

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p>UKAS MEDICAL 9059</p> <p>Accredited to ISO 15189:2022</p>	<p>HCA International Limited, operating as HCA Laboratories</p> <p>Issue No: 017 Issue date: 13 March 2025</p>	
	<p>Shropshire House Shropshire Place/Queens Yard Capper Street London WC1E 6JA</p>	<p>Contact: Katherine Scouler Tel: +44 (0)207 034 4592 E-Mail: katherine.scouler@hcahealthcare.co.uk Website: hcalaboratories.co.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Shropshire House Shropshire Place/Queens Yard Capper Street London WC1E 6JA</p> <p>Local contact Katherine Scouler Head of Governance, Quality & Risk Mr Charles Percy - CEO Tel: +44 (0)207 486 5091</p>	<p>Microbiology Serology Clinical Immunology Biochemistry Haematology Blood Transfusion Administration Referrals Molecular Specimen Reception Cytopathology (inc. gynaecological & diagnostic) Histopathology (inc. routine & special staining, Decalcification & frozen sections)</p>	A
<p>London Bridge Hospital Laboratory London Bridge Hospital Tooley Street London SE1 2PR</p> <p>Local contact As above</p>	<p>Sample Reception Biochemistry Haematology Blood Transfusion EBUS clinic FNA clinic: Slide production, staining & mounting of fine needle aspirates for diagnostic cytology</p>	B
<p>LOC laboratory 95/97 Harley Street London W1G 6AF</p> <p>Local contact As above</p>	<p>Biochemistry Haematology</p>	C



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Site activities performed away from the main laboratory location listed above:

Location details	Local Contact	Activity	Locations
Outpatient Phlebotomy Rooms 111 Harley Street London W1G 6AW	Katherine Scouler Head of Governance, Quality & Risk Mr Charles Percy - CEO Tel: +44 (0)207 486 5091	Venesection	D
The Harley Street Clinic 16 Devonshire Street London	As above	EBUS Clinic	E
Portland Hospital 205 - 209 Great Portland Street London W1W 5AH	As above	Blood fridge storage only Fridge managed by Laboratory	F
Princess Grace Hospital 42-52 Nottingham Place London W1U 5NY	As above	Blood fridge storage only Fridge managed by Laboratory FNA clinic: Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.	G
Lister Hospital Chelsea Bridge Road London SW1W 8RH	As above	Blood fridge storage only Fridge managed by Laboratory FNA clinic: Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.	H
Wellington Hospital North and South Buildings Wellington Place London NW8 9LE	As above	Blood fridge storage only Fridge managed by Laboratory EBUS clinic FNA clinic: Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.	I
Harley Street Clinic 35 Weymouth Street London W1G 8BJ	As above	Blood fridge storage only Fridge managed by Laboratory	J



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Location details	Local Contact	Activity	Locations
10th Floor (H0) Cancer Centre Guy's Hospital Great Maze Pond London SE1 9RT	As above	Blood fridge storage only Fridge managed by Laboratory Rapid Frozen Section	K
The Shard Medical Centre The Shard 32 St Thomas Street London SE1 9BS	As above	FNA clinic: Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.	L
Platinum Medical Centre: 5-17 Lodge Road St John's Wood London NW8 7JA	As above	FNA clinic: Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.	M



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Haematology examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Full Blood Count	Sysmex XN20, XN10 and SOP: Haem/050	A, B, C
Blood	Basophils Eosinophils Lymphocytes Monocytes Neutrophils Immature Granulocytes (IG)	Light scatter and Fluorescent Flow Cytometry	A, B, C
Blood	Reticulocytes WBC	Fluorescent Flow Cytometry	
Blood	Haematocrit	Impedance, Calculations and histogram analysis. Calculated using the RBC pulse height detection method	A, B, C
Blood	Haemoglobin	RBC lysis by SLS, photometry at 55nm	A, B, C
Blood	MCH	Impedance, Calculations and histogram analysis. Calculated using patients' HGB and RBC values	A, B, C
Blood	MCHC	Impedance, Calculations and histogram analysis. Calculated using patients' HGB and HCT values	A, B, C
Blood	MCV	Impedance, Calculations and histogram analysis. Calculated using patients' HCT and RBC values	A, B, C
Blood	MPV	Impedance, fluorescent flow cytometry and machine calculated	A, B, C



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations for the purpose of clinical diagnosis</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Blood	Optical platelet count	Impedance and fluorescent flow cytometry Sysmex XN10 XN20 and SOP: Haem/050 cont'd	A, B, C
Blood	Platelets	Optical platelet count PLT-F	A,B,C A
Blood	RBC	Impedance with Hydro-dynamic focusing	A,B,C
Blood	RDW	Impedance, Calculations and histogram analysis	A,B,C
Blood	Morphology and identification	Blood film stained by using Sysmex SP-50 Slide Maker and Stainer (MGG stain) or backup Haematek staining machine (Mod Wrights stain) Read by Light microscopy SOP's: HAEM/006, HAEM/IOP/004	A
Bone Marrow	Morphology of Bone Marrow	Bone Marrow films stained by using Sysmex SP-50 Slide Maker and Stainer (MGG stain) or backup Haematek staining machine (Mod Wrights stain) and read by Light microscopy SOP's: HAEM/015, HAEM/IOP/004	A
Blood	ESR	STARSED RS ESR ANALYSER Westergren Reference Method SOP's: HAEM/IOP/017	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis (cont'd):</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	G6PD Screen	Trinity Biotech G6PDH Deficiency Kit Visual Fluorescence Screening of G6PD SOP: HAEM/009	A
Blood	Glycated Hb (HbA1c)	TOSOH G8 HPLC SOP: HAEM/IOP/046, HAEM/IOP/020	A
Blood	Glandular Fever Screen	Unipath - Clear view IM Kit Immunoassay SOP: HAEM/008	A
Blood	Haemoglobinopathy Screen: measurement of HbA2, HbF, HbS quantitation	TOSOH G-8 Cation Exchange HPLC SOP: HAEM/047, HAEM/IOP/020	A
EDTA Whole Blood	Kleihauer estimation of Foetal/Maternal haemorrhage (FMH)	Kleihauer Stain and light microscopy following alkali denaturation to detect foetal cells and calculation of bleed. SOP: HAEM/007	A
EDTA Whole Blood	Detection & speciation (thin films) of malaria parasites: <i>Plasmodium falciparum, Plasmodium malariae, Plasmodium ovale, Plasmodium vivax, Plasmodium knowlesi</i>	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy SOP: HAEM/012	A
EDTA Whole Blood	Detection of HRP2 and pLDH antigens for the identification of Malaria parasites	CareUS Malaria Malaria Antigen Test Malaria HRP2/pLDH Combo Test SOP: HAEM/042	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Citrate Plasma	International Normalised Ratio	STAGO STA-R MAX2 Calculated using the Patients PT and Reagent ISI Technoclone Ak-Calibrant INR Calibrators SOP's: HAEM/055, HAEM/049	A, B
Citrate Plasma	Prothrombin Time	SOP's: HAEM/055, HAEM/049	A, B
Citrate Plasma	Prothrombin Time 50:50	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/061, HAEM/049	A
Citrate Plasma	APTT and APTT (IV Heparin)	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/056, HAEM/049	A, B
Citrate Plasma	APTT 50:50	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/061, HAEM/049	A
Citrate Plasma	Clauss Fibrinogen	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/057, HAEM/049	A, B
Citrate Plasma	D-Dimer (FDP)	STAGO STA-R MAX2 Immunoturbidimetric Method SOP's: HAEM/058, HAEM/049	A, B
Whole blood	Protein C Activity	STAGO STA-R MAX2 Chromogenic Assay SOP's: HAEM/053, HAEM/049	A
Whole blood	Lupus (PTT-LA + DRVVT)	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/059, HAEM/049	A
Whole blood	Anti-Xa	STAGO STA Max 2 measurement of Low Molecular Weight Heparin (LMWH) using the STA® Liquid Anti-Xa assay SOP HAEM/060, HAEM/049	A



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EDTA Whole Blood	Sickle Cell Screen	TOSOH G8 / Sickledex Streck Sickledex – Solubility Deoxygenated HbS is Insoluble in presence of concentrated phosphate buffer solution and forms a turbid suspension. SOP: HAEM/010, Haem/047	A
Whole blood	HbA1c	Boronate Affinity HPLC, Menarini Hb9210 Premier, SOP: HAEM/065	A
	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: SOP: CC/IOP/097 in conjunction with manufacturer's instructions for analysis using Roche Cobas 6000:	
Serum	AFP (Alpha fetoprotein)	Sandwich Immunoassay	C
Serum	Albumin Magnesium Total Protein	Colorimetric 2-Point End Assay	B, C
Serum	Iron	Colorimetric Assay	B
Serum	Alanine Aminotransferase (ALT) Urea	Kinetic rate A Assay	B, C
Serum	Aspartate Aminotransferase (AST)	Enzymatic rate A Assay	B, C
Serum	Alkaline Phosphatase	Colorimetric Rate A Assay according to IFCC	B, C
Serum	Bicarbonate	Absorbance assay	B



