

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>9059</p> <p>Accredited to ISO 15189:2012</p>	<p><b>HCA International Limited, operating as HCA Laboratories</b></p> <p>Issue No: 008 Issue date: 17 September 2021</p>	
	<p>Shropshire House Shropshire Place/Queens Yard Capper Street London WC1E 6JA</p>	<p>Contact: Dorothy Kasibante Tel: +44 (0)207 034 4616 Fax: +44 (0)207 487 2721 E-Mail: dorothy.kasibante@hcahealthcare.co.uk Website: hcalaboratories.co.uk</p>

Testing performed by the Organisation at the locations specified below

### 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><b>Local contact</b> Dorothy Kasibante Risk &amp; Compliance Manager</p> <p>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 &amp; diagnostic) Histopathology (inc. routine &amp; special staining, Decalcification &amp; frozen sections)</p>	A
<p>London Bridge Hospital Laboratory London bridge Hospital Tooley Street London SE1 2PR</p> <p><b>Local contact</b> As above</p>	<p>Sample Reception Biochemistry Haematology Blood Transfusion EBUS and Slide production, staining &amp; mounting of fine needle aspirates for diagnostic cytology</p>	B
<p>LOC laboratory 59/97 Harley Street London W1G 6AF</p> <p><b>Local contact</b> As above</p>	<p>Biochemistry Haematology</p>	C
<p>Sydney Street Lab 102 Sydney Street, Chelsea, SW3 6NJ</p> <p><b>Local contact</b> As above</p>	<p>Biochemistry Haematology</p>	D



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

<b>Location details</b>	<b>Local Contact</b>	<b>Activity</b>
Outpatient Phlebotomy Rooms 111 Harley Street London W1G 6AW	Dorothy Kasibante Risk & Compliance Manager  Mr Charles Percy - CEO Tel: +44 (0)207 486 5091	Venesection
The Harley Street Clinic 16 Devonshire Street London	As above	EBUS Clinics
Portland Hospital 205 - 209 Great Portland Street London W1W 5AH	As above	Blood fridge storage only Fridge managed by Laboratory
Princess Grace Hospital 42-52 Nottingham Place London W1U 5NY	As above	Blood fridge storage only Fridge managed by Laboratory Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.
Lister Hospital Chelsea Bridge Road London SW1W 8RH	As above	Blood fridge storage only Fridge managed by Laboratory Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.
Wellington Hospital North and South Buildings Wellington Place London NW8 9LE	As above	Blood fridge storage only Fridge managed by Laboratory EBUS and Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.
Harley Street Clinic 35 Weymouth Street London W1G 8BJ	As above	Blood fridge storage only Fridge managed by Laboratory
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
The Shard Medical Centre The Shard 32 ST Thomas Street London, SE1 9BS	As above	Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.
Platinum Medical Centre: 5-17 Lodge Road, St John's Wood, London NW8 7JA	As above	Slide production, staining & mounting of fine needle aspirates for diagnostic cytology.



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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	Symex XN20, XN10 XN10, XN20 XN20 and SOP: Haem/050	A B, C D
	Basophils Eosinophils Lymphocytes Monocytes Neutrophils Immature Granulocytes (IG) Reticulocytes WBC	Light scatter and Fluorescent Flow Cytometry	
	Haematocrit	Fluorescent Flow Cytometry	
	Haemoglobin	Impedance, Calculations and histogram analysis. Calculated using the RBC pulse height detection method RBC lysis by SLS, photometry at 55nm	
	MCH	Impedance, Calculations and histogram analysis. Calculated using patients' HGB and RBC values	
	MCHC	Impedance, Calculations and histogram analysis. Calculated using patients' HGB and HCT values	
	MCV	Impedance, Calculations and histogram analysis. Calculated using patients' HCT and RBC values	
	MPV	Impedance, fluorescent flow cytometry and machine calculated	
	Platelets	Impedance and fluorescent flow cytometry	



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HUMAN BODY FLUIDS cont'd	<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	Platelets	Sysmex XN10 XN20 and SOP: Haem/050 cont'd  optical platelet count PLT-F	A,B,C,D A
Blood	RBC	Impedance with Hydro-dynamic focusing	A,B,C,D
Blood	RDW	Impedance, Calculations and histogram analysis	
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, LB/IOP/017	A, B



