


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL 8628 Accredited to ISO 15189:2012	<b>Wye Valley NHS Trust</b>	
	Issue No: 007    Issue date: 20 October 2020	
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Testing performed at the above address only		

### Site activities performed away from the location listed above:

Location details	Activity
Blood Issue Fridge Nuffield Hospital Venns Lane Hereford HR1 1DF	Blood Issue Fridge No testing occurs on this site, blood storage 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	<u>Haematological examinations to assist in clinical diagnosis</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous Whole Blood: EDTA	Full Blood Count <ul style="list-style-type: none"> <li>• Haemoglobin estimation</li> <li>• Differential white cell count</li> <li>• Reticulocytes</li> <li>• Red Blood Cells</li> <li>• Platelet (Impedance)</li> <li>• Platelets (Optical)</li> <li>• Mean Cell Volume</li> <li>• Mean Cell Haemoglobin</li> <li>• Mean Cell Haemoglobin Concentration</li> <li>• Haematocrit</li> </ul> A measure of the viscosity of plasma (PV) Blood Film staining Blood Film reporting of normal and abnormal morphologies including White Blood Cell Differential (% and absolute count) Erythrocyte Sedimentation Rate (ESR)	Sysmex XN1000 Analysers SOP XN1000 SLS Haemoglobin detection method Flow cytometry method using semiconductor laser Hydrodynamic Focusing (DC method) HA/HA/SOP/040 Hydrodynamic Focusing (DC method) Flow cytometry method using semiconductor laser Calculated from RBC, HCT and HB RBC cumulative pulse height detection method Benson Viscometer capillary viscosity SOP PV SOP RAL RAL automated slide stainer Manual microscopy SOP BFEXAM Westergren Method SOP ESR



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations to assist in clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous Whole Blood: EDTA	Infectious mononucleosis screen	Latex agglutination Biokit Monogen kit SOP IM
	Identification and quantification of normal and abnormal Haemoglobins	Sebia Capillary flex 2 – capillary zone electrophoresis SOPs CAPELEC & FOQ
Citrated blood	Blood coagulation Studies	<b>Sysmex CS2500 Optical, turbidimetry–</b>
	Activated partial thromboplastin time.	DMMAPTT
	Prothrombin Time	DMPT
	INR	DMINR
	Fibrinogen	DMF
	Lupus anticoagulant	LA
	D-Dimer	DMFVIII
	FVIII	
	Inhibitor Screen	
	INR	KC4 coagulometer - mechanical end point detection)
	Activated partial thromboplastin time	
	Prothrombin Time	KC4INR
Venous Whole Blood: EDTA	Solubility test – presence of Haemoglobin S	Microgen Products S Test – solubility test based on decreased solubility of HbS SOL



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations to assist in clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous Whole Blood: EDTA	Detection of Malarial pLDH and HRP11 antigens  Detection of Malaria Parasites	Immunochromatographic assay using Core Malaria Pan/Pv/Pf Kit SOP MALP  Malaria Parasite staining and microscopy Thin Film – Giemsa pH7.2 stain. Thick Film Field's stain MALP
Bone Marrow	Detection of abnormal and normal Bone Marrow morphologies	Shandon staining machine-MGG- May Grunwald Giemsa stain, FE - Perls Prussian blue manual stain. BMEXAM – Manual microscopy Bone Marrow examination SOP BMEXAM.
Bone Marrow Trepines	Detection of abnormal and normal Bone Marrow morphologies	Leica ASP 300 Tissue Processor Embedded at Sakura Tek 5 embedding centre Leica RM2245 rotary microtome Haematoxylin & Eosin stain on the Sakura DRS2000 staining machine Immuno stains: Ventana Benchmark Ultra Manual microscopy Bone Marrow examination SOP BMEXAM