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: SOP SOP: CC/IOP/097 in conjunction with manufacturer's instructions for analysis using Roche Cobas 6000:	
Serum	Calcium	Photo-colorimetric method 2-Point End	B, C
Serum	Calcium (corrected) Globulin Estimated GFR (eGFR)	Calculated	B, C
Serum	Cancer Antigen 125 Cancer Antigen 15-3 Cancer Antigen 19-9	Sandwich immunoassay	B, C
	Carcinoembryonic Antigen (CEA) Thyroid Stimulating hormone (TSH)	Competitive Immunoassay	B, C B
	Chloride Potassium Sodium	Indirect potentiometric assay	B B, C
Serum	Amylase Cholesterol HDL Cholesterol Enzymatic Creatinine Triglycerides	Enzymatic-colorimetric 1-point assay	B B, C B B B
Serum	C Reactive Protein	Particle enhanced immune-turbidimetry	B, C
Serum	CK	Absorbance	B
Serum	CKMB	Immunological UV	B
Serum	Creatinine	Jaffe Kinetic colorimetric Rate A assay	B, C



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Serum	Gamma GT	Enzymatic colorimetric Rate A assay	B, C
Serum	Glucose	UV test enzymatic reference 2-Point end Assay with hexokinase	B, C
Serum	Inorganic Phosphate	Molybdate UV 2-Point End Assay	B, C
Serum	Lactate Dehydrogenase (LDHI2) derived from IFCC	UV Rate A assay	B, C
Serum	Conjugated bilirubin Total Bilirubin	Colorimetric diazo method 2-Point End	B B, C
Serum	NT Pro BNP Procalcitonin Prostate Specific Antigen Troponin T HS	Sandwich immunoassay	B
Serum	Unsaturated Iron Binding Capacity	FerroZine reaction method	B
Serum	Albumin Alkaline Phosphatase Lactate Lithium Magnesium Serum Iron Total Bilirubin Total Protein	Colourimetric End point	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: SOP: CC/105 in conjunction with manufacturer's instructions for analysis using Roche Cobas 8000:	
Serum	Alpha-1-antitrypsin Apolipoprotein B Ant streptolysin – O (A.S.O) Titre Beta 2 Microglobulin C3 C4 Caeruloplasmin IgA IgG IgM Lipoprotein (a) Rheumatoid factor	Immunoturbidimetric	A
	Alanine Aminotransferase (ALT) CK Urea	Kinetic rate method	A
Urine	Urine Urea	Kinetic rate method	A
Serum	CK-MB	Immunoenzymatic	A
Serum	Amikacin Phenytoin Cocaine Metabolites	KIMS	A
Urine	Amphetamine Metabolites Barbiturates Benzodiazepines Cannabis Metabolites Methadone Opiate Metabolites	KIMS	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: SOP: CC/105 in conjunction with manufacturer's instructions for analysis using Roche Cobas 8000:	
Serum	Bicarbonate Enzymatic Creatinine Vancomycin	Enzymatic method	A
Urine	Urine Alcohol	Enzymatic method	A
Serum	Amylase Gamma GT HDL Cholesterol Triglyceride Uric Acid	Enzymatic colourimetric	A
EDTA Plasma	Homocysteine	Enzymatic colourimetric method	A
Urine	Urine Amylase Urine Uric Acid	Enzyme colourimetric	A
Serum	Aspartate Aminotransferase (AST) Lactate Dehydrogenase	Enzymatic rate method	A
Serum	Calcium	Photo-colourimetric method	A
Urine	Urine Calcium	Photo-colourimetric method	A
Serum	Chloride Potassium Sodium	Indirect potentiometry	A
Urine	Urine Chloride Urine Potassium Urine Sodium	Indirect potentiometry	A



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Serum	Cortisol DHEA Sulphate Digoxin 25 OH-Vitamin D (Vit D2 + D3) Free T3 Free T4 Oestradiol Vitamin B12	Competitive immunoassay	A
Serum	C Reactive Protein	Particle-enhanced immunoturbidimetry	A
Serum	Creatinine	Kinetic colourimetric assay	A
Urine	Urine Creatinine	Kinetic colourimetric assay	A
Serum	Conjugated Bilirubin	Diazo method	A
Plasma (fluoride oxalate)	Glucose	Timed endpoint method	A
Plasma (fluoride oxalate)	Glucose Tolerance Test (GTT) (Non-obstetric)	Timed endpoint method (Ref: INFO 6)	A
Plasma (fluoride oxalate)	Glucose Tolerance Test (GTT) (Obstetric)	Timed endpoint method (Ref: INFO 39)	A
Plasma (fluoride oxalate)	GTT and Insulin	Timed end point method (Glucose) Ref: INFO 79	A
Urine	Urine Albumin Urine Protein	Turbidimetric method	A



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Serum and Urine	Renal Tubular Reabsorption of Phosphate using serum and urine phosphate	Molybdate end point method & Kinetic colourimetric assay Ref: INFO 7	A
Serum	Unsaturated Iron Binding Capacity	FerroZine reaction method	A
Serum	CCP	IgG-capture test principle	A
Serum	AMH	Sandwich immunoassay	A
Serum	Calcium (corrected) Estimated GFR (eGFR) Free Androgen Index (FAI) Globulin Iron Binding Saturation % Non-HDL Cholesterol (LDL)	Calculated	A
Serum	Paraprotein Quantitation	Sebia Hydrasys Electrophoresis System, Sebia Phoresis Software in conjunction with procedure SOP CC/102	A
Serum	Protein abnormalities screening	Sebia Hydrasys Electrophoresis System in conjunction with procedure SOP: CC/102 Hydrigel protein migration (Electrophoretic separation)	A
Serum	Paraprotein bands identification and classification	Sebia Hydrasys Electrophoresis System - Antisera immunofixation in conjunction with procedure SOP: CC/102	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Serum	Serum Osmolality	Osmo1 Single Osmometer, Freeze point depression in conjunction with procedure. SOP:CC/107	A
Urine	Urine osmolality	Osmo1 Single Osmometer, Freeze point depression in conjunction with procedure. SOP:CC/107	A
Serum and Urine	Water Deprivation Test for detection of diabetes insipidus	SOP:CC/107 Ref: INFO 9	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	SOP: Trans/IOP/011 _Using Ortho Vision/Vision Max Analysers - Column agglutination technology	A, B
Blood	Antibody Screen for the detection of: Rhesus blood group antibodies: anti-Cw, anti-C, anti-c, anti-D, anti-E, anti-e Kell system blood group antibodies: anti-K, anti-k, anti-Kpa Kpb Kidd blood group antibodies: Anti-Jka, Anti-Jkb Duffy blood group antibodies: Anti-Fya, Anti-Fyb Lutheran blood group antibodies: anti-Lu a, Lub MNS blood group antibodies: Anti-M, anti-N, anti-S, anti-s	SOP: Trans/IOP/011 _Using Ortho Vision/Vision Max Analysers - Column agglutination technology	A, B



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Blood	Antibody Screen for the detection of (continued): Lewis blood group antibodies: Anti-Lea, anti-Leb P blood group antibodies: anti-P	SOP: Trans/IOP/011 _Using Ortho Vision/Vision Max Analysers - Column agglutination technology	A, B
Blood	ABO Rh D Paediatric Blood Group(Newborn)	SOP: Trans/IOP/011 _Using Ortho Vision Max Analysers -Column agglutination technology	A
Blood	Red Cell Phenotyping(Rh/K) Rhesus blood group antigens: C, c, D, E, e Kell system blood group antigens: K	SOP: Trans/IOP/011 _Using Ortho Vision Max Analysers -Column agglutination technology	A
Plasma	Antibody investigation, detection and identification by Indirect Antiglobulin Test(IAT) of: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	SOP: Trans/IOP/011 _Using Ortho Vision Max Analysers -Column agglutination technology	A
Plasma	Antibody investigation, detection and identification (by Enzyme panel) of: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	SOP: Trans/IOP/011 _Using Ortho Vision/Vision Max Analysers - Column agglutination technology	A