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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:	
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/IOP/046, 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:  Plasmodium falciparum Plasmodium malariae Plasmodium ovale Plasmodium vivax Plasmodium Knowlesi	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy SOP: HAEM/012	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:	
EDTA Whole Blood	Detection of HRP2 and pLDH antigens for the identification of Malaria parasites	CareStart Malaria Malaria Antigen Test Malaria HRP2/pLDH Combo Test SOP: HAEM/042	A
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
	Prothrombin Time	SOP's: HAEM/055, HAEM/049	A, B
	Prothrombin Time 50:50	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/056, HAEM/049	A
	APTT and APTT (IV Heparin)	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/056, HAEM/049	A, B
	APTT 50:50	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/061, HAEM/049	A
Plasma - Citrate	Clauss Fibrinogen	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/057, HAEM/049	A, B
	D-Dimer (FDP)	STAGO STA-R MAX2 Immunoturbidimetric Method SOP's: HAEM/058, HAEM/049	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:	
Whole blood	Protein C Activity	STAGO STA-R MAX2 Chromogenic Assay SOP's: HAEM/053, HAEM/049	A
	Lupus( PTT-LA + DRVVT)	STAGO STA-R MAX2 Viscosity Based Detection System SOP's: HAEM/059, HAEM/049	A
	Anti-Xa	STAGO STA Max 2 measurement of Low Molecular Weight Heparin (LMWH) using the STA® Liquid Anti-Xa assay SOP HAEM/060	A
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
Serum	<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 SOP: CC/IOP/097 in conjunction with manufacturer's instructions for analysis using Roche Cobas 6000: Sandwich Immunoassay	C
	AFP (Alpha feto protein)		
	Albumin Magnesium Total Protein	Colorimetric 2-Point End Assay SOP: CC/IOP/097	B, C, D



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis cont'd</u>	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: Kinetic rate A Assay	
Serum	Alanine Aminotransferase (ALT) Urea		B, C, D
	Aspartate Aminotransferase (AST)	Enzymatic rate A Assay	B, C, D
	Alkaline Phosphatase	Colorimetric Rate A Assay according to IFCC	B, C, D
	Calcium	Photo-colorimetric method 2-Point End	B, C, D
	Calcium (corrected) Globulin Estimated GFR (eGFR)	Calculated	B, C, D
	Cancer Antigen 125 Cancer Antigen 15-3 Cancer Antigen 19-9	Sandwich immunoassay	B, C, D
	Carcinoembryonic Antigen (CEA)		B, C, D
	Chloride	Indirect potentiometric assay	B
	Potassium Sodium		B, C, D
	Cholesterol	Enzymatic-colorimetric 1-point assay	B, C, D
	C Reactive Protein	Particle enhanced immune-turbidimetry	B, C, D





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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis cont'd</u>	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	Creatinine	Jaffe Kinetic colorimetric Rate A assay	B, C, D
	Gamma GT	Enzymatic colorimetric Rate A assay	B, C, D
	Glucose	UV test enzymatic reference 2-Point end Assay with hexokinase	B, C, D
	Inorganic Phosphate	Molybdate UV 2-Point End Assay	B, C, D
	Lactate Dehydrogenase (LDHI2) derived from IFCC	UV Rate A assay	B, C, D
	Total Bilirubin	Colorimetric diazo method 2-Point End	B, C, D
	Procalcitonin Prostate Specific Antigen	Sandwich immunoassay	B, C, D



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis cont'd</u>	SOP: CC/105 in conjunction with manufacturer's instructions for analysis using Roche Cobas 8000: Colourimetric End point Colourimetric	A
Serum	Albumin Alkaline Phosphatase Lactate Lithium Magnesium Serum Iron Total Bilirubin Total Protein		A
Serum	Alpha-1-antitrypsin Apolipoprotein B Antistreptolysin – O (A.S.O) Titre Beta 2 Microglobulin C3 C4 IgA IgG IgM Lipoprotein (a)	Immunoturbidimetric	A
	Alanine Aminotransferase (ALT) CK Urea	Kinetic rate method	A
Urine	Urine Urea		A
Serum Urine	Amikacin Barbiturates Benzodiazepines Cocaine Metabolites	KIMS	A
Urine	Amphetamine Metabolites Cannabis Metabolites Methadone Opiate Metabolites Phenytoin		
Serum	Ammonia	Enzymatic assay	A



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



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis cont'd</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Serum		SOP: CC/105 in conjunction with manufacturer's instructions for analysis using Roche Cobas 8000:	A
Serum	Cortisol DHEA Sulphate Digoxin 25 OH-Vitamin D (Vit D2 + D3) Free T3 Free T4 Oestradiol Vitamin B12	Competitive immunoassay	A
	C Reactive Protein	Particle-enhanced immunotubidimetry	A
	Creatinine	Kinetic colourimetric assay	A
Urine	Urine Creatinine		A
Serum	Conjugated Bilirubin	Diazo method	A
CSF Plasma	CSF Glucose Glucose Glucose Tolerance Test (Non-obstetric) Glucose Tolerance Test (Obstetric) GTT and Insulin GTT and Growth hormone	Timed end point method	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis cont'd</u>	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: Turbidimetric method	A
CSF Urine	CSF Protein Urine Albumin Urine Protein		A
Serum and Urine	Renal Tubular Reabsorption of Phosphate using serum and urine phosphate	Molybdate end point method & Kinetic colourimetric assay	A
Serum	Unsaturated Iron Binding Capacity	FerroZine reaction method	A
	Vitamin B12 25 OH-Vitamin D (Vit D2 + D3)	Competitive immunoassay	A
	CCP	IgG-capture test principle	A
	AMH	Sandwich immunoassay	A
	PH	Whatman pH 1-12 indicator paper	A
Serum	Calcium (corrected) Estimated GFR (eGFR) Free Androgen Index (FAI) Globulin Iron Binding Saturation % Non-HDL Cholesterol (LDL)	Calculated	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis cont'd</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Serum	Paraprotein Quantitation	Sebia Hydrasis Electrophoresis System, Sebia Phoresis Software in conjunction with procedure SOP CC/102	A
Serum & Urine	Protein abnormalities screening	Sebia Hydrasis Electrophoresis System in conjunction with procedure SOP: CC/102 Hydragel protein migration (Electrophoretic separation)	A
Serum	Paraprotein bands identification and classification	Sebia Hydrasis Electrophoresis System - Antisera immunofixation in conjunction with procedure SOP: CC/102	A
Serum/urine	Serum Osmolality Water Deprivation Test for detection of diabetes insipidus	Advanced Micro Osmometer 3320 and 3300, Freeze point depression in conjunction with procedure SOP: CC/IOP/06	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 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



