

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9403

Accredited to
ISO 15189:2022

Royal United Hospitals Bath NHS Foundation Trust

Issue No: 021 Issue date: 31 October 2025

Department of Pathology
Combe Park
Bath
BA1 3NG

Contact: Wayne Vietri
Tel: +44 (0)1225 821770
Fax: +44 (0)1225 826272
E-Mail: wayne.vietri@nhs.net
Website: <http://www.ruh.nhs.uk>

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity
Address Department of Blood Sciences Royal United Hospitals NHS Foundation Trust Combe Park Bath BA1 3NG Local contact Wayne Vietri Tel: +44 (0) 1225 821770	Routine Haematology Routine Biochemistry Blood Transfusion Coagulation Immunology Microbiology
Address Department of Histopathology Royal United Hospitals NHS Foundation Trust Combe Park Bath BA1 3NG Local contact Wayne Vietri Tel: +44 (0) 1225 821770	Routine Histopathology Special Stains Immunohistochemistry Diagnostic non-gynae cytology Interpretation and reporting Intra-operative frozen sections Mortuary services (body receipt, storage and release)

Site activities performed away from the locations listed above:

Location details	Activity
Royal United Hospitals, address as above: A&E Theatres William Budd (Haem/Oncology) Princess Anne Wing (Maternity)	Blood storage only Fridge managed by laboratory
Royal United Hospitals NHS Foundation Trust Combe Park Bath BA1 3NG	Archives Storage of records only



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented inhouse procedures with manufacturer's instructions
Sweat	Sweat Conductivity	3120 Sweat-Chek Analyser using electrical conductivity QMS/SOP/CH/MAN/61
CSF	Xanthochromia	Perkin-Elmer Lambda 25 uv spectrophotometer using spectrophotometry and WinLab Software QMS/SOP/CH/MAN/43
Urine	Bence Jones Protein confirmation and typing	Immunofixation using Sebia Hydrasys 2 using agarose gel electrophoresis and visual interpretation QMS/SOP/CH/MAN/16
Plasma, Serum, Urine	Osmolality Osmolar Gap	OsmoPRO Multisample Micro-osmometer, Freezing point depression, SOP/CH/MAN/37
Sweat	Sweat Chloride	ELITech Chloride meter, SOP/CH/MAN/87
Faeces	Calprotectin	Beckman Coulter AU5800 SOP/CH/BCK/7



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented inhouse procedures with manufacturer's instructions
Serum, Plasma, Urine	Sodium Potassium Chloride	Ion Selective Electrode
Serum, Plasma	ALP	Kinetic colour
Serum, Plasma	ALT	Kinetic UV
Serum, Plasma	Albumin (BCP Sentinel)	Colourmetric
Serum, Plasma, Urine,	AMY	Enzymatic colour
Serum, Plasma	AST	Kinetic UV
Serum, Plasma	Bilirubin (Total)	Photometric colour
Serum, Plasma, Urine	Calcium	Photometric
Serum, Plasma	Cholesterol	Enzymatic colour
Serum, Plasma	CPK	Kinetic UV
Serum, Plasma	GGT	Enzymatic colour
Serum, Plasma, Urine, CSF	Glucose	Enzymatic UV
Serum, Plasma	HDL Cholesterol	Enzymatic colour
Plasma, CSF	Lactate	Enzymatic colour
Serum, Plasma	Lipase	Enzymatic colour
Serum, Plasma, Urine	Magnesium	Photometric colour
Serum, Plasma	Acetaminophen (Paracetamol)	Enzyme Immunoassay
Serum, Plasma, Urine	Phosphate	Photometric UV
Serum, Plasma	Salicylate (Siemens)	Enzyme Immunoassay
Serum, Plasma	Serum Indices	Photometric
Serum, Plasma	Total Protein	Photometric colour
Serum, Plasma	Triglyceride	Enzymatic colour
Serum, Plasma, Urine	Urea	Kinetic UV
Serum, Plasma, Urine	Creatinine	Enzymatic colour
Serum, Plasma, Urine	Uric Acid	Enzymatic colour
Serum, Plasma	ACE (Sentinel)	Photometric
Serum, Plasma	Bicarbonate	Enzyme
Serum, Plasma	Bilirubin (direct)	Wako Vanadate Oxidation method
Serum, Plasma	Fructosamine (Sentinel)	Photometric
Serum, Plasma	Iron	Photometric colour
Serum, Plasma	LDH (IFCC)	Kinetic UV
Serum, Plasma	Bile Acid (Sentinel)	Enzyme cycling colour
Serum	Lithium (Thermo Infinity)	Spectrophotometric
EDTA Plasma	Ammonia (Thermo Infinity)	Direct enzyme
Urine	Urine Albumin	Turbimetric
CSF, Urine	UP (Total Protein)	Turbimetric
Serum, Plasma	Alpha-1-Antitrypsin	Immunoturbidometric Photometry
Serum, Plasma	Complement (C3)	Immuno-turbimetric
Serum, Plasma	Complement (C4)	Immuno-turbimetric
Serum, Plasma	CRP	Immuno-turbimetric