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EDTA Whole Blood	Direct Antiglobulin Test (DAT)	SOP: Trans/IOP/011 _Using Ortho Vision/Vision Max Analysers - Column agglutination technology	A
EDTA Whole Blood	Manual Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	SOP: Trans/002_Using Ortho Biovue Cassettes- Column agglutination technology	A, B
EDTA Whole Blood	ABO Rh D Paediatric Blood Group(Newborn)	SOP: Trans/002_Using Ortho Biovue Cassettes- Column agglutination technology	A
EDTA Plasma	Manual Antibody Screen for the detection of: Rhesus blood group antibodies: anti-Cw, anti-C, anti-c, anti-D, anti-E, -anti-e Kell system blood group antibodies: anti-K, anti-k, anti-Kpa Kpb Kidd blood group antibodies: Anti-Jka, Anti-Jkb Duffy blood group antibodies: Anti-Fya, Anti-Fyb Lutheran blood group antibodies: anti-Lu a, Lub MNS blood group antibodies: Anti-M, anti-N, anti-S, anti-s	SOP: Trans/006_Using Ortho Biovue System Cassettes- Column agglutination technology	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd):	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
EDTA Plasma	Manual Antibody Screen for the detection of: (cont'd) Lewis blood group antibodies: Anti-Lea, anti-Leb P blood group antibodies: anti-P	SOP: Trans/006_ Using Ortho Biovue System Cassettes- Column agglutination technology	A
EDTA Plasma	Manual Serological Crossmatching	SOP: Trans/014_ Using Ortho Biovue System Cassettes- Column agglutination technology	A, B
EDTA Whole Blood	Red Cell Phenotyping other Kell system blood group antigens: K, k, Kpa Kpb Kidd blood group antigens: Jka, Jkb, Duffy blood group antigens: Fya, Fyb, Lutheran blood group antigens: Lu a, Lub MNS blood group antigens: M, N, S, s, Lewis blood group antigens: Lea, Leb, P blood group antigens: P	SOP: Trans/013_ Using Ortho Biovue Cassettes or Tube Technique	A
EDTA Plasma	Antibody investigation by detection and identification of: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	SOP: Trans/007_ Using Ortho Biovue System- Column agglutination technology	A
EDTA Whole Blood	Manual Direct Antiglobulin Test (DAT)	SOP: Trans/008_ Using Ortho Biovue System- Column agglutination technology	A



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Routine samples: Aspirates/Fluids Cellular/Fluid Material on Swabs CSF Pus Biopsy/Tissues Respiratory samples Faeces Tips IUCDs</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p>Isolation of micro-organisms of Clinical Significance</p>	<p>In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals.</p> <p>Manual inoculation of selected culture media and incubation using in-house procedures: Bact/005 Inoculation and incubation of Cultures Bact/010 Procedure for the culture of swabs Bact/012 Microscopy and Culture of Cerebrospinal Fluid Bact/014 Investigation of Respiratory Samples Bact/015 Faecal Culture Bact/016 Investigation of Fluids from Normally Sterile Sites Bact/018 Investigation of Catheter Tips Bact/020 Investigation for Bordetella sp. Bact/021 MRSA Screening Bact/023 Tissue and Biopsy Culture Bact/088 Group B Streptococci Screening Bact/093 ESBL Screening Bact/100 Procedure for the culture of Yeast Bact/108 Carbapenem Resistant Organism Screening Bact/121 Procedure for Cytospin Preparations Bact/123 Procedure for the Investigation on Female Genital Swabs Bact/133 Investigation of Mycobacteria sp. Bact/134 Investigation of Ear/Nose/Throat (ENT), Mouth and Eye Swabs</p> <p>WI Micro 053 WI Micro 027</p>	<p>A</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd):	In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals.	
Urine	Detection of: White blood cells Red blood cells pH Ketones Glucose Protein Casts Nitrates	COBAS u601 Automated inoculation and optical reading of urinalysis dipsticks. SOP: BACT/011 COBAS Urisys 1100 analyser Electro-optical assessment using Roche Combo Test Ux strips SOP: WI Micro 060	A
Respiratory samples Tissues Fluids Early morning urine CSF Cellular/Fluid Material	Isolation and presumptive identification of Acid-alcohol fast bacilli	Manual culture or automated liquid culture using Auramine phenol staining and incident-light fluorescence, Ziehl-Neelsen, iodine staining as appropriate and microscopic examination using in-house procedures: Bact/060 Bact/004 Bact/099 In conjunction with manufacturer's instructions using bioMerieux BD MGIT	A
Cellular material on swabs Primary screening swabs: Nose, axilla, groin, throat, hairline. Other swabs	Screening for MRSA	Culture onto a selective chromogenic agar (Oxoid) Using SOP Bact/021: MRSA Screening	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd):	In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals.	
Blood cultures	Isolation of micro-organisms of Clinical Significance	BD BACTEC FX 400 using SOPs: BACT/013 Processing a Positive Blood Culture BACT/113 Manual Gram staining method BACT/121 Procedure for Cytospin Preparations BACT/131 Bactec FX Blood Cultures	A
Cultures isolated in-house from routine & blood samples listed above	Identification of microorganisms of clinical significance	Traditional, biochemical, or mass spectrometry (MALDI-TOF-MS) identification tests using SOPs: Bact/024 Investigation of Specimens for Fungi Bact/026 Staph Latex Bact/029 Catalase Test Bact/031 Streptococcal grouping Bact/032 Identification of Streptococcus pneumoniae Bact/037 Oxidase Test Bact/038 Analytical Profile Index (API) System Bact/089 Identification of Neisseria gonorrhoeae Bact/127 MALDI-TOF-MS	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd):	In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals.	
Bacteria and Yeast isolates	Susceptibility testing of micro-organisms	Disc diffusion and gradient minimum inhibitory concentration determination, microbroth dilution using the European Committee on Antimicrobial Susceptibility Testing (EUCAST) methodology: SOP: BACT/119 Antimicrobial Susceptibility Testing	A
Yeast isolates	Susceptibility testing	Sensititre Microbroth dilution for susceptibility testing (CLSI method for yeasts) SOP: BACT/129 YeastOne Sensititre	A
Hair Nail Skin	Detection, Isolation and identification of clinically significant dermatophytes	Staining (inc. lactophenol cotton blue) and microscopic examination using in-house procedure: BACT/024 Investigation of Specimens for Fungi	A
CSF	Detection of white cells, red cells, and microorganisms of clinical significance	Microscopy using in-house procedures: BACT/012 Microscopy and Culture of Cerebrospinal Fluid BACT/103 Hemacolor Differential Stain	A
Respiratory samples (Sputum, BAL) Sterile fluids Tissues	Detection of <i>M. tuberculosis</i> (Mtb) and rpoB gene Rifampicin resistance	Cepheid Infinity Cepheid PCR Kit SOP: Immuno/061 BACT/114 GeneXpert MTB/RIF Ultra assay	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd):	In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals:	
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Auramine phenol staining and incident-light fluorescence microscopy Modified examination using in-house procedure: Bact/059 Investigation of Specimens for Ova, Cysts and Parasites	A
Faeces	Faecal Haemoglobin	HM-JACKarc Automated Quantitative Faecal Haemoglobin Immunochemical Testing system using Integrated Sphere Latex Turbidimetry BACT/135 qFIT	A
Smears from Routine samples: Aspirates Cellular/Fluid Material on Swabs Fluids Tissues Respiratory samples IUCDs Blood cultures	Detection, identification and quantification of White blood cells, Red blood cells, Bacterial cells, Yeast cells and fungal hyphae	Manual and automated Staining (inc. Gram) and microscopic examination using in-house procedure: BACT/121 BACT/113 BACT/103 BACT024 SOP: BACT/130 Polystainer. Automated Gram-staining machine.	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd):	In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals:	
Faeces	Giardia antigen	Qualitative immunochemical testing using Immunochromatography card (remel) and in-house procedure: BACT/080	A
Faeces	Detection of <i>Clostridiodes difficile</i> glutamate dehydrogenase and Toxins A & B	Membrane immunochromatographic assay using in-house procedure: Bact/046 in conjunction with manufacturer's instructions using C diff Immunochromatography card (Tech lab)	A
Faeces	Detection of ova, cysts and parasites (OCP)	Formol-ether concentration method (Parasep midi) and microscopic using in-house procedure: BACT/059	A
Faeces	Detection of <i>Helicobacter pylori</i> antigen	Immunochromatography card (HPSA Stat) and in-house procedure: BACT/072	A
Urine	Isolation of Micro-organisms of clinical significance	Manual inoculation of culture media, using in-house procedure: BACT/106	A
Faecal Screen	Isolation of bacterial pathogens: <i>Campylobacter spp.</i> <i>Clostridium difficile</i> <i>Escherichia coli</i> O157 <i>Salmonella sp.</i> <i>Shigella spp.</i> <i>Vibrio spp.</i> <i>Yersinia spp.</i>	Manual inoculation of culture media, using in-house procedures: BACT/015	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures aligned with current UK SMLs, manufacturer's guidelines and equipment manuals:	
Urine	Detection of <i>Schistosoma haematobium</i> ova	Centrifugation, microscopy of deposit, terminal urine using in-house procedure: BACT/059	A
Female genital tract swabs	Diagnosis of bacterial vaginosis (BV)	Gram stained microscopic examination against Hay's criteria using in-house procedures: BACT/123 BACT/113 BACT/130 (Automated)	A
LVS Swabs, Rectal swabs	Group B Streptococci screening	Manual inoculation of culture liquid/media and incubation. BACT/088	A
Faeces, Rectal swabs, Throat swabs	Screening for the presence of ESBL producers	Manual inoculation of culture media and incubation. BACT/093	A



