LP-HAE-SYSMEX
1030 Haematology - .09 Examination of malarial parasites	Malaria Testing using Antigen and Antibody kits;		Immunochromatographic Test and Microscopy	Test Kit/ Microscope	CE	ISO15189 5.5/ LP-HAE-M-DIAG

	Thick and thin blood films					
1030 Haematology - .20 Bone marrow examination	Bone marrow staining and examination	Bone Marrow	Microscopy	Microscope	CE	ISO15189 5.5/ LP-HAE-BMLABEL
1030 Haematology - .40 Limited haemostasis related tests	Anti Xa-assay	Blood	Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-ANTIXA
	Factor Assays (FII, FV, FVII, FVIII, FIX, FX, FXI, FXII)		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-FA
	Lupus Screen (DRVVT, Silica Clotting Time)		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-LUPUS
	Thrombin Time		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-TT
	Thrombophilia Screen (Protein C, Protein S, Anti-Thrombin, Activated Protein C resistance)		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-SAMPRETS/ LP-HAE-STOREC/ LP-HAE-THROMBOPHILIA
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT)		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-COAG
	D-Dimers		Latex Immunoassay	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-COAG
	Fibrinogen		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-COAG
	International Normalised Ration (INR)		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-COAG
	Prothrombin Time (PT)		Optical	IL ACL TOP 550 Coagulation Analyser	CE	ISO15189 5.5/ LP-HAE-COAG
1030 Haematology - .55 Iron studies	Haemosiderin	Urine	Cytochemistry	N/A	CE	ISO15189 5.5/ LP-HAE-IRONSTN

	Iron Stain for Bone Marrow	Bone Marrow	Cytochemistry	N/A	CE	ISO15189 5.5/ LP-HAE-IRONSTN
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen using Clearview	Peripheral Blood	Clearview kit method	Clearview kit	CE	ISO15189 5.5/ 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	ISO15189 5.5/ LP-HAE-CLEARLAB
	Acute Leukaemia Panel and Chronic Leukaemia Panel		Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	ISO15189 5.5/ LP-HAE-IMMLEUK
	CD34 Quantitation	Peripheral Blood and peripheral blood apheresis samples	Flow Cytometry	Navios EX Flow Cytometer (Beckman Coulter)	CE	ISO15189 5.5/ LP-HAE-CD34
1030 Haematology - .99 Miscellaneous tests	Sickle Cell Screen	Blood	Turbimetric	N/A	CE	ISO15189 5.5/ LP-HAE-SCT

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	Cut Up; Tissue Processing; Embedding; Microtomy; Automated and Manual Haematoxylin and Eosin Staining; Coverslipping **4	Human Tissue	Leica ASP6025, Leica300 and Peloris 3	Based on standard method		ISO15189 5.5/ LP-HIS-TISSPROC/ LP-HIS-VIP/ 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

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

Leica CM1900 cryostat	Based on standard method		ISO15189 5.5/ LP-HIS-FRESHFS/ LP-HIS-LIQNIT/ LP-HIS-MCLASS1
Prisma automated slide stainer and G2 coverslipper	Based on standard method		ISO15189 5.5/ LP-HIS-INTQC/ LP-HIS-AXPSREQ/ LP-HIS-SECTW/ LP-HIS-PRISMA/ LP-HIS-G2COVER
Dako Artisan Link Pro Special Stainer	CE		ISO15189 5.5/ LP-HIS-ARTISANPRO/ LP-HIS-EQASP
Manual	Based on standard method		ISO15189 5.5/ 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			ISO15189 5.5/ LP-HIS-REPPER-2/ LP-HIS-REPOR/PR

	Breast Screening Pathology
1051 Histopathology - .09 Immunohistochemistry	Automated and Semi-Automated Immunohistochemistry **2,4: AE1/3, ALK1, Androgen Receptor Basal Cell Cocktail, Beta-Catenin, BCI2, BCI6, BEREP4, BRAF V600E Cam5.2, Calponin, Calretinin, CD10, CD117, CD138, CD15, CD20, CD23, CD3, CD30, CD31, CD34, CD4, CD45, CD5, CD56, CD68, CD79A, CD8, CDX2, Chromogranin, CK20, CK5/6, CK7, C-myc, CMV, Cyclin D1, D2-40,