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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:	
Blood	Red Cell Phenotyping(Rh/K) Rhesus blood group antigens: C, c, D, E, e	SOP: Trans/IOP/011 _Using Ortho Vision Max Analysers - Column agglutination technology	A
Plasma	Kell system blood group antigens: K 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
	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
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





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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	SOP: Trans/006_Using Ortho Biovue System Cassettes-Column agglutination technology	A
EDTA Plasma	Manual Antibody Screen for the detection of: (cont'd)  Lutheran blood group antibodies: anti-Lu a, Lub MNS blood group antibodies: Anti-M, anti-N, anti-S, anti-s 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



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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 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, B
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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HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures aligned with current Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals.	
Routine samples: Aspirates Cellular/Fluid Material on Swabs Fluids Tissues Respiratory samples Faeces Tips IUCDs Blood cultures Skin/Nail/Hair	Isolation of micro-organisms of Clinical Significance	Manual inoculation of selected culture media and incubation using in-house procedures: Bact/005 Bact/010 Bact/012 Bact/014 Bact/015 Bact/016 Bact/018 Bact/020 Bact/021 Bact/023 Bact/024 Bact/112 WI Micro 053	A
Urine	Detection of: White blood cells Red blood cells PH Ketones Glucose Protein Casts Nitrates	Siemens Cliniteck 500 and in-house procedure and manual microscopy Bact/011	A
Urine	Isolation of micro-organisms of Clinical Significance	SOP: BACT/011 COBAS 6500 Automated inoculation and optical reading of urinalysis dipsticks.	



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HUMAN BODY FLUIDS (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis	In-house documented procedures aligned with current Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals.	
Blood cultures	Isolation of micro-organisms of Clinical Significance	SOP: BACT/013, BACT/113, BACT/121, BACT/131  BD FX 400. Optical density. Indicator colour change if bacteria respire which changes the pH.	A
Respiratory samples, tissues, fluids, early morning urine, CSF	Isolation and presumptive identification of Mycobacterium species	SOP: BACT/004, BACT/099, BACT/133 Optical Density/ fluorescence	A
Cellular material on swabs Primary screening swabs: Nose, axilla, groin, throat, hairline. Other swabs	Screening for MRSA	Culture onto a selective chromatic agar (Oxoid). Bact/021	A



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<p>HUMAN BODY FLUIDS AND TISSUES cont'd</p> <p>Cultures isolated in-house from routine &amp; blood samples listed above</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis cont'd</u></p> <p>Identification and sensitivity of microorganisms of clinical significance</p>	<p>In-house documented procedures aligned with current Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals.</p> <p>Disc diffusion and gradient minimum inhibitory concentration determination using the European Committee on Antimicrobial Susceptibility Testing (EUCAST) methodology: SOP: BACT/119</p> <p>MALDI-TOF A mass-spectrometry technique for the analysis and identification of microorganisms, SOP: BACT/127</p> <p>Sensititre Microbroth dilution for susceptibility testing SOP: BACT/129</p> <p>Biochemical (eg. API) Immunological analysis (eg. Latex/agglutination testing) Bact/026 Bact/029 Bact/030 Bact/031 Bact/037 Bact/038 Bact/042 Bact/043 Bact/044 Bact/045 Bact/065 Bact/068 Bact/069 Bact/074 Bact/089 Bact/110/119</p>	<p>A</p>