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HUMAN BODY FLUIDS	<u>Serology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Faeces	Faecal calprotectin	Automated ELISA using DS2 analyser and in-house procedure: SOP: Immuno/IOP/015,	A
Serum	Interferon- γ	Quantiferon-TB Gold Plus Interferon Gamma Release Assay (IGRA) Automated ELISA using DS2 analyser and in-house procedure: SOP: Immuno/IOP/015	A
Serum	Detection of: Hepatitis B surface Ag HBsAg Confirmation Hepatitis B core total Hepatitis B core IgM Measles IgG Mumps IgG Epstein-Barr Virus IgG, IGM, EBNA IgG Varicella Zoster IgG CMV IgG Rubella IgM CMV IgM HIV Duo Toxoplasma IgM Hepatitis e Ag Hepatitis e Ab Lyme IgG, IGM	Using Biomerieux VIDAS30 (EIA): SOP: Immuno/IOP/012	A



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HUMAN BODY FLUIDS (cont'd)	<u>Serology examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods incorporating manufacturers' instructions where relevant	
Serum	Detection of: Measles IgG and IgM Mumps IgG and IgM HTLV I/II EBV IgG and IgM EBV EBNA VZV IgG CMV IgG and IgM Toxo IgM Borrelia IgG and IgM	Using Diasorin Liaison XL CLIA SOP: Immuno/067	A
Urine	Detection of: Legionella pneumophila serotype 1 antigen Streptococcus pneumoniae soluble antigen	Membrane immunochromatographic assay using: BINAX NOW Kit Immunochromatographic assay. SOP: Immuno/041 SOP: Immuno/042	A



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HUMAN BODY FLUIDS (cont'd)	<u>Serology examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods incorporating manufacturers' instructions where relevant	
Serum	Hepatitis A Antibody (Total) Hepatitis B Core Antibody	SOP: CC/105 (ECLIA)	A
Serum	Hepatitis A Antibody (IgM) Rubella IgG	SOP: CC/105 (ECLIA)	A
Serum	Hepatitis B Surface Antigen	SOP: CC/105 (ECLIA)	A
Serum	Hepatitis B Antibody Hepatitis C Antibody	SOP: CC/105 (ECLIA)	A
Serum	HIV-1/2 Antibodies	SOP: CC/105 (Competitive immunoassay)	A
Serum	Toxoplasma IgG	SOP:CC/105 (ECLIA method)	A
Serum	Detection of Syphilis Total Antibody	SOP: CC/105 (Immunoturbidimetric method)	A
Serum	Detection of COVID antibodies: Anti-SARS-CoV-2 (qualitative) Anti-SARS-CoV-2 S (quantitative)	Using the Elecsys assay kit SOP: CC/105 (ECLIA)	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab in VTM or dry swab	Detection of SARS-CoV-2 (COVID-19) virus RNA, specific gene sequences N & RdRP	Real-time RT-PCR using: Abbott m2000 RealTime System and SARS-CoV-2 Amplification Kit SOP: Immune 064 Abbott M2000	A
Nasopharyngeal swabs in VTM/UTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, N2 and E gene targets	Real -Time Polymerase Chain Reaction (RT-PCR) using Xpress assay on Cepheid GeneXpert Infinity SOP: Immuno IOP/061	A
Nose, Throat swabs	Detection of SARS/FluA/FluB/RSV SARS-CoV-2 genes N2 and E FluA FluB RSV	Xpert Xpress Multiplex, SARS/FluA/FluB/RSV on the Cepheid Infinity SOP for the GeneXpert Infinity 48 system SOP: Immuno IOP/061	A
Combined Nasopharyngeal and Oropharyngeal (Nose & Throat) Swab in VTM or dry swab	Detection of SARS-CoV-2 (COVID-19) virus RNA, specific gene sequences N & RdRP	Cepheid Xpert Infinity using SARS-CoV-2 Single Plex PCR Assay. SOP Immuno 061	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd):</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Nose, throat swabs nasopharyngeal samples, nasopharyngeal aspirates	Detection of: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A, including subtypes H1, H1-2009, and H3 Influenza B Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) specific gene sequences S & N (For General Population testing) Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus Bordetella parapertussis (IS1001) Bordetella pertussis (ptxP) Chlamydia pneumoniae Mycoplasma pneumoniae	Film Array Respiratory Panel 2.1 plus on the Biomerieux Biofire Film Array Torch System SOP: Immuno IOP 018	A
Dry swab, Nasal Asps, Red UTM Tube Nasal swabs	Detection of Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	Cepheid Infinity Cepheid PCR Kit: SOP: Immuno/061	A
Rectal Swab	Carbapenem-resistant Enterobacterales (CRE)	Cepheid Infinity Cepheid PCR Kit: SOP: Immuno/061	A
Nasal swabs	Detection of methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	Gene Xpert PCR SOP: IMMUNO/IOP/014	B
Throat swab (Eswab in VTM)	Detection of Group A Streptococcus	Cepheid Infinity, RT PCR SOP: IMMUNO/061	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Detection of Autoantibodies: Anti-Nuclear Antibodies (ANA) Gastric Parietal Cell (GPC) Anti-Smooth Muscle (SMA) Anti-mitochondrial (AMA) Liver Kidney Microsomal (LKM) Anti-dsDNA by <i>Crithidia lucillae</i> (CLIFT) Anti-Neutrophil Cytoplasmic Antibodies (ANCA) Anti-Endomysial IgA (EMA)	Indirect immunofluorescence assays (IFA) and fluorescent microscopy (QUANTA-Lyser 3000): SOP: ClinIMM/004 QL3000 IFA	A
Serum	Detection of autoantibodies: Anti-MPO ANCA Anti-PR3 ANCA Anti-GBM Anti-Intrinsic Factor Anti-Thyroglobulin (TG) IgG	Phadia 250 - fluorescent enzyme immunoassay (FEIA) SOP Ref: ClinImm/002 Phadia 250 & 1000	A
Serum	Anti-dsDNA IgG ENA screen	SOP Ref: ClinImm/002	A
Serum	Detection of autoantibodies: Anti-TTG IgA Anti-DGP IgA Anti-DGP IgG	BIO-FLASH – chemiluminescence (CLIA) SOP Ref: ClinImm/028 BIO-FLASH & Associated Assays	A
Serum	Anti-Cardiolipin IgG Anti-Cardiolipin IgM Anti-B2 Glycoprotein 1 IgG Anti-B2 Glycoprotein 1 IgM	SOP Ref: ClinImm/028/004	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Detection of autoantibodies:	Manual Immunoblot assay using the Blue Diver Instrument, manufactures instructions and in-house procedure:	
Serum	Detection of Liver Antibodies anti-SLA and anti-LC1	SOP: ClinImm/023 BlueDiver Immunoblot	A
Serum	Detection of Anti-F-actin IgG	SOP: ClinImm/023	A