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous blood EDTA; Red cells</p> <p>Venous blood EDTA; plasma</p>	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Blood Grouping by antigen detection:</p> <p>A, B and O groups Rh D grouping</p> <p>Rh grouping system: C c E e K grouping system: K MN grouping system: MN Ss grouping system: Ss Duffy grouping system: Fya Fyb Kidd grouping system: Jka Jkb</p> <p>Detection and identification of the following Antibodies:</p> <p>ABO blood group antibodies: anti-A, anti-B</p> <p>Rh blood group antibodies: anti-Cw, anti-C, anti-c, anti-E, anti-e, anti-D</p> <p>Kell blood group antibodies: anti-K, anti-k, anti-Kpa</p> <p>MNSs blood group antibodies: anti-M, anti-N, anti-S, anti-s</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Processing samples for blood grouping and antibody screening on Ortho <b>Vision</b>– BTAGS Protocol for processing Antenatal samples SOP BTAN</p> <p>Or Manual blood grouping by Ortho SOP BTMBG Tube blood group SOP BTRTG</p> <p>Red Cell Phenotyping using Ortho Technology BTPHEN</p> <p>Processing samples for blood grouping and antibody screening on Ortho Vision– SOP BTAGS</p> <p>Or Manual blood grouping by Ortho SOP BTMBG Manual Antibody screening by Ortho SOP BTAS SOP Antibody Investigation by Ortho SOP BTABID</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous blood EDTA; plasma	Detection and identification of the following Antibodies:  Lewis blood group antibodies: Anti-Le(a), anti-Le(b)  P blood group antibodies: Anti-P1  Lutheran blood group antibodies: Anti-Lua	Processing samples for blood grouping and antibody screening on Ortho Vision– SOP BTAGS  Or Manual blood grouping by Ortho SOP BTMBG Manual Antibody screening by Ortho SOPBTAS Manual Antibody Investigation by Ortho SOP BTABID
Venous blood EDTA; plasma	Compatibility testing; - Compatibility testing of patients plasma with donor cells	Processing samples for crossmatching on the Ortho VisionSOP BTGXM  Or Manual crossmatching using Ortho Technology SOP BTMCM
Venous blood EDTA; whole blood	Direct Antiglobulin Test (Direct Coombs)	Direct anyiglobin test using Ortho Technology SOP BTDAT
Venous blood EDTA; red cells	Red cell phenotyping	Red Cell Phenotyping using Ortho Technology BTPHEN
Venous blood EDTA; whole blood	Kleihauer for foetal/maternal bleed estimation reported as ml foetal red cells in maternal circulation	Acid elution – Kleihauer – Betke method. BTKT



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Urine & CSF	Quantification of: Total Protein Albumin	Roche c501 Turbidimetric method SOP CMOD001 SOP CMOD003
Serum/Plasma	Caeruloplasmin Transferrin/Iron Binding Ca Immunoglobulins G Immunoglobulins A Immunoglobulins M A1 Antitrypsin Complement C3 Complement C4 Rheumatoid Factor CRP	Roche c501 Immunoturbidimetric method SOP CMOD005 SOP CMOD013 SOP CMOD014 SOP CMOD014 SOP CMOD014 SOP CMOD053 SOP CMOD054 SOP CMOD055 SOP CMOD057 SOP CMOD007
Serum, Plasma & CSF	Lactate  Glucose	Roche c501 analyser Lactate Oxidase method SOP CMOD004  Roche c501 analyser Hexokinase method SOP CMOD011
Serum, Plasma & Urine	Sodium Potassium	Roche c501 analyser ISE method SOP CMOD035 SOP CMOD035
Serum, Plasma & Urine	Urea Magnesium Inorganic Phosphate Uric Acid  Amylase Calcium Creatinine	Roche c501 Analyser SOP CMOD022 – Kinetic Urease SOP CMOD016 – Xylidyl Blue SOP CMOD018 - Molybdate SOP CMOD023 – Endpoint Uricase  SOP CMOD028 – G7 Substrate SOP CMOD030 – NM BAPTA SOP CMOD032 - Jaffe