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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 Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals:	
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	A
CSF	Isolation of microorganisms of clinical significance	Microscopy for the presence of white cells, red cells, microorganisms using in-house procedures: BACT/012 BACT/103	A
Blood	Isolation of microorganisms of clinical significance	Liquid culture, using in-house procedures: Bact/118 Bact/013 in conjunction with manufacturer's instructions using BD Bactec FX	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 Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals:	
Respiratory samples Tissues Fluids Early morning urine CSF Cellular/Fluid Material on Swabs	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
Respiratory samples Sterile fluids Tissues Positive cultures	Detection of M. Tuberculosis (Mtb) and rpoB gene Rifampicin resistance	Cepheid Infinity Cepheid PCR Kit SOP: Immuno/061, BACT/114	A
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Auramine phenol staining and incident-light fluorescence microscopic examination using in-house procedure: Bact/058	A
Faeces	Q-Fit	HM-JACKarc Automated Quantitative Faecal Haemoglobin Immunochemical Testing system using Integrated Sphere Latex Turbidimetry to measure faecal haemoglobin concentration using a highly sensitive latex reagent coated with polyclonal antibodies to human Faeceshaemoglobin. SOP Reference: BACT/137	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 Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals:	
Smears from Routine samples: Aspirates Cellular/Fluid Material on Swabs Fluids Tissues Respiratory samples Faeces 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/101	A
Faeces	Giardia antigen	SOP: BACT/130 Polystainer. Automated Gram-staining machine.  Qualitative immunochemical testing using Immunochromatography card (remel) and in-house procedure: Bact/080	A
Faeces	Detection of <i>Clostridium 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 Helicobacter pylori antigen	Immunochromatography card (HPSA Stat) and in-house procedure: Bact/072	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 Public Health England (PHE) Standards for Microbiological Investigations (SMIs), manufacturer's guidelines and equipment manuals:	
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: Campylobacter spp. Clostridium difficile Escherichia coli O157 Salmonella sp. Shigella spp. Vibrio spp. Yersinia spp.	Manual inoculation of culture media, using in-house procedures: Bact/015 Bact/042 Bact/043 Bact/044 Bact/045	A
Urine	Detection of <i>Schistosoma haematobium ova</i>	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/101	A
Female genital tract swabs	Detection of <i>Trichomonas vaginalis</i>	Culture and microscopic examination using in-house procedure: Bact/123	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:	
Serum	Cardiolipin IgG Cardiolipin IgM Histone antibodies	Automated ELISA using DS2 analyser and in-house procedure: SOP: Immuno/IOP/015	A
Faeces	Faecal calprotectins		
Serum	Helicobacter IgG HTLV 1/2	Grifols Triturus IBL ELISA Kit DIA.PRO ELISA Kit SOP: Immuno/IOP/10	A
Serum	Measles IgM Mumps IgM	Diesse Chorus Diesse ELISA Kit SOP: Immuno/IOP/013	A
Serum	TB QuantiFERON Detection of latent TB Detection of M. tuberculosis. Detection of rifampicin resistance.	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	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: 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
Urine	Detection of: Legionella Antigen S.pneumoniae Antigen Pregnancy hCG Testing	BINAX NOW Kit Immunochromatographic assay. SOP: Immuno/041 SOP: Immuno/042 SOP: Immuno/029	A
Serum	Schistosoma Antibody Echinococcus Antibody	Firefly Scientific Haemagglutination and SOP: Immuno/055	
Serum	Amoebic Antibody	ELITex Bicolor Slide agglutination assay and procedure: SOP: Immuno/056	
	Hepatitis A Antibody (Total) Hepatitis B Core Antibody	Documented procedures & manufacturer's instructions for ROCHE COBAS 8000 with specific reference to: SOP: CC/105 (Competitive immunoassay)	
Serum	Hepatitis A Antibody (IgM) Rubella IgG	SOP: CC/105 ( $\mu$ -Capture test principle)	A
Serum	Hepatitis B Surface Antigen	SOP: CC/105 (Sandwich immunoassay)	A
	Hepatitis B Antibody Hepatitis C Antibody	SOP: CC/105 (Sandwich immunoassay)	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 ROCHE COBAS 8000 with specific reference to: SOP: CC/105 (Competitive immunoassay) cont'd	
Serum	HIV-1/2 Antibodies Toxoplasma IgG  Detection of Syphilis	SOP: CC/105 Immunoturbidimetric method	A
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  For:	Documented in house methods including DHSC requirements for private providers of COVID-19 General Population testing  Real-time RT-PCR using: Abbott m2000 RealTime System and SARS-CoV-2 Amplification Kit SOP: Immune 064 Abbott M2000	A
Samples self-collected	General Population testing  <u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:  Cepheid Infinity Cepheid PCR Kit SOP: Immuno/061	A