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum</p>	<p><u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):</p> <p>Detection and quantification of Total IgE Allergen g6, Timothy Allergen g12, Cultivated rye Allergen t3, Common silver birch Allergen w6, Mugwort Allergen w21, Wall pellitory Allergen m2, Cladosporium herbarum Allergen m6, Alternaria alternata Allergen d1, House dust mite Allergen d2, House dust mite Allergen e1, Cat dander Allergen e5, Dog dander Allergen f1, Egg white Allergen f2, Milk Allergen f4, Wheat Allergen f14, Soybean Allergen h1, House dust (Greer Labs Inc) Allergen g3, Cocksfoot Allergen t17, Japanese cedar Allergen m3, Aspergillus fumigatus Allergen m5, Candida albicans Allergen e3, Horse dander Allergen f5, Rye Allergen f8, Maize, Corn Allergen f11, Buckwheat Allergen f13, Peanut Allergen f33, Orange Allergen g1, Sweet vernal grass Allergen g2, Bermuda grass Allergen g4, Meadow fescue Allergen g5, Rye-grass Allergen g8, Meadow grass, Kentucky blue Allergen g9, Redtop, Bentgrass Allergen g10, Johnson grass Allergen h2, House dust (Hollister-Stier Allergen m4, Mucor racemosus Allergen t2, Grey alder Allergen t4, Hazel</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002</p>	<p>A</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	A
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen t5, American beech Allergen t7, Oak Allergen t9, Olive Allergen t12, Willow Allergen w2, Western ragweed Allergen w3, Giant ragweed Allergen w8, Dandelion Allergen w9, Plantain (English), Ribwort Allergen w10, Goosefoot, Lamb's quarters Allergen f3, Fish (cod) Allergen m1, Penicillium chrysogenum Allergen t1, Box-elder Allergen e4, Cow dander Allergen e6, Guinea pig epithelium Allergen e70, Goose feathers Allergen e85, Chicken feathers Allergen e86, Duck feathers Allergen f6, Barley Allergen f7, Oat Allergen f9, Rice Allergen f10, Sesame seed Allergen f12, Pea Allergen f15, White bean Allergen f18, Brazil nut Allergen f20, Almond Allergen f23, Crab Allergen f24, Shrimp Allergen f25, Tomato Allergen f26, Pork Allergen f75, Egg yolk Allergen f83, Chicken Allergen w19, Wall pellitory Allergen g17, Bahia grass Allergen f27, Beef Allergen f31, Carrot Allergen f35, Potato Allergen f36, Coconut Allergen f37, Blue mussel	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	



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Issue No: 017 Issue date: 13 March 2025