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented inhouse procedures with manufacturer's instructions
Serum, Plasma	Haptoglobin	Immuno-turbimetric
Serum, Plasma	Immunoglobulin A	Immuno-turbimetric
Serum, Plasma	Immunoglobulin G	Immuno-turbimetric
Serum, Plasma	Immunoglobulin M	Immuno-turbimetric
Serum, Plasma	Immunoglobulin E	Immuno-turbimetric
Serum, Plasma	Transferrin (Siemens)	Immuno-turbimetric
Serum, Plasma	Carbamazepine	Enzyme Immunoassay
Serum, Plasma	Digoxin (Siemens)	Immuno inhibition
Serum, Plasma	Phenobarbitone (Siemens)	Enzyme Immunoassay
Serum, Plasma	Phenytoin (Siemens)	Enzyme Immunoassay
Serum, Plasma	Theophylline (Siemens)	Enzyme Immunoassay
Serum, Plasma	Gentamicin (Siemens)	Enzyme Immunoassay
Serum, Plasma	Vancomycin (Siemens)	Enzyme Immunoassay
		Beckman Coulter Unicel DxI 800 SOP/CH/BCK/2
Serum, Plasma	AFP	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	CA125	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	CA 15.3	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	CA 19.9	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	CEA	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	Cortisol	Competitive binding immunoenzymatic immunoassay
Serum, Plasma	Ferritin	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	Folate	Competitive binding receptor assay
Serum, Plasma	Free T3	Competitive binding immunoenzymatic immunoassay
Serum, Plasma	Free T4	Two step enzymatic immunoassay
Serum, Plasma	FSH	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	HCG	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	LH	Two site immunoenzymatic (sandwich) immunoassay



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Serum, Plasma EDTA Plasma	Estradiol sensitive Parathyroid Hormone	Competitive binding receptor assay Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma Serum, Plasma	PCT Progesterone	Chemiluminescent immunoassay Competitive binding immunoenzymatic immunoassay
Serum, Plasma Serum	Prolactin PSA	One step enzymatic immunoassay Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	SHBG	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	Testosterone	Competitive binding immunoenzymatic immunoassay
Serum, Plasma	Troponin I	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	TSH	Two site immunoenzymatic (sandwich) immunoassay
Serum, Plasma	Vitamin B12	Competitive binding immunoenzymatic immunoassay
Serum, Plasma	Vitamin D (Total)	Two step competitive binding immunoenzymatic immunoassay
		Radiometer ABL90 flex plus SOP/POCT/62
Whole blood Whole blood, Serum, Plasma Whole blood Whole blood Whole blood, Serum, Plasma Whole blood, Serum, Plasma Whole blood, Serum, Plasma	Bilirubin Ionised calcium pCO ₂ pH Sodium Potassium Bicarbonate (calculated)	Spectrophotometry Potentiometry Potentiometry Potentiometry Potentiometry Potentiometry Potentiometry $cHCO_3-(P) = 0.23 \times pCO_2 \times 10^{(pH-pKp)}$ where $pKp = 6.095$ $cH+(T) = 10^{(9-pH(T))}$
Whole blood Whole blood, Serum, Plasma Whole blood Whole blood Whole blood, Serum, Plasma	H ⁺ Chloride Glucose (calculated) Lactate (calculated) Standard Base excess (calculated)	Potentiometry Amperometry Amperometry $cBase(B) = (1 - 0.014ctHb)(cHCO_3-(P) - 24.8 + (1.43 ctHb + 7.7)(pH - 7.4))$