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum and plasma</p>	<p><u>Biochemistry examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification of:</p> <p>Total Protein Albumin Bile Acids Cholesterol Direct (conjugated) Bilirubin</p> <p>Lactate Dehydrogenase</p> <p>Iron Gamma GT HDL Cholesterol (LDL Calculated) Paracetamol Total Bilirubin Triglycerides</p> <p>Alcohol</p> <p>Alkaline Phosphatase ALT AST Creatine Kinase Theophylline</p> <p>Salicylate</p> <p>Angiotensin Converting Enzyme</p> <p>Gentamicin Vancomycin Hydroxybutyrate</p> <p>Fructosamine</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Roche c501 Analyser</p> <p>SOPCMOD020 - Biuret SOP CMOD024 - BCG SOP CMOD002 – CLS Enzymatic SOP CMOD006 – Chol. Oxidase SOP CMOD008 – <b>Vanadate Oxidation</b></p> <p>SOP CMOD015 – DGKC Pyruvate to Lactate SOP CMOD009 – Ferrozine SOP CMOD010 – Carb SOP CMOD012 – Enzymatic SOP CMOD017 – Arylacylamidase SOP CMOD019 – Diazo SOP CMOD021 – Glycerol Phosphate Oxidase SOP CMOD025 – Alcohol Dehydrogenase SOP CMP026 – PNP SOP CMP027 – TRIS without PLP SOP CMP029 – TRIS without PLP SOP CMOD031 – NAC IFCC SOP CMOD033 – KIMS Immunoassay</p> <p>SOP CMOD046 - Salicylate Hydroxylase SOP CMOD049 – Buhlmann FAPGG Kinetic SOP CMOD050 – Cedia EIA SOP CMOD051 - EIA SOP CMOD052 – Biostat enzymatic endpoint SOP CMOD056 – Nitro Blue Tetrazolium oxynitroanilide</p>





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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Faeces	Detection of Faecal Occult Blood	Alpha Laboratories'Haemascreen' Kit- Guaiaconic acid method SOP CMAN014-Semi quantitative  HM-JACK analyser Immunoturbidimetric CMAN018 Faecal Immunochemical Testing
Venous Whole Blood: EDTA	Quantification of Blood Gases (pH, PCO <sub>2</sub> , PO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> , O <sub>2</sub> SAT, Base Excess, Na <sup>+</sup> , K <sup>+</sup> )  Quantification of: Carboxyhaemoglobin Methaemoglobin	Roche Cobas b221 Blood Gas Analyser SOP CEMERG009  SOP CEMERG009
Urine	Detection of 5HIAA (Screening Method)	Manual method – Nitrosonaphthol SOP CMAN011
Urine & faeces	Urinary and Faecal Reducing Substances (semi-quantitative)  Quantification of:	Manual Method – Benedicts Reagent SOP CMAN006
Serum, Plasma & Urine	Osmolality	Advanced Instruments/Vitech Osmometer 3300 – Freezing Point Depression SOP CEMERG002
Venous Whole Blood: EDTA/Fluoride	Glycosylated Haemoglobin	Sebia Capillarys flex 2 – capillary zone electrophoresis SOP CCZE001