Dako Omnis Immunostainer ,Ventana Benchmark XTs & Benchmark Ultra	All CE marked except SSR2A, IgG4, Glutamine Synthetase & c-myc		ISO15189 5.5/ LP-HIS-VENTBENCHMARKXT/ Ventana User Manual/ LP-HIS-DAKOOMNIS/ LP-HIS-BENCHMARKULTRA/ LP-HIS-REPOR/PR/ LP-HIS-REPHER2/ LF-HIS-IMMUNOWBK

	<p>Desmin, DOG1, Double Stain Breast (p63-AE1/3), Double Stain Lung Adeno (TTF-1 - Napsin A), Double Stain Lung Squamous (p63-Ker5/6), Double Stain Lymphatic Invasion (AE1/3 - D2-40), EBV (In situ hybridisation, ISH), E-Cadherin, EMA, ERG, GATA-3, GCDFP-15, Glutamine Synthetase, Glypican 3, Her2Neu, H. Pylori, Hepar, HSV1, HMB45, IgG4, Ki67, Kappa (ISH), Lambda (ISH), Mammaglobin, Melan A, MLH1, MSH2, MSH6, Muc 4, Mum-1, Napsin A, OCT4, Oestrogen Receptor, P5045/ Racemase, p-16,</p>					
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	P53, P63, PAX5, PAX8, PD-L1 (SP263), PLAP, PMS2, Progesterone Receptor, PSA, RCC, ROS1, S100, SMA, SSR2A, Stat 6 Synaptophysin, TdT (Terminal Deoxynucleotidyl Transferase), TTF-1, Vimentin, WT-1					
1051 Histopathology - .10 Fluorescence in situ hybridisation	FISH Her2 **4	Human Tissue/ Slide	Dako Omnis Immunostainer	CE		ISO15189 5.5/ LP-HIS- DAKOOMNIS
1052 Cytopathology - .02 Non gynaecological cytology	Exfoliative and FNA cytology	Urinary Cytology Serous fluid Cytology Respiratory Cytology and FNAs	Thin Prep 2000, Leica ST5020			ISO15189 5.5/ 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	Automated and Semi- Automated Immunocytochemistry **2,4: AE1/3, ALK1, Androgen Receptor Basal Cell Cocktail, Beta-Catenin, BCI2,		Dako Omnis Immunostainer , Ventana Benchmark XTs & Benchmark Ultra	All CE marked except SSR2A, IgG4, Glutamine Synthetase, HbsAg & c-myc		ISO15189 5.5/ LP-HIS- VENTBENCHMARKXT/ LP-HIS-DAKOOMNIS