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Nasopharyngeal swabs in VTM/UTM	Detection of: Detection and differentiation of lineage $\beta$ -betacoronavirus ( $\beta$ - $\beta$ 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
Dry swab, Nasal Asps, Red UTM Tube Nasal swabs Urines vaginal/endo swabs Rectal Swab	Rapid Flu A/B/RSV MRSA C.Trachomatis/N.gonorrhoea CRE	Cepheid Infinity Cepheid PCR Kit SOP: Immuno/061	A
Nasal swabs	detection of methicillin-resistant Staphylococcus aureus (MRSA)	Gene Xpert PCR SOP: IMMUNO/IOP/014	B
NP samples (Nose/throat/NP/NPA samples)	RESPPCR22 Assay	Biofire FilmArray Biomerieux SOP: Immuno/060 Immuno/IOP/018	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:	
Blood	Detection of:  Anti-Nuclear Antibodies and other Autoantibodies including Gastric parietal cell Antibodies, Mitochondrial Antibodies, Smooth Muscle Antibodies, Liver Kidney Microsomal Antibodies	Documented procedures for manual indirect immunofluorescence assay and fluorescent microscopy as specified below:  SOP: ClinIMM/IOP/004	A
Blood	Double Stranded DNA Antibody Screen using Crithidia lucillae	SOP: ClinImm/009	A
Blood	Endomysial Antibodies using monkey oesophagus sections	SOP: ClinImm/006	A
Blood	Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	SOP: Clin/Imm/008	A
Blood	Adrenal autoantibodies Islet Cell autoantibodies Muscle autoantibodies	SOP: ClinImm/007	A
Blood	Detection of Glomerular basement membrane autoantibodies (GBM)	Documented procedure for manual Quick Card Immunochromatographic assay SOP: ClinImm/016	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis cont'd</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	A
Blood	Detection of:  Liver Antibodies anti-SLA and anti-LC1 Intrinsic Factor and Gastric Parietal Cell Antibodies ANCA Assay for MPO, PR3 and GBM Antibodies Detection of:	Manual Immunoblot assay using the Blue Diver Instrument, manufactures instructions and in-house procedure:  SOP: ClinImm/023	A
Blood	Double Stranded DNA Antibodies	In house documented procedures for the DS2 Analyser performing Enzyme-linked Immunoabsorbant Assay (ELISA) as specified below: SOP: ClinImm/003	A
Blood	Anti-Thyroid Peroxidase (TPO) Anti-Thyroglobulin (TG)	SOP: ClinImm/005	A
Blood	ENA (Extractable Nuclear Antigens) Screen Assay	SOP: ClinImm/013	A
Blood	Extractable Nuclear Antigen specificities (ENA): Anti SS-A (Ro) Anti SS-B (La) Anti-RNP Anti-Sm Anti-Jo-1 Anti-Scl-70	SOP: ClinImm/017	A
	Myeloperoxidase (MPO) Proteinase-3 (PR3)	SOP: ClinImm/012	A
	Intrinsic Factor Assay	SOP: ClinImm/014	A
	Anti- Transglutaminase (tTG) antibodies	SOP: ClinImm/019	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis cont'd</u>	In house documented procedures based on equipment manuals and standard methods as specified below using DS2 Analyser performing Enzyme-linked Immunoabsorbant Assay (ELISA) as specified below: SOP: ClinImm/015	A
Blood	Deamidated Gliadin IgA and IgG antibodies		
	Detection and quantification of Total IgE, Specific IgG4	Phadia Immucap 250 analyser fluorescence solid phase immunoassay	
	Detection and quantification of specific IgE to the following allergens: Poplar (Cottonwood) Mid Season Tree Mix Early Season Tree Mix Codfish Gad c 1 Sheep's Milk Whey – Cows Whey – Sheep's Cow's Milk nBos d lactoferrin Pork Beef Lamb/Mutton Chicken Turkey Goose Duck Codfish Salmon Trout Tuna Swordfish Red Snapper Coley Hake Halibut Herring Mackerel Pilchard Plaice Sardine Sole	SOP: ClinImm/I0P/002	A





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HUMAN BODY FLUIDS (cont'd)  Blood	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)  Detection and quantification of specific IgE to the following allergens (cont'd) Haddock Anchovy Eel Carp Cyp c 1 Crab Shrimp Shrimp rPen a1 Lobster Crayfish Langoustine Clam Mussel Oyster Scallop Octopus Squid Abalone Snail Cow's Milk Cow's Milk nBos d4 Cow's Milk nBos d5 Cow's Milk nBos d8 Goats Milk Cheddar Cheese Blue Cheese Feta Cheese Mushroom Bakers Yeast Honey Egg Yolk Egg White Egg nGal d1 Egg nGal d2 Egg nGal d3 Vanilla Coffee Tea Fennel Seed Corn Flour Millet Oat Flour	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	A



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)  Sesame Seed Linseed Pumpkin Seed Wheat Maize Wheat Gliadin Wheat rTri a 14 Wheat rTri a19 Barley Rape Seed/Oil Buckwheat Rye (Food) Rye Grass Poppy Seed Sunflower Seed Wheat Gluten Gelatin Bovine Suxamethonium Allergy Quaternary Ammonium Morphine Allergy Soy Bean Soy Bean nGly m4 Soy Bean nGly m5 Soy Bean nGly m6 Cocoa Bean Castor Bean Black Olive Pecan Nut Walnut Walnut rJug r3 Coconut Macadamia Nut Chestnut Lupine Seed Pea Bamboo Shoot	SOP: ClinImm/10P/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)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)  Chick Pea Lentil Almond Nut Pine Nut Brazil Nut Brazil Nut rBer e1 Hazel Nut Hazel Nut Cor A1 Hazel Nut Cor A9 Hazel Nut Cor A14 Hazel Nut Cor A8 Peanut Peanut rAra h 1 Peanut rAra h 2 Peanut rAra h 3 Peanut rAra h 8 Peanut rAra h 9 Peanut IgG4 Pistachio Nut Cashew Nut Peach Peach PRU P3 LTP Fig Pineapple Apple Apple rMal d 1 Apple rMal d 3 Pear Apricot Banana Cherry Peach rPRU P1 Peach rPRU p4 Date Grape Rice Artichoke	SOP: ClinImm/I0P/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)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)	SOP: ClinImm/I0P/002	A
	Avocado Grapefruit Rhubarb Kiwifruit Mango Melon Watermelon Plum Lemon Orange Strawberry Raspberry Blackberry Blueberry Lime Papaya Redcurrant Tomato Fennel Coriander Cabbage Broccoli Carrot Cauliflower Radish Garlic Green Pepper Chilli Pepper Onion Asparagus Beetroot Brussel Sprouts Celery Celery rApi g 1.01 Cucumber Lettuce		