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum & Plasma	Quantification of:  CEA hsTroponin T Thyroid Stimulating Hormone Free T4 Testosterone Free T3 Ferritin Vitamin B12 Folate BHCG Progesterone Digoxin Thyroid Peroxidase Antibodies AFP Cortisol Follicle Stimulating Hormone Oestradiol Luteinsing Hormone Ig E Prolactin Macroprolactin Prostate Specific Antigen CA125 Total 25 hydroxy Vitamin D	Roche e601 Analyser– Chemiluminescent Immunoassay SOP CME 003 SOP CME 004 SOP CME 005 SOP CME006 SOP CME007 SOP CME008 SOP CME009 SOP CME010 SOP CME011 SOP CME012 SOP CME014 SOP CME015 SOP CME016 SOP CME017 SOP CME018 SOP CELEC001 SOP CELEC002 SOP CELEC003 SOP CELEC007 SOP CELEC009 SOP CELEC012 SOP CME001 SOP CME002 SOP CME019
Serum	Plasma Protein Paraprotein Quantification Detection of Cryoglobins  Paraprotein Typing  Detection, quantification and typing of:	SOP CPP003 SOP CPP004 SOP CPP006  Sebia Hydrasys Immunofixation Electrophoresis SOP CPP001
Urine	Bence Jones Protein	Sebia Hydrasys - Gel electrophoresis SOP CPP002.



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Urine & Faeces	Detection of: Xylose Glucose Galactose Lactose Fructose Sucrose	Manual method – Thin Layer Chromatography SOP CMAN007
CSF	Quantification of: CSF Xanthochromia	Uvikon XS Spectrophotometer Direct spectroscopy SOP CMSP001
Venous Whole Blood: EDTA	Ammonia	ArkrayPocketChem Blood Ammonia Meter SOP CEMERG015
Serum / Plasma/ Urine/ Sweat	Chloride	Corning/Sherwood 925 Chloride Analyser – Coulometry SOP CEMERG001
Serum	Lithium	Corning/Sherwood 410 Flame Photometer – Flame Photometry SOP CFLAME003
Faeces	Faecal Calprotectin	Phadia ImmunoCap 250 Analyser using indirect enzyme reaction SOP CMAN016



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examinations for the purpose of clinical diagnosis</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum / Plasma	Detection of:  Tissue Autoantibodies (LKS) Endomysial Antibodies Antinuclear Antibodies Antineutrophil Cytoplasmic Antibodies (ANCA)	BioDiagnostics Slides, Beeline 220, Leica DM LB – immunofluorescence microscopy SOP CIMM002 SOP CIMM003 SOP CIMM004 SOP CIMM012
Serum / Plasma	Detection and Quantification of:  Double Stranded DNA Antibodies Anticardiolipin G Anticardiolipin M Glomerular Basement Membrane Antibodies PR3 MPO Tissue Transglutaminase Antibodies	Phadia ImmunoCap 250 Analyser – ELISA method SOP CIMM022  SOP CIMM019 SOP CIMM018 SOP CIMM018 SOP CIMM015  SOP CIMM020 SOP CIMM020  SOP CIMM011
Serum / Plasma	Extractable Nuclear Antibodies (ENA) Profile 6 tests SS-A/Ro SS-B/La Sm RNP Scl70 Jo-1	Launch Diagnostics / Orgentech ENA Combi ELISA Kit SOP CIMM009