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented inhouse procedures with manufacturer's instructions
Whole blood	Total Haemoglobin	Spectrophotometry
Whole blood	sO ₂	Spectrophotometry
Whole blood	FO ₂ Hb	Spectrophotometry
Whole blood	FCOHb	Spectrophotometry
Whole blood	FHHB	Spectrophotometry
Whole blood	FmethHb	Spectrophotometry
Whole blood	FHbF	Spectrophotometry
Whole blood	pO ₂	Optical
Urine, serum	Paraprotein bands identification and classification	
Serum	Paraprotein bands identification and classification	Sebia Capillarys 3 flex using immunosubtraction and Phoresis software QMS/SOP/CH/MAN/62
Serum	Serum Protein Electrophoresis: Monoclonal protein band identification and quantitation	Sebia Capillarys3 flex using capillary zone electrophoresis and Phoresis Software (endo-osmotic flow) QMS/SOP/CH/MAN/62



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented inhouse procedures with manufacturer's instructions
Serum, plasma	Automation Calculated Tests	Calculated
Serum, plasma	Adjusted calcium	
Serum, plasma	AKI	
Serum, plasma	Cholesterol HDL ratio	
Serum, plasma	eGFR	
Serum, plasma	Globulin	
Serum, plasma	Iron saturation	
Serum, plasma	LDL Cholesterol	
Serum, plasma	Macroprolactin	
Serum, plasma	PSA (log)	
Serum, plasma	Non-HDL Cholesterol	
Serum, plasma	TIBC	
	Manual Laboratory Calculated Tests:	
Urine	Albumin creatinine ratio	
Urine	Albumin excretion	
Urine	Amylase creatinine ratio	
Whole blood, serum, plasma	Base excess	
Urine	BJP excretion	
Urine	Calcium creatinine ratio	
Urine	Calcium excretion	
Serum, plasma, urine	Calcium excretion index	
Urine	Creatinine clearance	
Urine	Creatinine excretion	
Whole blood, serum, plasma	ctCO ₂ (P)	
Urine	Magnesium excretion	
Serum, plasma	Osmolality (calc)	
Urine	Phosphate excretion	
Urine	Potassium excretion	
Urine	Protein excretion	
Urine	Protein creatinine ratio	
Urine	Sodium excretion	
Serum, plasma, urine	TMP/GFR	
Urine	Urate excretion	
Urine	Urea excretion	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examination activities for the purposes of clinical diagnosis</u>	Documented inhouse procedures with manufacturer's instructions
Blood - serum	anti-nuclear antibody screen and titre (IgG) HEp-2 autoimmune profile (AIP) – ANA, AMA, ASMA, AGPC, LKM-1 (IgG) anti-dsDNA (crithidia luciliae) (IgG) pemphigus/pemphigoid antibody screen and titre (IgG and IgA) endomysial antibodies (IgA and IgG) anti-neutrophil cytoplasmic antibodies (ANCA) (IgG)	Inova Diagnostics Quantalyser 240 using indirect immunofluorescence and Fluorescent Microscope SOP/IMM/GEN/5 SOP/IMM/GEN/29 SOP/IMM/GEN/103 SOP/IMM/GEN/6 SOP/IMM/GEN/3 SOP/IMM/GEN/8
Blood - serum	anti-dsDNA IgG anti-extractable nuclear antigen (ENA) screen IgG (anti-Ro, La, U1-RNP, Sm, Scl-70, Jo-1) anti-tissue transglutaminase (tTG) IgA ANCA anti-myeloperoxidase (MPO) IgG ANCA anti-proteinase-3 (PR3) IgG anti-thyroid peroxidase (TPO) IgG anti-cardiolipin (ACL) IgG and IgM	DYNEX DS2 using enzyme linked immunosorbent assay SOP/IMM/GEN/31