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)  Marrow Pumpkin Spinach Mint Potato Sweet Potato Paprika Cinnamon Rosemary Bayleaf Aniseed Basil Oregano Marjoram Mustard Saffron Cardamon Clove Nutmeg Black Pepper Parsley Tarragon Thyme Ginger Curry Fenugreek Aubergine Sage Quinine Sulphate (Allergy) Paracetamol (Allergy) Hops (Allergy) MSG Allergy Birch Tree (Silver) Birch rBet v 1 PR-10 Birch rBet v 2 Profillin Birch rBet v 4 Ca binding Prot	SOP: ClinImm/I0P/002	A



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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)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)  Birch rBet v 6 Grey Alder Tree Hazel Tree London Plane Box Elder Oak Tree Walnut Tree Cedar Tree, Japanese Cedar Tree Beech Tree Olive Tree Olive rOle e 1 Horse Chestnut Tree Willow Tree Eucalyptus Tree Pine Tree Mesquite Ash Tree Cypress Tree Elm Tree Bermuda Grass Sweet Vernal Grass Velvet Grass Cultivated Rye Rye Grass Timothy Grass Timothy Grass rPhl p1 Timothy Grass rPhl p2 Timothy Grass rPhl p4 Timothy Grass rPhl p5b Timothy Grass rPhl p6 Timothy Grass rPhl p7 Timothy Grass rPhl p11 Timothy Grass rPhl p12 Cocksfoot Meadow fescue	SOP: ClinImm/I0P/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)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)	SOP: ClinImm/I0P/002	A
	Meadow grass (Kentucky blue) Ragweed, Common Ragweed, Western Ragweed, Giant Ragweed, False Mugwort Plantain, English Goosefoot/LQuarters Goldenrod Nettle Wall Pellitory (P.officinalis) Wall Pellitory (P.judaica) Wall Pellitory rPar j2 Rape pollen Rose Lavender Lilac Lily Penicillium notatum Cladosporium Pityrosporum (malassezzia sp) Aspergillus fumigatus Aspergillus fumigatus rAsp f1 Aspergillus fumigatus rAsp f2 Aspergillus fumigatus rAsp f3 Aspergillus fumigatus rAsp f4 Aspergillus fumigatus rAsp f6 Candida (allergy testing) Mugwort nArt V3 Alternaria alternate Alternaria rAlt a1 Helminthosporium Cat Dander-epithelium Cat rFel d 1		