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum / Plasma</p> <p>Serum / Plasma</p>	<p><u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification of Allergen Specific IgE:</p> <p>Egg White, Wheat, Milk, Cod, Peanut, Soya Bean, Hazelnut, Brazil Nut, Almond, Shrimp, Coconut, Cheese, Cashew, Walnut, Food Mix, Seafood Mix, Nut Mix, Cat, Horse, Dog, House Dust Mite, Tree, Mixed Tree, Grass, Aspergillus, Mixed Mould, Latex, Bee, Wasp</p> <p>Quantification of Cyclic Citrillunated Peptide (CCP) Antibodies</p> <p>Extractable Nuclear Antibodies (ENA) Screen 1 test</p> <p>(U1RNP (RNP 70, A, C), SS-A/Ro (60kDa, 52kDa), SS-B/La, Centromere B, Scl-70, Jo-1 proteins, Sm proteins)</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia Immucap 250 Analyser Immunoassay: SOP CICAP001</p> <p>Phadia Immucap 250 Analyser Immunoassay: SOP CICAP002</p> <p>Phadia Immucap 250 Analyser Immunoassay: SOP CICAP003</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>FFPE slides (Formalin fixed paraffin embedded) and frozen sections</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Demonstration of:</p> <p>Basophilic and eosinophilic structures</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Supported by:</p> <p>Specimen dissection – SOP CP CU 2: Astec downdraft benches Thermo Cassette printer</p> <p>Tissue processing Leica ASP300 tissue processor CP-TP-5: VIP 5 tissue processor CP VIP5 62: VIP 2000 tissue processor CP VIP2000 65: Vantage Tracking System PU 7: CU2: TE6: Tissue Embedding Sakura embedding centre CP-TE 6:</p> <p>Tissue Sectioning Leica microtomes CP-TS/PU 7:</p> <p>Cryotomy Intra-operative Frozen sections Cryostat CP-FS 35:Microscope</p> <p>Interpretive/diagnostic microscopy and reporting Office SOP 4:</p> <p>Macroscopic and Microscopic examination</p> <p>Sakura stainer/ Leica coverslipper using Haematoxylin and Eosin (H &amp; E) stains CP-DRS 10, CP-CVS 48:</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections.</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Demonstration of:</p> <p>Acid and Neutral Mucopolysaccharides</p> <p>Amyloid</p> <p>Haematopoietic cells</p> <p>Helicobacter Pylori</p> <p>Reticulin fibres</p> <p>Gram positive and negative bacteria</p> <p>Fungi</p> <p>Elastic fibres, connective tissue and nuclei</p> <p>Tissue morphology, differentiating muscle, connective tissue and cytoplasm</p> <p>Nuclei and connective tissue</p> <p>Fibrin and connective tissue</p> <p>Melanin</p> <p>Connective tissue and muscle</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in-house procedures for manual Tinctorial Histochemical Special Stains CP STAINING MANUAL; Standard Staining Procedures 1-28</p> <p>Alcian blue-PAS</p> <p>Congo red</p> <p>Giemsa</p> <p>Giemsa (modified) for Helicobacter Pylori</p> <p>Gordon and Sweets reticulin stain</p> <p>Gram</p> <p>Grocott methenamine silver</p> <p>Elastic van Gieson</p> <p>Haematoxylin and eosin (manual) Or Haematoxylin and eosin (rapid)</p> <p>Haematoxylin Van Gieson (HVG)</p> <p>Martius scarlet blue (MSB)</p> <p>Masson Fontana</p> <p>Masson Trichrome</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Alcohol fixed cell smears	Demonstration of:  Differential identification of mesothelial, macrophage and malignant cells in fluid preparations	Special Tinctorial Histochemical Staining continued  May Grunwald Giemsa
Formalin fixed/ paraffin embedded tissue sections	Removal of melanin to allow visualisation of nuclear features.  fungal hyphae, spores and protozoa.	Melanin Bleach  Methenamine Silver staining (MST)
Frozen tissue sections	Neutral lipid	Oil Red "o"
Formalin fixed/ paraffin embedded tissue sections	Hepatitis B surface antigen and copper associated protein  Differential identification of epithelial and other cell types in fluid specimens	Orcein (Shikata's)  Papanicolau
	Polysaccharides including glycogen	Periodic acid Schiff (PAS)
	Polysaccharides excluding glycogen	Periodic acid Schiff after diastase digestion
	Haemosiderin	Perl's Prussian blue
	Melanin	Schmorl's technique
	Mast cells	Toluidine blue
	Calcium salts	Von Kossa





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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections.</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Demonstration of:</p> <p>Mycobacterium spp including tuberculosis</p> <p>Immunohistochemistry to detect the following:</p> <p>Embryonic cells in normal tissues and germ cell tumours</p> <p>Anaplastic large cell lymphoma</p> <p>Epithelial cells</p> <p>Epithelial cells</p> <p>T cells, B cells in the mantle zone</p> <p>Follicular centre B cells</p> <p>Marker of low molecular weight cytokeratins</p> <p>Intestinal epithelium</p> <p>Mesothelial cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Special Tinctorial Histochemical Staining (cont'd)</p> <p>Ziehl-Neelsen (ZN)</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:</p> <p>Alpha feto protein</p> <p>ALK</p> <p>AE1/AE3</p> <p>Ber EP4</p> <p>Bcl-2 oncoprotein</p> <p>bcl-6</p> <p>CAM 5.2</p> <p>CDX2</p> <p>Calretinin</p>