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HUMAN BODY FLUIDS (cont'd) Blood - serum	<u>Immunological examination activities for the purposes of clinical diagnosis (cont'd)</u> scleroderma (nucleolar) associated antibody profile Ig G(anti-Scl-70, CENP-A, CENP-B, fibrillarin (U3-RNP), RNAP III, NOR-90, Th/To, PM-Scl, Ku, PDGFR, Ro-52) anti-glomerular basement membrane (GBM), anti-myeloperoxidase (MPO) anti-proteinase-3 (PR3) anti-M2 anti-LKM-1 anti-LC-1 anti-nuclear antibody profile IgG (anti-nRNP/Sm, Sm, RNP70, RNPA, RNPC, SS-A(Ro-60), Ro-52, SS-B(La), Scl-70, PM-Scl, Jo-1, CENP-B, PCNA, dsDNA, nucleosomes, histones, ribosomal-P, AMA-M2) myositis associated antibody profile IgG (anti- Mi-2a and b, TIF1g, MDA5, NXP2, SAE, Ku, PM-Scl 75 and 100, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52) anti-cN-1a	Documented inhouse procedures with manufacturer's instructions Automated immunoblotting using Euroblot One SOP/IMM/GEN/129



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis.</u> <u>Automated - General Haematology</u>	Documented inhouse procedures with manufacturer's instructions
Whole blood – EDTA	Plasma Viscosity	Benson BV using Capillary technique SOP/HA/VI/4
Whole blood – EDTA	Detection of heterophile antibodies specific to Infectious Mononucleosis (IM)	MONOLATEX using a latex immunodiagnostic technique: manual SOP/HA/ML/3
Whole blood – EDTA	Detection and identification of: <i>P. falciparum</i> <i>P. Ovale</i> <i>P. Vivax</i> <i>P. Malariae</i>	Manual staining technique of Thick and Thin films (using MGG, Giemsa and Fields stain) with examination by light microscopy SOP/HA/CY/5
Bone marrow aspirate	Detection of abnormalities	Manual staining technique (using MGG stain) with examination by light microscopy SOP/HA/SP/15
Bone marrow aspirate	Detection of abnormalities	Manual staining technique (using Clin Tech Perls Prussian Blue) with examination by light microscopy SOP/HA/CY/4
Cerebral Spinal Fluid (CSF)	White blood cells	Shandon Cytospin III with staining on Sysmex SP10 (using MGG) and examination by light microscopy: semi-automated SOP/IMM/GEN/13
Urine	Haemosiderin	Manual staining technique (using Iron Stain with examination by light microscopy SOP/HA/CY/13
Whole blood – EDTA	Sickle cell Solubility screen	Clin Tech turbidometric technique: manual SOP/HA/SP/11

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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis.</u> <u>Automated - General Haematology</u> (cont'd)	Documented inhouse procedures with manufacturer's instructions
Whole blood – EDTA	G6PD Screen	Trinity Biotech – Spectrophotometry: semi – automated SOP/HA/SP/2
Whole blood	Full Blood Count, including: Haemoglobin (Hb) Red Blood Cell count (RBC) Mean Corpuscular Haemoglobin (MCH) Mean Corpuscular Haemoglobin Concentration (MCHC) Mean Cell Volume (MCV) RBC Distribution Width (RDW) Haematocrit (HCT) Platelet count (PLT) Mean Platelet Volume (MPV) White Blood Cell count (WBC) and differential, including Basophil # Basophil % Eosinophil # Eosinophil % Lymphocyte # Lymphocyte % Monocyte # Monocyte % Nucleated RBC (NRBC) # Nucleated RBC (NRBC) % Neutrophil # Neutrophil % Reticulocytes count # Reticulocyte count %	Beckman Counter DxH 900 SOP/HA/ML/74 Photometric Measurement Coulter Principle Calculated Calculated Derived from RBC Histogram Derived from RBC Histogram Calculated Coulter Principle Derived from PLT Histogram Coulter Principle Calculated VCS 360 Technology Calculated VCS 360 Technology Calculated VCS 360 Technology Calculated VCS 360 Technology Calculated VCS 360 Technology Calculated VCS 360 Technology Calculated Calculated Documented in-house methods to meet the requirements of the Sick cell and Thalassemia screening programme, as defined in the laboratory QA evidence requirements.