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen f40, Tuna Allergen f41, Salmon Allergen f44, Strawberry Allergen f45, Yeast Allergen f47, Garlic Allergen f48, Onion Allergen f49, Apple Allergen i6, Cockroach, German Allergen t6, Mountain juniper Allergen t8, Elm Allergen t10, Walnut Allergen t11, Maple leaf sycamore, Londo Allergen t14, Cottonwood Allergen t15, White ash Allergen t16, White pine Allergen t18, Eucalyptus, Gum-tree Allergen t19, Acacia Allergen t20, Mesquite Allergen t22, Pecan, Hickory Allergen t23, Italian/Mediterranean/Fune Allergen w5, Wormwood Allergen w11, Saltwort (prickly), Russia Allergen w12, Goldenrod Allergen w13, Cocklebur Allergen w14, Common pigweed Allergen w15, Scale, Lenscale Allergen w16, Rough marshelder Allergen w18, Sheep sorrel Allergen w20, Nettle Allergen m8, Setomelanomma rostrata Allergen m9, Fusarium proliferatum Allergen m10, Stemphylium herbarum Allergen m12, Aureobasidium pullulans Allergen m13, Phoma betae Allergen m14, Epicoccum purpurascens Allergen f79, Gluten Allergen f80, Lobster	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	A
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen f81, Cheese, cheddar type Allergen f82, Cheese, mold type Allergen f84, Kiwi fruit Allergen f85, Celery Allergen f87, Melon Allergen d70, Storage mite Allergen d71, Storage mite Allergen e82, Rabbit epithelium Allergen e84, Hamster epithelium Allergen i71, Mosquito Allergen t70, Mulberry Allergen f89, Mustard Allergen f91, Mango Allergen f92, Banana Allergen f93, Cacao Allergen f94, Pear Allergen f95, Peach Allergen f96, Avocado Allergen m70, Pityrosporum orbiculare Allergen t73, Australian pine Allergen e71, Mouse epithelium Allergen e72, Mouse urine proteins Allergen f50, Chub mackerel Allergen f58, Pacific squid Allergen f61, Sardine, Pilchard Allergen i8, Moth Allergen f256, Walnut Allergen f17, Hazel nut Allergen w1, Common ragweed Allergen f201, Pecan nut Allergen f259, Grape Allergen f210, Pineapple Allergen f215, Lettuce Allergen f207, Clam Allergen f245, Egg Allergen m207, Aspergillus niger Allergen f202, Cashew nut Allergen f203, Pistachio Allergen f290, Oyster	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen f299, Sweet chestnut Allergen f338, Scallop Allergen d201, House dust mite Allergen t41, White hickory Allergen f253, Pine nut, pignoles Rare Allergen t211, Sweet gum Allergen i206, Cockroach, American Allergen f345, Macadamia nut Allergen g13, Velvet grass Allergen i1, Honey bee venom Allergen w7, Marguerite, Ox-eye daisy Allergen c1, Penicilloyl G Allergen c2, Penicilloyl V Allergen g7, Common reed Allergen g15, Cultivated wheat Allergen i2, White-faced hornet venom Allergen i5, Yellow hornet venom Allergen t21, Melaleuca, Cajeput-tree Allergen g11, Brome grass Allergen g14, Cultivated oat Allergen g16, Meadow foxtail Allergen d3, House dust mite Allergen p1, Ascaris Allergen w4, False ragweed Allergen w17, Firebush (Kochia) Allergen m7, Botrytis cinerea Allergen m11, Rhizopus nigricans Allergen m15, Trichoderma viride Allergen m16, Curvularia lunata Allergen f86, Parsley Allergen f88, Mutton Allergen d72, Storage mite Allergen e78, Budgerigar feathers Allergen e80, Goat epithelium Allergen e81, Sheep epithelium Allergen e83, Swine epithelium Allergen k75, Isocyanate TDI Allergen k76, Isocyanate MDI Allergen k77, Isocyanate HDI	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen e87, Rat epithelium, serum Allergen e88, Mouse epithelium, serum Allergen i73, Blood worm Allergen f90, Malt Allergen k74, Silk Allergen i75, European hornet venom Allergen k80, Formaldehyde/Formalin Allergen d74, House dust mite Allergen i70, Fire ant Allergen g70, Wild rye grass Allergen c73, Insulin human Allergen k72, Ispaghula Allergen e89, Turkey feathers Allergen g71, Canary grass Allergen i72, Green nimitti Allergen k70, Green coffee bean Allergen k71, Castor bean Allergen k81, Ficus spp. Allergen k84, Sunflower seed Allergen t72, Queen palm Allergen c70, Insulin porcine Allergen c71, Insulin bovine Allergen d73, Storage mite Allergen e73, Rat epithelium Allergen e74, Rat urine proteins Allergen e75, Rat serum proteins Allergen e76, Mouse serum proteins Allergen f209, Grapefruit Allergen f214, Spinach Allergen f225, Pumpkin Allergen f254, Plaice Allergen f51, Bamboo shoot Allergen f54, Sweet potato Allergen f55, Common millet Allergen f56, Foxtail millet Allergen f59, Octopus Allergen f60, Jack mackerel, Scad Allergen p4, Anisakis Allergen o1, Cotton, crude fibers	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	A
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen m205, Trichophyton rubrum Allergen k82, Latex Allergen i3, Common wasp venom Allergen i4, Paper wasp venom Allergen f231, Milk boiled Allergen f242, Cherry Allergen f237, Apricot Allergen f216, Cabbage Allergen f235, Lentil Allergen f218, Paprika, Sweet pepper Allergen f280, Black pepper Allergen f284, Turkey meat Allergen f204, Trout Allergen g202, Maize, Corn Allergen t208, Linden Allergen e201, Canary bird feathers Allergen f208, Lemon Allergen m202, Acremonium kiliense Allergen e213, Parrot feathers Allergen t210, Privet Allergen f205, Herring Allergen f213, Rabbit Allergen f244, Cucumber Allergen f255, Plum Allergen f260, Broccoli Allergen c74, Gelatin bovine Allergen m36, Aspergillus terreus Allergen f147, Gulf flounder Allergen f182, Lima bean Allergen f381, Red snapper Allergen f42, Haddock Allergen t37, Bald cypress Allergen t44, Hackberry Allergen t56, Bayberry Allergen t57, Red cedar Allergen t71, Red mulberry Allergen w23, Yellow dock Allergen w46, Dog fennel Allergen w82, Careless weed	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	A
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen t201, Spruce Rare Allergen e209, Gerbil epithelium Allergen f206, Mackerel Allergen w203, Rape Rare Allergen m203, T. pullulans Rare Allergen m204, U. chartarum Allergen e215, Pigeon feathers Allergen f271, Anise Allergen f261, Asparagus Allergen f262, Aubergine, eggplant Allergen f269, Basil Allergen f278, Bay leaf Allergen f288, Blueberry Rare Allergen f217, Brussel sprouts Allergen f265, Caraway Allergen f291, Cauliflower Allergen f279, Chilipepper Allergen Rf220, Cinnamon Allergen f268, Clove Allergen f221, Coffee Allergen f281, Curry (Santa Maria) Allergen f289, Date Rare Allergen f277, Dill Rare Allergen f219, Fennel seed Allergen f270, Ginger Allergen f263, Green pepper (unripe seed) Allergen f247, Honey Allergen f274, Marjoram Allergen f212, Mushroom (champignon) Allergen Rf282, Nutmeg Allergen f283, Oregano Allergen f293, Papaya Rare Allergen f294, Passion fruit Allergen f224, Poppy seed Allergen f287, Red kidney bean Allergen f272, Tarragon Allergen f222, Tea Allergen f273, Thyme	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen f234, Vanilla Allergen f236, Cow's milk whey Allergen o201, Tobacco leaf Allergen f258, Squid Allergen f300, Goat milk Rare Allergen g203, Salt grass Allergen t209, Horn beam Rare Allergen i203, Mediterr. flour moth Allergen f303, Halibut Allergen f302, Mandarin (tangerine, clem Rare Allergen f301 Persimon (kaki fruit) Allergen f306, Lime Allergen Rk210, Maleic anhydrid Allergen f309, Chick pea Allergen m208, Chaetomium globosum Allergen f312, Swordfish Allergen i204, Horse fly Allergen f313, Anchovy Allergen f314, Snail Allergen f315, Green bean Allergen f317, Coriander Rare Allergen t214, Date Allergen f320, Crayfish Rare Allergen e219, Chicken serum prot. Allergen f325, Sheep milk Allergen f328, Fig Allergen f329, Watermelon Rare Allergen f332, Mint Allergen f335, Lupine seed Allergen f337, Sole Allergen Rf341, Cranberry Allergen i205, Bumble bee Allergen f343, Raspberry Rare Allergen f344, Sage Allergen m228, Aspergillus flavus Allergen e77, Budgerigar droppings Allergen k78, Ethylene oxide	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen k79, Phthalic anhydride Allergen i76, Berlin beetle Allergen k83, Cotton seed Allergen o70, Seminal fluid Allergen c5, Ampicilloyl Allergen c6, Amoxicilloyl Allergen w22, Japanese Hop Allergen i77, European paper wasp venom Allergen g201, Barley Allergen m80, Staphylococcal enterotoxin Allergen m81, Staphylococcal enterotoxin Allergen e200, Canary bird droppings Allergen f124, Spelt wheat Allergen t25, European ash Allergen c8, Chlorhexidine Allergen f369, Catfish Allergen f384, Whitefish Allergen f413, Pollock Allergen f414, Tilapia Allergen f415, Walleye pike Allergen t45, Cedar elm Allergen t55, Scotch broom Allergen w45, Alfalfa Allergen c260, Morphine Allergen c261, Pholcodine Allergen t205, Elder Allergen t203, Horse chestnut Rare Allergen e208 Chinchilla epithelium Rare Allergen e214, Finch feathers Allergen w206, Camomile Rare Allergen w207, Lupin Allergen w204, Sunflower Rare Allergen m201 Tilletia tritici Rare Allergen e203, Mink epithelium Rare Allergen e206, Rabbit serum prot.	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	A
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Rare Allergen e211, Rabbit, urine prot. Allergen Re212, Swine, urine proteins Rare Allergen f264, Eel Allergen f211, Blackberry Rare Allergen f267, Cardamon Allergen f276, Fennel fresh Rare Allergen f246, Guar, guar gum Rare Allergen f275, Lovage Rare Allergen f266, Mace Rare Allergen f226, Pumpkin seed Allergen f227, Sugar-beet seed Rare Allergen f286, Mare's milk Rare Allergen f296, Carob Allergen f297, Gum arabic Rare Allergen f298, Tragacanth Allergen t206, Chestnut Rare Allergen t207, Douglas fir Rare Allergen e217, Ferret epithelium Allergen f304, Langust (spiny lobster) Rare Allergen t217, Peppertree Allergen t212, Cedar Rare Allergen f305, Fenugreek Allergen f307, Hake Allergen f308, Sardine (Pilchard) Allergen m209, Penicillium glabrum Allergen f311, Megrin Allergen t213, Pine Allergen f316, Rape seed Rare Allergen f319, Beetroot Rare Allergen f322, Red currant Allergen m211, Trichophyton ment. Allergen Rc208, Tetanus toxoid Allergen f324, Hop Allergen e218, Chicken droppings Rare Allergen f326, Sheep whey Rare Allergen f333, Linseed Rare Allergen o211, Mealworm Allergen t218, Virginia live oak	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen c202, Suxamethonium Succinylch Rare Allergen f340, Cochineal extract Allergen f342, Olive Allergen f346, Abalone Rare Allergen f347, Quinoa Rare Allergen k214, Bougainvillea Allergen m223, Staphylococcal enterotoxi Rare Allergen m226, S. enterotoxin TSST Rare Allergen t223, Oil Palm Allergen t222, Cypress Allergen m227, Malassezia spp. Allergen c7, Cefaclor Allergen f76, nBos d 4, Milk Allergen f77, nBos d 5, Milk Allergen f78, nBos d 8, Milk Allergen f232, nGal d 2, Egg Allergen f233, nGal d 1, Egg Allergen e94, rFel d 1, Cat Allergen e101, rCan f 1, Dog Allergen f419, rPru p 1, Peach Allergen f420, rPru p 3, Peach Allergen f421, rPru p 4, Peach Allergen d203, rDer p 2, House dust mite Allergen w231, nArt v 1, Mugwort Allergen t215, rBet v 1, Birch Allergen t216, rBet v 2, Birch Allergen g205, rPhl p 1, Timothy Allergen e220, rFel d 2, Cat serum album Allergen e221, nCan f 3, Dog serum album Allergen g212, rPhl p 12, Timothy Allergen g215, rPhl p 5b, Timothy Allergen t224, rOle e 1, Olive	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd) Serum (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd): Detection and quantification of Total IgE (cont'd) Allergen d202, rDer p 1, House dust mite Allergen k87, nAsp o 21, Aspergillus ory Allergen i208, rApi m 1, Honey bee Allergen i209, rVes v 5, Common wasp Allergen i211, rVes v 1, Common wasp Allergen k202, nAna c 2, Pineapple Allergen e222, nSus s PSA, Swine serum Allergen k213, nSus s, Swine Allergen o214, MUXF3, CCD, Bromelain Allergen f434, rMal d 1 PR-10, Apple Allergen i217, rApi m 10, Honey bee Allergen i214, rApi m 2, Honey bee Allergen i216, rApi m 5, Honey bee Allergen f449, rSes l 1 Sesame seed Allergen f416, rTri a 19, Wheat Allergen e102, rCan f 2, Dog Allergen f417, rApi g 1.01, Celery Allergen f422, rAra h 1, Peanut Allergen f423, rAra h 2, Peanut Allergen f424, rAra h 3, Peanut Allergen f425, rCor a 8, Hazel nut Allergen w230, nAmb a 1, Ragweed Allergen f426, rGad c1, Cod Allergen g216, nCyn d 1, Bermuda grass Allergen t226 nCup a 1, Cypress Allergen w232 nSal k 1, Saltwort Allergen f427, rAra h 9 LTP, Peanut Allergen f428 rCor a 1 PR-10, Hazel nut Allergen w233, nArt v 3, Mugwort Allergen f430, rAct d 8, Kiwi Allergen d205, rDer p 10 House dust mite Allergen f431, nGly m 5, Soy Allergen f432, nGly m 6, Soy Allergen t227, nOle e 7, Olive	In house documented procedures based on equipment manuals and standard methods as specified below: Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd) Serum (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd): Detection and quantification of Total IgE (cont'd) Allergen i210, rPol d 5, Euro paper wasp Allergen e226, rCan f 5, Dog Allergen t240, rOle e 9, Olive Allergen e204, nBos d 6 BSA, Cow Allergen k208, nGal d 4, Egg Allergen f323, nGal d 3, Egg Allergen g206, rPhl p 2, Timothy Allergen t220, rBet v 4, Birch Allergen g208, nPhl p 4, Timothy Allergen g209, rPhl p 6, Timothy Allergen g210, rPhl p 7, Timothy Allergen g211, rPhl p 11, Timothy Allergen m218, rAsp f 1, Aspergillus fum Allergen m219, rAsp f 2, Aspergillus fum Allergen m220, rAsp f 3, Aspergillus fum Allergen t221, rBet v 2, rBet v 4, Birch Allergen w211, rPar j 2, Wall pellitory Allergen g213, rPhl p1 rPhl p5b, Timothy Allergen m221, rAsp f 4, Aspergillus fum Allergen m222, rAsp f 6, Aspergillus fum Allergen g214, rPhl p7 rPhl p12, Timothy ImmunoCAP o212, Streptavidin Allergen k215, rHev b 1, Latex Allergen k217, rHev b 3, Latex Allergen k218, rHev b 5, Latex Allergen k220, rHev b 6.02, Latex Allergen k221, rHev b 8, Latex Allergen k224, rHev b 11, Latex Allergen Ro213, MBP (maltose binding protein) Allergen f351, rPen a 1, Shrimp Allergen f353, rGly m 4, Soy	In house documented procedures based on equipment manuals and standard methods as specified below: Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd) Serum (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd): Detection and quantification of Total IgE (cont'd) Allergen f352, rAra h 8, Peanut Allergen f354, rBer e 1, Brazil nut Allergen f355, rCyp c 1, Carp Allergen t225, rBet v 6, Birch Allergen m229, rAlt a 1, Alternaria Allergen e227, rEqu c 1, Horse Allergen f433, rTri a 14 LTP, Wheat Allergen e228, rFel d 4, Cat Allergen f435, rMal d 3 LTP, Apple Allergen f436, nAct d 1, Kiwi Allergen w234, rPla l 1, Plantain Allergen f98, Gliadin Allergen f439, rCor a 14, Hazelnut Allergen e229, rCan f 4 Dog Allergen f440, nCor a 9, Hazelnut Allergen f443, rAna o 3, Cashew nut Allergen f441, rJug r 1, Walnut Allergen f442, rJug r 3, LTP, Walnut Allergen t241, rPla a 1, Maple leaf syc Allergen o215, alpha-Gal TG, bovine Allergen d209, rDer p 23 House dust mite Allergen f447, rAra h 6 Peanut Allergen e230, rCan f 6, Dog Allergen e231, rFel d 7, Cat Allergen f454, rPru p 7, Peach Allergen gx1, Grass pollen Allergen gx2, Grass pollen Allergen gx3, Grass pollen Allergen gx4, Grass pollen Allergen wx1, Weed pollen Allergen wx3, Weed pollen Allergen wx5, Weed pollen Allergen wx6, Weed pollen Allergen tx1, Tree pollen Allergen tx4, Tree pollen Allergen tx5, Tree pollen Allergen tx6, Tree pollen Allergen ex1, Animal proteins Allergen mx1, Moulds Allergen hx2, House dust	In house documented procedures based on equipment manuals and standard methods as specified below: Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen fx1, Food Allergen fx2, Food Allergen fx3, Food Allergen wx2, Weed pollen Allergen wx7, Weed pollen Allergen tx7, Tree pollen Allergen tx8, Tree pollen Allergen tx9, Tree pollen Allergen ex70, Rodents Allergen ex71, Feathers Allergen ex72, Cagebirds Allergen mx2, Moulds Allergen fx70, Spices Allergen fx71, Spices Allergen fx72, Spices Allergen ex2, Animal proteins Allergen fx73, Meat Allergen fx74, Fish Allergen fx7, Food Allergen fx13, Vegetables Allergen fx14, Vegetables Allergen fx15, Fruits Allergen fx16, Fruits Allergen fx18, Food Allergen fx20, Food Allergen fx29, Fruits Allergen fx30, Fruits Allergen fx31, Fruits Allergen mx4, Moulds Allergen fx77, Food Allergen wx209, Ambrosia sp. Allergen fx17, Fruits Allergen tx10, Tree pollen Allergen rx2, Regional Allergen rx1, Regional Allergen rx3, Regional Allergen gx6, Grass pollen Allergen fx21, Fruits Allergen fx22, Nuts Allergen fx5, Food	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd):	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum (cont'd)	Detection and quantification of Total IgE (cont'd) Allergen fx24, Food Allergen fx25, Food Allergen fx28, Food Allergen fx27, Food Allergen fx26, Food Allergen rx5, Regional Allergen rx6, Regional Allergen rx7, Regional Allergen U901, Hemp	Fluorescence solid phase immunoassay (ImmunoCAP assays on Phadia 1000) SOP: ClinImm/002	A
Serum, plasma	Detection of: Specific IgE (quantitative) Total IgE (semi-quantitative)	Solid phase immunoassay using the Allergy Explorer Multiarray Allergy test, ALEX IgE (version: ALEX2) ImageExplorer and Raptor Analysis software SOP: ClinImm/030	A