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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>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin fixed/ paraffin embedded tissue sections	Immunohistochemistry to detect the following:  Cells containing carcinoembryonic antigen, principally in the gastrointestinal tract  Endometrial glands, appendix, ovary, cervix and luminal cells of the fallopian tube  Low molecular weight keratins  T cells  T cells and mantle zone B cells  Immature and germinal centre B cells  Immature B lymphocytes  B cells  Mature B cells and follicular dendritic cells  Follicular dendritic cells and EBV transformed blasts  Reed Sternberg and Hodgkin's cells	Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:  CEA (Monoclonal)  Ca 125  CAM5.2  CD3  CD5  CD10  CD15  CD20  CD21  CD23  CD30



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections.</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Endothelial marker</p> <p>Pan leucocyte marker</p> <p>Marker of neural and peptide cells</p> <p>Macrophages</p> <p>B cell marker</p> <p>Mast and gastro-intestinal stromal cells</p> <p>Plasma cells</p> <p>Intestinal epithelium</p> <p>Neuroendocrine cells</p> <p>Squamous and myoepithelial cells</p> <p>Glandular and transitional epithelium</p> <p>Gastrointestinal epithelium</p> <p>Cells within squamous epithelium and mantle cell lymphoma</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:</p> <p>CD34</p> <p>CD45 (LCA)</p> <p>CD56</p> <p>CD68 (KP1)</p> <p>CD79a</p> <p>CD117 (c-kit)</p> <p>CD138</p> <p>CDX2</p> <p>Chromogranin A</p> <p>CK5/6</p> <p>CK7</p> <p>CK20</p> <p>Cyclin D1</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections.</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Muscle intermediate filaments</p> <p>Mast and gastrointestinal tumour cells</p> <p>Cell adhesion molecules and indicative of ductal carcinoma breast</p> <p>Epithelial cells</p> <p>Breast and endometrium</p> <p>Trophoblasts</p> <p>Melanosomes</p> <p>Immunoglobulin producing cells eg plasma cells</p> <p>Leydig and Sertoli cells</p> <p>Cells producing kappa light chain immunoglobulin</p> <p>Proliferation</p> <p>Melanocytes</p> <p>Pan cytokeratin marker</p> <p>mRNA/ p16 HPV biomarker</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:</p> <p>Desmin</p> <p>DOG-1</p> <p>E-CADHERIN</p> <p>EMA</p> <p>Estrogen Receptor</p> <p>HCG</p> <p>HMB 45</p> <p>IgM</p> <p>Inhibin</p> <p>Kappa lc</p> <p>Ki 67</p> <p>MELAN-A</p> <p>MNF116</p> <p>P16</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides	Immunohistochemistry to detect the following:	Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:
	Tumour suppressor gene	P 53
	Basal cell marker	P63
	Placental Alkaline Phosphatase in the diagnosis of seminoma	PLAP
	Breast and endometrial glands	Progesterone receptor
	Prostate	PSA
	Melanocytes, sweat ducts and neuroendocrine cells	S100
	Muscle mesenchymal marker	Smooth muscle actin
	Neuroendocrine	Synaptophysin
	Early B cells, thymocytes	TdT
	Lymphatic endothelium	Thrombomodulin
	Lumen of thyroid follicles	Thyroglobulin
	Thyroid and lung adenocarcinoma	TTF-1
	Mesenchymal marker	Vimentin
	Wilm's tumour	WT1