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HUMAN BODY SAMPLES	<u>Molecular Haematological examination activities for the purposes of clinical diagnosis</u>	Documented inhouse procedures with manufacturer's instructions
DNA	FV Leiden and Prothrombin (FII) mutation detection	DNA extraction, amplification and detection using real-time PCR on Cepheid Genexpert GX16 with Xpert Factor II and Factor V Assay Kits SOP/DNA/41
Plasma	Coagulation	Werfen ACL TOP 750, Turbidometry, PT & INR – SOP/HA/CO/36 aPTT – SOP/HA/CO/38 Clauss Fibrinogen – SOP/HA/CO/39
	PT INR aPTT Claus Fibrinogen D-dimer	Werfen ACL TOP 750, Immunoturbidimetry, SOP/HA/CO/40



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis.</u>	Documented inhouse procedures with manufacturer's instructions
Whole blood – EDTA (packed red cells & plasma)	Blood Group by detection and identification of antigens: RhD positive A RhD positive B RhD positive O RhD positive AB RhD positive RhD negative A RhD negative B RhD negative AB RhD negative O Rh D negative	Automated using Immucor Neo Iris analyser using Liquid Phase microplate SOP/BB/AUT/16 And Automated using Immucor Echo analyser using Liquid Phase microplate SOP/BB/AUT/14 And Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 and Manual tube spin agglutination using Medion Immuncent III centrifuge: SOP/BB/XM/18
Whole blood – EDTA (packed red cells & plasma)	Antibody Screen by detection of antibodies to: Rh 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 Kidd blood group antibodies: Anti-Jka, anti-Jkb Duffy blood group antibodies: Anti-Fya, anti-Fyb Lutheran blood group antibodies: Anti-Lua, 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-P1	Automated using Immucor Echo analyser using Solid Phase Red Cell Adherence Indirect Antiglobulin Test (IAT) SOP/BB/AUT/14 and Automated using Immucor Neo Iris analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 and Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And Manual Diamed Column gel IAT technology SOP/BB/MAN/3



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented inhouse procedures with manufacturer's instructions
Blood – EDTA (packed red cells)	Red cell phenotyping for Antigens of the following systems: Rh – C,D,E,c,e Kell – K Duffy – Fya, Fyb MNSs – M,N,S,s Lewis – Lea, Leb	Automated using Immucor Echo analyser using Liquid Phase microplate SOP/BB/AUT/14 And Automated using Immucor Neo Iris analyser using Liquid Phase microplate SOP/BB/AUT/16 And Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And Manual tube spin agglutination using Medion Immuncent III centrifuge: SOP/BB/XM/18 And Manual Diamed Column gel IAT technology SOP/BB/MAN/3
Blood – EDTA (plasma)	Antibody Identification: Rh – C,D,E,c,e,Cw Kell – K,k,Kpa Duffy – Fya, Fyb MNSs – M,N,S,s Kidd – Jka, Jkb Lutheran – Lua, Lub Lewis – Lea, Leb P –P1	Automated using Immucor Echo analyser using Solid Phase Red Cell Adherence Indirect Antiglobulin Test (IAT) SOP/BB/AUT/14 and Automated using Immucor Neo Iris analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 and Manual Diamed Column gel IAT technology SOP/BB/MAN/3



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented inhouse procedures with manufacturer's instructions
Blood – EDTA (packed red cells)	Direct Antiglobulin Technique (DAT)	Diamed Column gel IAT technology SOP/BB/MAN/14
Whole Blood – EDTA	Feto-Maternal Haemorrhage Estimation (FMH) – Kleihauer	Clin -Tech Shepard's Kit acid elution & Eosin counterstain with examination by Nikon Eclipse 50i microscope: Manual SOP/BB/MAN/4
Whole blood – EDTA (packed red cells & plasma)	Compatibility testing of patients plasma with donor cells	Cross matching using automated methods: Immucor Echo analyser using solid phase red cell adherence IAT SOP/BB/AUT/14 and Immucor Neo Iris analyser using solid phase red cell adherence IAT SOP/BB/AUT/16 and Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And manual methods: Manual Diamed Column gel IAT technology SOP/BB/MAN/3
Whole blood – EDTA (packed red cells & plasma)	Transfusion Reaction	Various manual and automated methods – described above (panel includes Cross-match, DAT, Automated Blood Group & Screen, Antibody identification). SOP/BB/MAN/8
	Reading and recording of all Manual Investigations using the Banjo-ID reader	Documented in – house procedures with manufacturer's instructions Banjo ID-reader – SOP/BB/MAN/18