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Human Body Fluids (cont'd)	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u>  Detection and quantification of specific IgE to the following allergens (cont'd)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Cat rFel d 2 Dog Dander Dog rCan f 1 Dog rCan f 2 Dog rCan f 3 Dog rCan f 5 Horse Dander Horse Equ c3 Horse Equ c1 Horse Serum Proteins Cow Dander Cow d 6 BSA Sheep Epithelium Guinea Pig Epithelium Hamster Epithelium Rat Epithelium/Protein Gerbil Epithelium Mouse Epithelium/Protein Mouse Epithelium Mouse Urine Proteins Rabbit Epithelium Budgerigar droppings Budgerigar feathers Canary feathers Pigeon feathers Pigeon droppings Chicken Feathers Duck Feathers Goose Feathers Parakeet droppings Parakeet feathers Parrot feathers Swine Swine Sus PSA D.pteronyssinus D.pteronyssinus nDer p1	SOP: ClinImm/I0P/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)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)  D.pteronyssinus nDer p2 D.pteronyssinus nDer p10 D.ferinae D.microceras Tyrophagus putrescentiae Euroglyphus maynei Blomia Tropicalis Honeybee venom (IgG) Honey Bee venom IgE Honey Bee Venom rApi m1 Common Wasp Common Wasp rVes v1 Common Wasp rVes v5 Paper Wasp Paper Wasp rPol d5 Vespular Wasp White Faced Hornet Yellow Faced Hornet Mosquito Cockroach (B.germanica) Cockroach, American Moth Anisakis Fire Ant Horsefly Latex Allergy Latex rHev b1 Latex rHev b3 Latex rHev b5 Latex rHev b6.01 Latex rHev b6.02 Latex rHev b8 Latex rHev b9 Latex rHev b11 Sulphonamides IgE Amoxicilloyl	SOP: ClinImm/I0P/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)	Documented procedures & manufacturer's instructions for Phadia Immunocap 250 analyser fluorescence solid phase immunoassay (cont'd)	
Blood	Detection and quantification of specific IgE to the following allergens (cont'd)  Ampicilloyl Cefaclor Penicilloyl G Penicilloyl V Codeine (Allergy) Ibuprofen (Allergy) Aspirin (Allergy) Caseine IgG Rifampicin Allergy Lactoglobulin IgE (allergy) Metronidazole Allergy Atracurium Besylate Allergy Hollister-Stier (House dust) Cow's Milk (IgG4)	SOP: ClinImm/I0P/002	A
Blood	MPO PR3 GBM Intinsic Factor TTG IgG	Phadia 250 - fluorescent enzyme immunoassay (FEIA) SOP Ref: ClinImm/002	A
Blood	ENA screen dsDNA Antibodies TTG IgA DGP IgA DGP IgG	BIO-FLASH – chemiluminescence (CLIA) SOP Ref: ClinImm/028	A
	ANA Tissue Autoantibodies Anti-dsDNA antibodies by Crithidia ANCA Anti-Endomysial IgA antibodies Anti-Endomysial IgG antibodies	QUANTA-Lyser 3000 – Indirect Immunofluorescence (IFA) SOP Ref: ClinImm/004	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 with specific reference to:	
Formalin fixed paraffin-embedded tissue & cell blocks, alcohol fixed or air dried cytology smears.	DNA analysis for the detection of variant sequences associated with diagnostic, prognostic or therapeutic implications	DNA extraction using Qiagen Extraction commercial kit DNA extraction and SOP's: SCMD/006 SCMD/IOP/002	A
Formalin fixed paraffin-embedded tissue or DNA	Somatic mutation detection in the following genes for the purposes of treatment stratification: BRAF KRAS NRAS-BRAF EGFR	Real-time PCR amplification of DNA using: Biocartis CE-IVD assay on Idylla Platform Real-time PCR amplification of DNA using SOP's: SCMD/IOP/003 SCMD/017/18/13	A
Formalin fixed paraffin-embedded tissue or DNA	Microsatellite Instability (MSI) testing for Lynch Syndrome Pre-screen and Checkpoint Inhibitor Immunotherapy Sensitivity. Screens 7 monomorphic homopolymer regions for instability.	Real-time PCR amplification of DNA using: Biocartis CE-IVD assay on Idylla Platform Real-time PCR amplification of DNA using SOP's: SCMD/IOP/003 SCMD/028	A
DNA	Detection of sequence variants for the purposes of clinical diagnosis, prognosis and treatment stratification  Somatic Multi-Gene Panel 1 (MGP-1) Targeted gene sequencing of selected regions in the following genes: AKT1, ALK, BRAF, CTNNB1, DDR2, EGFR, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, KRAS, MAP2K1, MET, NOTCH1, NRAS, PIK3CA, PTEN, SMAD4, STK11, TP53	Next-generation sequencing using Life Technologies Oncomine Solid Tumour panel on Ion Torrent PGM NGS Sequencer. Analysis by hybrid commercial/in-house bioinformatics pipeline and SOP's: SCMD/019 SCMD/020 SCMD/021 SCMD/IOP/002 SCMD/015	A



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HUMAN BODY TISSUE AND FLUIDS con'td	<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	Somatic NGS gene panel-4 (SNVs & CNGs)	Thermo Ion Torrent PGM and/or S5 Prime with associated hardware suites, SNV calling via comparison to reference sequence, CNG calling via statistical analysis of data distribution. SOP: SCMD/027, SCMD/030	A
RNA from FFPE	Somatic NGS gene panel-4 (Gene Fusions)	Thermo Ion Torrent PGM and/or S5 Prime with associated hardware suites, fusion calling via comparison of RT-PCR product sequences to reference fusion transcript library. SOP: SCMD/027, SCMD/030	A
DNA	Somatic Multi-Gene Panel 2 (MGP-2) Targeted gene sequencing of selected regions in the following genes:  ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, EZH3, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, JAK2, JAK3, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53, VHL	Life Technologies Cancer Hotspot v.2 panel on Ion Torrent PGM NGS Sequencer. Analysis by hybrid commercial/in-house bioinformatics pipeline.  SOP: SCMD/019 SCMD/020 SCMD/021 SCMD/IOP/002 SCMD/015	A



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HUMAN BODY TISSUE AND FLUIDS con'td	<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:	A
DNA	Somatic Multi-Gene Panel 3 (MGP-3) Targeted gene sequencing of selected regions in the following genes:  AKT1, ALK, AR, BRAF, CDK4, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, PDGFRA, PIK3CA, RAF1, RET, ROS1, SMO	DNA component of Life Technologies Oncomine Focus Cancer panel on Ion Torrent PGM NGS Sequencer. Analysis by hybrid commercial/in-house bioinformatics pipeline.  SOP: SCMD/019 SCMD/020 SCMD/021 SCMD/IOP/002 SCMD/015	
DNA	Targeted somatic mutation detection at codon 600 of the BRAF gene for the purpose of clinical diagnosis, prognosis and treatment stratification	Qiagen Therascreen CE-IVD assay on Rotor Gene-Q Platform Real-time PCR amplification of DNA  SOP: 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	
Blood	EGFR targeted mutation detection	Roche Cobas EGFR v2 CE-IVD assay on Lightcycler z480 platform. Real-time PCR amplification of DNA  SOP: SCMD/014	