	BCI6, BEREP4, BRAF V600E Cam5.2, Calponin, Calretinin, CD10, CD117, CD138, CD15, CD20, CD23, CD3, CD30, CD31, CD34, CD4, CD45, CD5, CD56, CD68, CD79A, CD8, CDX2, Chromogranin, CK20, CK5/6, CK7, C-myc, CMV, Cyclin D1, D2-40, Desmin, DOG1, Double Stain Breast (p63-AE1/3), Double Stain Lung Adeno (TTF-1 - Napsin A), Double Stain Lung Squamous (p63- Ker5/6), Double StainLymphatic Invasion (AE1/3 - D2-				
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	<p>40), EBV (In situ hybridisation, ISH), E-Cadherin, EMA, ERG, GATA-3, GCDFP-15, Glutamine Synthetase, Glypican 3, Her2Neu, H. Pylori, Hepar, HSV1, HMB45, IgG4, Ki67, Kappa (ISH), Lambda (ISH), Mammaglobin, Melan A, MLH1, MSH2, MSH6, Muc 4, Mum-1, Napsin A, OCT4, Oestrogen Receptor, P5045/ Racemase, p-16, P53, P63, PAX5, PAX8, PD-L1 (SP263), PLAP, PMS2, Progesterone Receptor, PSA, RCC, ROS1, S100,</p>				
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	SMA, SSR2A, Stat 6, Synaptophysin, TdT (Terminal Deoxynucleotidyl Transferase), TTF-1, Vimentin, WT-1					
1055 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Assays for somatic variants in DNA sequences: Semi- automated BRAF/ NRAS mutation testing	Human tissue and cytology cell blocks	Semiautomated BRAF/ NRAS mutation testing: Roche Lightcycler 480 11 Real Time PCR analyser	CE		ISO15189 5.5/ LP-HIS- MICRODIS/ LP-HIS- DNACOBAS/ LP-HIS- NRASBRAFTTEST
	Assays for somatic variants in DNA sequences: Semi- Automated EGFR mutation testing		Semiautomated EGFR mutation testing: Roche Lightcycler 480 11 Real Time PCR analyser	CE		ISO15189 5.5/ LP-HIS- MICRODIS/ LP-HIS- DNACOBAS/ LP-HIS- EGFRTEST
	Assays for somatic variants in DNA sequences: Semi- automated KRAS mutation testing		Semiautomated KRAS mutation testing: Roche Lightcycler 480 11 Real Time PCR analyser	CE		ISO15189 5.5/ LP-HIS- MICRODIS/ LP-HIS- DNACOBAS/ LP-HIS- KRASSTEST

The laboratory is accredited for a flexible scope of testing in the following categories

- 1 Range of measurement may be extended*
- 2 Parameters may be added*
- 3 Test matrices may be added*
- 4 Equipment/kit*

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 15-30mg/dl, BJP programme has a limit of detection of 1-5mg/dl	ISO15189 5.5/ 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	0.1-100kUA/L	ISO15189 5.5/ LP-IMM-PHADIA
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Rheumatoid Factor (RF)		IgM RF measured by immunoassay on the Phadia250	CE	0.4-200 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti GBM antibodies		Detected by immunoassay on the Phadia250	CE	0.8-680 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
	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 0.8 - >/=472 MPL-U/ml	ISO15189 5.5, LP-IMM-PHADIA
	Anti-CCP antibodies	Detected by immunoassay on the Phadia250	CE	0.4-340 U/ml	ISO15189 5.5/ LP-IMM-PHADIA	

Anti-dsDNA antibodies
Anti-ENA antibodies
Anti-ENA Profile including: Anti-Ro, Anti-La, Anti-Sm, Anti-U1RNP, Anti-Scl-70, Anti-Jo-1
Anti-LKM antibodies
Anti-mitochondrial antibodies
Anti-MPO antibodies
Anti-neutrophil cytoplasmic antibodies (ANCA)

Detected by immunoassay on the Phadia250	CE	0.5-400 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
Screen at 1/20 by IIF on C. luciliae using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
Detected by immunoassay on the Phadia250	CE	0.03-32 (ratio)	ISO15189 5.5/ LP-IMM-PHADIA
Detected by immunoassay on the Phadia250	CE	Measuring Ranges: Anti-Ro: 0.3 - >= 240U/ml, Anti-La: 0.3 - >= 320U/ml, Anti-Sm: 0.1 - >= 120U/ml, Anti-U1RNP: 0.3 - >= 240U/ml, Anti-Scl-70: 0.4 - >= 320U/ml, Anti-Jo-1: 0.3 - >= 240U/ml	ISO15189 5.5, LP-IMM-PHADIA
Screen at 1/40 by IIF on composite block of liver, kidney, stomach using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
Screen at 1/40 by IIF on composite block of liver, kidney, stomach using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
Detected by immunoassay on the Phadia250	CE	0.2-134 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
Screen at 1/20 by indirect immunofluorescence (IIF) on ethanol fixed neutrophils using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA