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented inhouse methods and manufacturer's operating instructions to support clinical diagnosis
Throat swab and nasopharyngeal aspirate	Detection of SARS-CoV-2, Flu A & B and RSV	Real-time PCR using Cepheid GeneXpert, QMS/SOP/MIC/12
Faeces	Detection of <i>Clostridioides difficile</i>	Real-time PCR using Cepheid GeneXpert, QMS/SOP/MIC/3
Faeces and Vomit samples	Detection of Norovirus	Real-time PCR using Cepheid GeneXpert, QMS/SOP/MIC/4
Faeces	Microbiology examination activities for the purpose of clinical diagnosis Detection of <i>Clostridioides difficile</i> toxin A & B	Manual EIA using Meridian Immunocard, QMS/SOP/MIC/5
HUMAN BODY TISSUE	<u>Histological examination activities for the purposes of clinical diagnosis</u>	Inhouse documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections	Special stains to detect the following: Acid mucins Acid mucins, alkaline mucins Amyloid Elastic Fibres Granular inclusions	Manual: H&E staining – HI-78 Frozen section staining (Manual H&E) - HI-11 Manual special staining techniques using documented in house procedures for staining with: Alcian Blue Periodic Acid Schiff's Stain – HI-48 Alcian Blue Periodic Acid Schiff's Stain with Diastase – HI-49 Congo Red – HI-63 Elastin van Gieson – HI-70 Giemsa – HI-74



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Inhouse documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Special stains to detect the following: (cont'd)	Manual special staining techniques using documented in house procedures for staining with:
	Helicobacter Pylori	Giemsa method for Helicobacter – HI-75
	Demonstration of fungi	Grocott's Modification of Gomori's Methenamine Silver - SOP-HI-77
	Gram positive and gram negative bacteria	Hucker Conn/Twort – HI 82
	Connective Tissues	Martius Scarlet Blue – HI-90
	Melanin	Masson Fontana – HI-91
	Muscle and Collagen	Masson Trichrome – HI-92
	Basement Membranes	Methenamine silver for basement membranes – HI-94
FFPE and Frozen sections	Iron	Perls Prussian Blue – HI-102
	Glycogen/mucin	Periodic Acid Schiff – HI-103
	Reticulin Fibres	Reticulin stain – modified Gomori – HI-106
	Copper	Rhodanine – HI-107
	Metachromasia (mast cells, cartilage matrix, some connective tissue, mucopolysaccharides)	Toluidine Blue for Metachromasia – HI-108
	Copper associated protein	Rubeanic Acid – HI-110
	Calcium	Von Kossa – HI-112
	Hepatitis B	Shikata's Orcein – HI-114
	Amyloid	Siruis Red – HI-116



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Inhouse documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Special stains to detect the following: (cont'd)	Manual special staining techniques using documented in house procedures for staining with:
	Epithelial mucin	Southgates Mucicarmin – HI-118
	Tubercule bacilli	Ziehl Neelsen – HI-122
	Nuclei collagen and muscle	Van Gieson
	Helicobacter and Spirochaetes	Warthin and Starry – HI-126
	M.leprae and other mycobacteria	Wade Fite – HI-125
Histological sections prepared in house as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy (qualitative analysis) using in house procedures and in accordance with manufacturers' instructions for microscopes: Leica DM4000, Leica DMRBE and Olympus BX43 HI-168 Histology Quality Control HI-188 Reporting Results HI-193 Internal Referrals HI-320 Intradepartmental Consultation



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HUMAN BODY TISSUE (cont'd)	<u>Non-gynaecological cytology examination activities for the purposes of clinical diagnosis:</u>	Inhouse documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Cytological sections prepared in house from samples listed above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy (Qualitative analysis) Using in house procedures: CY-112 In conjunction with manufacturer's instructions for: Leica DMLB, Olympus BX45 and Nikon Eclipse Microscopes
Synovial fluid	Joint Fluid Analysis for Crystals	Centrifuged sample manually examined using polarising microscopy SOP/CY/6 (Joint Fluid Preparation) SOP/CY/163 (Reporting of Joint Fluids for Crystals)



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy</u> Detection of sperm Sperm concentration	Manual method using documented in-house procedure SOP CY-138 – Post-vasectomy Semen Analysis by large volume chambers manual microscopy
Semen	<u>Fertility testing</u> Volume Sperm morphology excluding TZI scoring Sperm concentration Sperm motility Sperm vitality	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure SOPs CY-60, 61, 94, 99 Volume/weight Stained slides (Papanicolau) microscopy (Bright field) Microscopy (Phase contrast) Microscopy (Phase contrast) Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)
END		