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HUMAN BODY FLUIDS AND TISSUES	<u>Miscellaneous examination activities for the purposes of clinical diagnosis</u>		
Faeces	Occult blood	Qualitative immunochemical testing using Immunochromatography cards and in-house procedure: Bact/057	A
HUMAN BODY FLUIDS AND TISSUES cont'd	<u>Gynaecological Cytopathology</u>		
Cervical cells	Preparation and screening to identify or exclude cytological abnormalities for the purpose of diagnosis	<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
	Detection and Genotyping of Human papilloma virus (HPV) & STDs Chlamydia Tracomatis and Neisseria Gonorrhrea	GeneXpert XVI and SOP CYTO-015	



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<p>HUMAN BODY FLUIDS AND TISSUES cont'd</p> <p>Slides prepared in house from samples listed above</p>	<p><u>Gynaecological Cytopathology Cont'd</u></p> <p>Morphological assessment and interpretation/diagnosis</p>	<p><u>Microscopy (qualitative analysis)</u>            In-house procedures:            Cyto/001 - Procedure for Cytology Gynae Sample Preparation            CYTO/010 - Cytology Gynae hrHPV Primary Screening &amp; 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</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS AND TISSUES cont'd</p> <p>Cerebrospinal fluid (CSF)            Fine Needle Aspirate samples (FNA)            General body fluids            Bronchial Brushings, washings and sputum            Urine</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><u>Diagnostic Cytopathology</u></p> <p>Examination to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Examination to identify or exclude cytological abnormalities for the purpose of diagnosis</p>	<p>Preparation/centrifugation            In-house procedures:            Cyto/002 – Procedure for Non-Gynae Specimens Preparation            Cyto/003 – Procedure for Attending the Clinics            In conjunction with manufacturer's instructions using:            Thermo CL10 centrifuge            Thermo Shandon cytocentrifuge Cytospin 4            Thermo Fischer ST16 Sorvall centrifuge            Sorvall ST40 centrifuge (Cat 3 work)            ThinPrep 5000 Processor with autoloader            ThinPrep 2000 Processor            Extractor hood Class 1 MSC (Cat 3 work)            Extracor hood Class CAS            Biomat 1</p> <p><u>Staining</u>            Papanicolaou staining            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            Romanovsky staining            Manual method using in-house procedures:            Cyto/002 – Procedure for Non-Gynae Specimens Preparation            Cyto/003 – Procedure for Attending the Clinics.            Microscopy (qualitative analysis)</p>	<p>A</p>





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<p>HUMAN BODY FLUIDS AND TISSUES cont'd</p> <p>Slides prepared in house from samples listed above</p>	<p><u>Diagnostic Cytopathology cont'd</u></p> <p>Morphological assessment and interpretation/diagnosis</p>	<p><u>Microscopy using SOP's</u>            Cyto/020 Pathologist Reporting in Cytology and microscopes as follows:            Olympus BX46            Olympus BX43            Olympus BX53</p>	<p>A</p>





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Fixed, Fresh and frozen tissue	Assessment of Basophilic and eosinophilic tissue structures	<p>HIST/028 – Histology Procedure for Microtomy Using the: Leica RM2235 microtomes</p> <p>Routine Haematoxylin &amp; Eosin (H&amp;E) staining and coverslipping</p> <p>Automated method using: HIST/054 – Histology procedure for the Use of the Leica ST5020 Stainer HIST/058 – Procedure for Using the Dako Coverstainer Using the: Dako Coverstainer Leica ST5020 Multistainer</p> <p>Rapid Frozen Section Cryotomy and manual H&amp;E staining method using: 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)</p> <p>Using the: Leica CM1950 Cryostat</p>	A
FFPE sections on glass slides	<p>Histochemistry analysis for detection of:</p> <p>Acid and sulphated mucins Amyloid Elastic fibres and collagen Gram positive and Gram negative organisms Fungi Collagen and fibrosis Elastic tissue and Hepatitis B surface antigen inclusion bodies Liberated aldehydes Haemosiderin Reticulin fibres</p>	<p>Leica ST4020 Small Linear stainer Alcian Blue – Acid and sulphated mucins Congo Red – Amyloid Miller's Elastic Van Gieson (EVG) – elastic fibres and collagen Gram – Gram positive and Gram negative organisms Grocott – Fungi Haematoxylin Van Gieson (HVG) – collagen and fibrosis</p>	A



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Slides prepared in house as above	Acid fast bacilli (e.g. M.tuberculosis)  Morphological assessment and interpretation/diagnosis	Orcein – Elastic tissue and Hepatitis B surface antigen inclusion bodies Periodic Acid Schiff (+/- diastase) – Liberated aldehydes Perl's Prussian Blue – Haemosiderin Reticulin – Reticulin fibres Ziehl-Neelson – Acid fast bacilli, e.g. M.tuberculosis  Microscopy (qualitative analysis) In-house procedures: HIST/049 – Pathologist Reporting in Histology  Using microscopes as follows: Olympus BX51 Olympus BX53	
END			