	Anti-Nuclear Antibody (ANA)		Screen at 1/80 by IIF on HEp2 using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
	Anti-Parietal Cell antibodies		Screen at 1/40 by IIF on composite block of liver, kidney, stomach using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
	Anti-PR3 antibodies		Detected by immunoassay on the Phadia250	CE	0.8-177 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
	Anti-smooth muscle antibodies		Screen at 1/40 by IIF on composite block of liver, kidney, stomach using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
	Anti-tissue transglutaminase (Anti-tTG) antibodies		Detected by immunoassay on the Phadia250	CE	0.1-128 U/ml	ISO15189 5.5/ LP-IMM-PHADIA
	IgA-anti-endomysial antibody (EMA)		Screen at 1/10 by IIF on monkey oesophagus using the Quantalyser 160	CE		ISO15189 5.5/ LP-IMM-QUANTA
1040 Immunology - .99 Miscellaneous tests	Cyclosporin	Whole blood (EDTA)	CMIA on Abbott Architect	CE	30-1500 ng/ml	ISO15189 5.5/ LP-IMM-ARCHITECT
	Tacrolimus		CMIA on Abbott Architect	CE	1.5-30 ng/ml	ISO15189 5.5/ LP-IMM-ARCHITECT

Head Office

Microbiology and Virology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
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.		standard method		ISO15189 5.5/ 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		standard method		ISO15189/ 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			N/A	ISO15189 5.5 LP-MIC-CRE/ESBL

	CRE/ ESBL screens				N/A	ISO15189 5.5 LP-MIC-CRE/ESBL
	Culture of General Bacteria on agar based culture media	Urine, faeces, sputum, BAL, AWO, bone marrow, CSF, body fluids, wound swabs, tissue, ulcers, genital swabs, throat, eyes, ears, IV tips, MRSA and VRE screens		standard method		ISO15189 5.5/ LP-MIC-URINE/ LP-MIC-SVRE/ LP-MIC-FAEC/ LP-MIC-TISS/ 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				ISO15189 5.5/ 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		ISO15189 5.5/ 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		ISO15189
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	ISO15189 5.5/ LP-MIC-FCDC
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	ISO15189 5.5/LP-MIC-AST
		Bacterial isolates	Alere PBP2a SA Culture colony Test	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
	Resist-4 O.K.N.V. Detection of Carbapenemase in bacterial culture		RESIST-4 O.K.N.V.	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
	Resist-4 O.K.N.V. Detection of Carbapenemase in bacterial culture for the identification of query CPE isolates	Bacterial Isolates	RESIST-4 O.K.N.V.	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03	CPE Identification of query CPE isolates from clinical and screening samples		Cepheid GeneXpert	CE marked	N/A	ISO15189 5.5/ LP-MIC-AST LP-MIC-GENEXPERT

Nucleic acid amplification tests, CE marked commercial systems						
	CPE: Identification of query CPE isolates from clinical and screening samples		Cepheid GeneXpert	CE marked		ISO15189 5.5/LP-MIC-AST LP-MIC-AST LP-MIC-GENEXPERT
	Detection of Influenza A, B and RSV	Viral Swab - nose or throat	Cepheid GeneXpert	CE marked	N/A	ISO15189 5.5/ LP-MIC-FLU LP-MIC-GENEXPERT
		Viral swabs - nose or throat	Cepheid GeneXpert	CE marked	N/A	ISO15189 5.5/ LP-MIC-FLU LP-MIC-GENEXPERT
	Molecular detection of faeces bacterial (and parasitic Cryptosporidium and Giardia) enteric pathogens including C. difficile	Faeces	EntericBio Gastro Panel 2 and EntericBio C. difficile	CE marked kits		ISO15189 5.5/ LP-MIC-FAEC/ LP-MIC-FCD
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		ISO15189 5.5/ 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		ISO15189 5.5/ LP-MIC-DERM/ LP-MIC-STAIN
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using	Automated identification of organisms (bacteria and yeast) using Biomerieux Vitek MS		Biomerieux VitekMS	CE marked		ISO15189 5.5/ LP-MIC-ID/ LP-MIC-VITEK2/ LP-MIC-AST