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HUMAN BODY TISSUE AND FLUIDS	<u>Molecular examination activities for the purposes of clinical diagnosis:</u>	Documented In-house Methods and Manufacturer's instructions for analyser, if applicable, with specific reference to:	
FFPE tissue	Preparation of slide-mounted tissue specimens	Manual procedures using SOPs: SCMD/003 SCMD/004	A
		Microtomy and slide mounting: Manual method using: SOP SCMD/003 and: Leica RM2125 RTS microtomes	A
		Routine Haematoxylin & Eosin (H&E) staining and coverslipping Manual method using: SOP SCMD/004	A
Formalin fixed paraffin-embedded tissue & cell blocks, alcohol fixed or air dried cytology smears.	DNA extraction for the detection of variant sequences associated with diagnostic, prognostic or therapeutic implications	DNA extraction using Qiagen column-based extraction and SOP's: SCMD/006 SCMD/IOP/002	A
DNA from FFPE tissue	Detection of key somatic mutations in the following genes for the purposes of clinical diagnosis, prognosis and treatment stratification: BRAF EGFR KRAS NRAS-BRAF	Real-time PCR amplification of DNA with Biocartis CE-IVD tests on the Idylla Platform using SOP's: SCMD/013 SCMD/017 SCMD/018 SCMD/IOP/003	A
DNA from FFPE tissue	Detection of Microsatellite Instability (MSI) Lynch Syndrome Pre-screening and Checkpoint Inhibitor Immunotherapy Sensitivity. Screens 7 monomorphic homopolymer regions for instability	Real-time PCR amplification of DNA with Biocartis CE-IVD assay on the Idylla Platform using SOP's: SCMD/IOP/003 SCMD/028	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
DNA from FFPE tissue	MGP-4 (DNA): NGS Multi-Gene Panel (bespoke) for the detection of specific targetable SNVs, small indels and CNGs	ThermoFisher Ion GeneStudio S5 Prime/Ion Chef System utilising both native and bespoke software and bioinformatics, SNV and small indel calling via comparison to reference sequence, CNG calling via statistical analysis of data distribution, using SOP's: SCMD/015 SCMD/027 SCMD/030	A
DNA from FFPE tissue	MGP-5: NGS Multi-Gene Panel (Oncomine BRCA Expanded) for detection of somatic variants associated with homologous repair disorder (HRD)	ThermoFisher Ion GeneStudio S5 Prime/Ion Chef system utilising both native and bespoke software and bioinformatics. SNV and small indel calling via comparison to reference sequence, using SOP's: SCMD/015 SCMD/027 SCMD/030	A
Formalin fixed paraffin-embedded tissue & cell blocks, alcohol fixed or air dried cytology smears.	RNA extraction for the detection of variant sequences associated with diagnostic, prognostic or therapeutic implications	RNA extraction using Qiagen column-based extraction and SOP's: SCMD/029 SCMD/IOP/002	A
RNA from FFPE tissue	MGP-4 (RNA): NGS Multi-Gene Panel (Oncomine Focus) for the detection of specific targetable gene arrangement (fusion) events	ThermoFisher Ion GeneStudio S5 Prime/Ion Chef System utilising both native and bespoke software and bioinformatics with associated hardware suites, fusion calling via detection of specific transcript sequences, using SOP's: SCMD/015 SCMD/027 SCMD/030	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
DNA from FFPE tissue	Detection of somatic mutation at codon 600 of BRAF for the purposes of clinical diagnosis, prognosis and treatment stratification	Real-time PCR amplification of DNA with Qiagen Therascreen CE-IVD assay on Rotor Gene-Q Platform using SOPs: SCMD/IOP/001 SCMD/007	A
Slide mounted tissue /cytology specimens	Assessment of the relative tumour content, as a proportion of all nucleated cells, for the purposes of assay eligibility requirements	Microscopic visual examination SOP: SCMD/005	A
Cervical cells	<u>Gynaecological Cytopathology activities for the purposes of clinical diagnosis</u> Preparation and screening to identify or exclude cytological abnormalities for the purpose of diagnosis	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to: <u>Liquid based cytology</u> In-house procedures based on Thin Prep method in conjunction with manufacturer's instructions using: ThinPrep 5000 processor with AutoLoader and Thin Prep 2000 processor Papanicolaou Staining in conjunction with manufacturer's instructions using: Sakura Tissue Tek Prisma Autostainer and Coverslipper and SOP's CYTO-001, CYTO-010	A
Cervical cells	Detection and genotyping of Human papilloma virus (HPV)	Qualitative real-time PCR for automated and rapid detection Automated method using GeneXpert XVI and SOP CYTO/015: Procedure for PCR Testing for HPV/CHL/GON	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd):	<u>Gynaecological Cytopathology activities for the purposes of clinical diagnosis</u> (cont'd):	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
Cervical cells	Detection of <i>Chlamydia Tracomatis</i> and <i>Neisseria Gonorrhoea</i> (CT/NG)	Qualitative real-time PCR for automated and rapid detection	A
Slides prepared in house from samples listed above	Morphological assessment and interpretation/diagnosis	Automated method using GeneXpert XVI and SOP CYTO/015: Procedure for PCR Testing for HPV/CHL/GON <u>Microscopy (qualitative analysis)</u> In-house procedures: CYTO/001 - Procedure for Cytology Gynae Sample Preparation CYTO/010 - Cytology Gynae hrHPV Primary Screening & Co-Testing CYTO/020 - Procedure for Pathologist Reporting in Cytology in conjunction with manufacturer's instructions using microscopes: Olympus BX46 Olympus BX43 Olympus BX53 Olympus BX51	A