MALDI-TOF Spectroscopy						
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Anerobic bacteria: Gradient MIC strips using EUCAST guidelines		Manual susceptibility testing by MIC strips using Eucast guidelines	standard method		ISO15189 5.5/ LP-MIC-AST
	General aerobic/CO2/microaerophilic bacteria: Automated susceptibility testing, manual susceptibility testing by disks and MIC strips using EUCAST guidelines		Automated susceptibility testing using Vitek 2. Manual sensitivities standard method using Eucast Guidelines	Vitek 2: CE marked		ISO15189 5.5/ LP-MIC-AST/ LP-MIC-VITEK2
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		ISO15189 5.5/ 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	ISO15189 5.5/ LP-MIC-AST/ LI-MIC-CREREP

SVPH Satellite Laboratory

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Adjusted Calcium **1,2,4	Serum	Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	ISO15189 5.5/ LP-SAT-ROCHE/ LP-CHEM-CALC
	Alanine Aminotransferase (ALT) **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Alkaline Phosphatase **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Amylase **1,2,3,4		Enzymatic Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Aspartate Aminotransferase (AST) **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5, LP-SAT-ROCHE
	Bilirubin - Total **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	C Reactive Protein **1,2,3,4		particle enhanced immunoturbidometric assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Calcium **1,2,3,4		Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Carbon Dioxide **1,2,3,4		Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE

Chloride **1,2,3,4
Cholesterol **1,2,3,4
CKD-EPI GFR **1,2,4
Creatine Kinase **1,2,3,4
Creatinine (Enzymatic) **1,2,3,4
eGFR **1,2,4
FT3 **1,2,3,4
FT4 **1,2,3,4
Gamma Glutamyl Transferase (GGT) **1,2,3,4
Glucose **1,2,3,4
HDL and LDL Cholesterol **1,2,3,4
Iron **1,2,3,4
Lactate Dehydrogenase **1,2,3,4
Magnesium **1,2,3,4
Phosphate **1,2,3,4

ISE	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Enzymatic Colourimetric Assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	ISO15189 5.5/ LP- SAT-ROCHE/ LP- CHEM-CALC
Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
enzymatic method measured photometrically	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Calculated	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
competitive immunoassay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
competitive immunoassay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Enzymatic colourimetric assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Homogeneous enzymatic colourimetric test	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Enzymatic assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Colourimetric end point assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE

	Potassium **1,2,3,4
	Sodium **1,2,3,4
	Triglycerides **1,2,3,4
	Troponin T high sensitivity **1,2,3,4
	TSH **1,2,3,4
	Urea **1,2,3,4
	Uric Acid **1,2,3,4
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin **1,2,3,4
	Calculated Globulin **1,2,4
	IgA **1,2,3,4
	IgE **1,2,3,4
	IgG **1,2,3,4
	IgM **1,2,3,4
	Total Protein **1,2,3,4
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamycin **1,2,3,4

ISE	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
ISE	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
Enzymatic Colourimetric assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
electrochemiluminescent sandwich Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
Enzymatic Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	ISO15189 5.5/ LP-SAT-ROCHE/ LP-CHEM-CALC
immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
sandwich immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
immunoturbidometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE

	Vancomycin **1,2,3,4		homogeneous enzyme immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Transferrin **1,2,3,4		immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Transferrin Saturation **1,2,4		Calculation	Roche Cobas 6000/ APEX iLab (Calculation)		ISO15189 5.5/ 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	ISO15189 5.5/ LP-SAT-ROCHE
	Vitamin B12 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	CA125 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	CA15-3 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	CA19-9 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	CEA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	HCG **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	PSA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c **1,2,3,4	Blood	Turbidimetric Inhibition Immunoassay with TTAB Haemolyzer	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE

*For laboratories with a flexible scope, the following footnote applies:
The laboratory is accredited for a flexible scope of testing in the following*

categories

1 Range of measurement may be extended

2 Parameters may be added

3 Test matrices may be added

4 Equipment/kit