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cerebrospinal fluid (CSF) Fine Needle Aspirates (FNA) General body fluids Bronchial brushings Washings Sputum Urine</p>	<p><u>Diagnostic Cytopathology activities for the purposes of clinical diagnosis:</u></p> <p>Examination to identify or exclude cytological abnormalities for the purpose of diagnosis</p>	<p>In house documented procedures and manufacturer's instructions using the following equipment:</p> <p><u>Preparation/centrifugation</u></p> <p>CYTO/002 – Procedure for Non-Gynae Specimens Preparation CYTO/003 – Procedure for Attending the Clinics</p> <p>In conjunction with manufacturer's instructions using: Thermo Shandon cytocentrifuge Cytospin 4 Thermo Fischer ST16 Sorvall centrifuge Sorvall ST40 centrifuge (Cat 3 work and cytology laboratory) ThinPrep 5000 Processor with autoloader ThinPrep 2000 Processor Extractor hood Class 1 MSC (Cat 3 work) Extractor hood Class CAS Biomat 1</p> <p>Workflow management using Pathhub LIMS</p>	<p>A</p>
<p>Fine needle aspirates (FNA)</p>	<p>Cellularity assessment (sample adequacy confirmation) followed by subsequent processing and analysis in the Cytopathology Laboratory (A)</p>	<p>Material/slide preparation followed by microscopy Manual methods using: SOP CYTO/020</p>	<p>FNA clinics: B G H I L M</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd):</p> <p>Ascitic fluid Bile Biliary brushings Breast cyst fluid Bronchial brushes Bronchial lavage Broncho-alveolar lavage Colonic brushings Hydrocele fluid Oesophageal brushings Ovarian cyst fluid Pericardial fluid Peritoneal fluid Pleural fluid Sputum Urine</p> <p>Slides prepared in house from samples listed above</p>	<p><u>Diagnostic Cytopathology activities for the purposes of clinical diagnosis</u> (cont'd):</p> <p>Examination to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>In house documented procedures and manufacturer's instructions using the following equipment:</p> <p><u>Papanicolaou staining</u> Automated method using in-house procedures: CYTO/002 – Procedure for Non-Gynae Specimens Preparation In conjunction with manufacturer's instructions using: Sakura Tissue Tek Prisma Autostainer and Coverslipper</p> <p><u>Romanovsky staining</u> Manual method using in-house procedures: CYTO/002 – Procedure for Non-Gynae Specimens Preparation CYTO/003 – Procedure for Attending the Clinics.</p> <p><u>Microscopy using SOPs</u> CYTO/020 Pathologist Reporting in Cytology and microscopes as follows: Olympus BX46 Olympus BX43 Olympus BX53</p>	<p>A</p> <p>A</p>



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<p>HUMAN TISSUES</p> <p>Tissues: biopsy, excision and resection</p> <p>Formalin Fixed Tissues</p>	<p><u>Histopathology activities for the purposes of clinical diagnosis:</u></p> <p>Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In house documented procedures and manufacturer's instructions using the following equipment:</p> <p><u>Dissection:</u> Manual method using: HIST/023 – Procedure for Histology Specimen Transfer HIST/025 – Procedure for Histology Cut-Up and Equipment Set-Up CP/09 - Cellular Pathology - Specimen Dissection Protocols SOP HIST/073 BMS Specimen Dissection</p>	A
		<p><u>Decalcification</u> Manual method using: HIST/025 – Procedure for Histology Cut-Up and Equipment Set-Up HIST/069 – Decalcification Procedures</p>	A
		<p><u>Tissue Processing</u> Automated method using: HIST/023 – Procedure for Histology Specimen Transfer HIST/008 – Histology Procedure for the use of the Leica Peloris II Processor HIST/080 – Histology Procedure for the use of the Leica Peloris III Processor</p> <p>Using the: Leica Peloris II Processor Leica Peloris III Processor</p>	A



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<p>HUMAN TISSUES (cont'd)</p> <p>Tissues: biopsy, excision and resection</p> <p>Formalin Fixed Tissues (cont'd)</p>	<p><u>Histopathology activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p>	<p>In house documented procedures and manufacturer's instructions using the following equipment:</p> <p><u>Embedding</u> Manual method using: HIST/010 – Procedure for Embedding Histological Specimens</p> <p>Using the: Leica Embedding Centres EG1150H Histocore Arcadia H Histocore Arcadia C</p> <p><u>Microtomy</u> Manual method using: HIST/028 – Histology Procedure for Microtomy Using the: Leica RM2235 microtomes</p> <p>Workflow management using Pathhub LIMS</p>	<p>A</p> <p>A</p>
<p>Formalin Fixed Paraffin Embedded (FFPE) tissue</p>	<p>Assessment of basophilic and eosinophilic tissue structures</p>	<p><u>Routine Haematoxylin & Eosin (H&E) staining and coverslipping</u></p> <p>Automated method using: HIST/054 – Histology procedure for the Use of the Leica ST5020 Stainer HIST/075 – Histology procedure for the Use of the Leica Histocore Spectra Stainer</p> <p>Leica ST5020 Multistainer Leica Histocore Spectra Stainer and Coverslipper</p>	<p>A</p>



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HUMAN TISSUES (cont'd)	<u>Histopathology activities for the purposes of clinical diagnosis (cont'd):</u>	In house documented procedures and manufacturer's instructions using the following equipment:	
Fresh tissue Frozen tissue	Intra-operative diagnosis	<u>Rapid Frozen Section Cryotomy and manual H&E staining method using:</u> HIST/006 – Procedure for cutting frozen section using the Leica CM1950UV Cryostat HIST/007 – Procedure for the Staining of Frozen Sections (manually and using the Leica Linear Stainer) Using the: Leica CM1950 Cryostat Leica ST4020 Small Linear stainer	A, K
FFPE tissues and cytological fluids	For the demonstration of:	<u>Special stains</u> Manual methods using in house procedures:	
	Acid and sulphated mucins	Alcian Blue SOP HIST/064	A
	Acid mucins/Neutral polysaccharides	Alcian Blue-Periodic Acid Schiff's (ABPAS) +/- Diastase SOP HIST/037	A
	Amyloid	Congo Red SOP HIST/047	A
	Elastic fibres and collagen	Miller's Elastic Van Gieson (EVG) SOP HIST/040	A
	Gram positive and gram negative organisms	Gram SOP HIST/036	A
	Liberated aldehydes	Periodic Acid Schiff (+/- diastase) (PAS) SOP HIST/036	A
	Haemosiderin	Perls' Prussian Blue SOP HIST/079	A



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HUMAN TISSUES (cont'd)	<u>Histopathology activities for the purposes of clinical diagnosis (cont'd):</u>	In house documented procedures and manufacturer's instructions using the following equipment:	
FFPE tissues and cytological fluids (cont'd)	For the demonstration of: (cont'd)	<u>Special stains (cont'd):</u> Manual methods using in house procedures:	
	Reticulin fibres	Reticulin SOP HIST/079	A
	Hepatitis B surface antigen Copper associated protein	Victoria Blue SOP HIST/081	A
	Acid fast bacilli	Ziehl-Neelsen SOP HIST/038	A
		Automated methods using the Ventana Benchmark SS automated stainer and in house procedures:	
	Elastic fibres	Elastic Von Gieson SOP HIST/079	A
	Fungi	Grocott SOP HIST/035 and HIST/079	A
	Haemosiderin	Perls' Prussian Blue SOP HIST/035 and HIST/079	A
	Reticulin fibres	Reticulin SOP HIST/035 and HIST/079	A
	Acid fast bacilli	Ziehl-Neelsen SOP HIST/035 and HICT/079	A
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: HIST/049 – Pathologist Reporting in Histology	A
		Using microscopes: Olympus BX51 Olympus BX53	
END			