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fluids from peritoneal and pleural cavities, brushings from bronchus and biliary tract, bronchial washings and fine-needle aspirations from breast and thyroid. Urine specimens CSF</p> <p>Thin layer preparations from body fluids</p> <p>Joint fluids</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of:</p> <p>Cells (nuclei and cytoplasm) and micro organisms</p> <p>Detection and identification of Crystals</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting SOP :CP 78: (Thyroid/breast FNA) SOP :CP 73: (Washings) SOP :CP 75: (Pleural/ascetic fluids) SOP :CP 76: (Bronchial brushings) SOP :CP 77: (Sputum) SOP :CP 79: (Urine) SOP :CP 80: (Cyst fluid, hydrocele fluid) Class 1 cabinet CP-CR 16: Microscopes</p> <p>Class 1 cabinet CP-CR 16: Microscopes</p> <p>T2000 Thin Prep Processor CP 74:</p> <p>Stainer CP-DRS 10: Coverslipper CP-CVS 48: Papanicolaou stain for Non-Gynae Specimens Procedure No: 28 in CP Staining manual: May-Grunwald Giemsa stain SOP No: 27 in CP Staining manual:</p> <p>Preparation and examination of Joint fluids for crystals using polarising microscopy SOP JFL 23: Centrifuge CP CEN 87: Leica microscope</p>



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities performed for the purpose of clinical diagnosis</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Routine samples:	Isolation of microorganisms of clinical significance	Manual inoculation, incubation and culture using:
Cellular and fluid material contained on Swabs from eyes, wounds, nose, throat, ears, genital sites, catheter tips, IUCDs , throat, ears, genital sites, Aspirates and Urine	Isolation of microorganisms of clinical significance	MIM4 for processing of routine swabs MIM8- Introduction to the preliminary identification of medically important bacteria MIM7- BSAC Antibiotic Susceptibility Testing MIM21- Staining Procedures MIM1- Investigation of Urines
Female genital tract swabs	Diagnosis of bacterial vaginosis	Manual microscopy using MIM4 Processing of routine swabs
Swabs, Fluids, urines and sputum	Isolation & identification of MRSA	Manual microscopy and manual inoculation and media culture using MIM4- processing of routine swabs MIM1- Investigation of Urines
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Manual microscopy and manual inoculation and media culture using MIM1
Blood	Isolation of micro-organisms of clinical significance	BacT/Alert Analyser MIM7 -Investigation of Blood Cultures MIM8 -Introduction to the preliminary identification of medically important bacteria
Faeces	General isolation and characterisation of micro-organisms of clinical significance	Manual inoculation, incubation and culture using MIM11 Investigation of faecal specimens for bacterial pathogens and their ID



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities performed for the purpose of clinical diagnosis- Cont'd</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Bacterial and yeast cultures (isolated in-house)	Identification and characterisation of micro-organisms	Manual biochemical, enzymatic, staining & microscopic methods using MIM8 Introduction to the preliminary identification of medically important bacteria
Bacterial cultures (isolated in-house)	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	Antimicrobial susceptibility testing by manual disk diffusion using BSAC guidelines and MIC determination using SOP MIM 7 BSAC Antibiotic Susceptibility Testing
Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material	Detection of parasites (ova, cysts, trophozoites and worms) of clinical significance	Unstained and iodine stained direct microscopic examination and/or Parasep faecal concentration, centrifugation and microscopic examination using SOP: MIM13 - Investigation of specimens other than blood for parasites
Faeces	Detection of Cryptosporidium	Modified Cold ZN incident-light microscopic examination using SOP MIM13- Investigation of specimens other than blood for parasites
Faeces	Detection of Helicobacter pylori antigen	Qualitative immune-chromatographic assay for detection of H.pylori antigen in faeces using SOP MIM 12 Detection of H.pylori in faeces
Skin, Hair and nail clippings	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and microscopy using: SOP MIM15 Isolation and identification of dermatophytes and other fungi MIM21 Staining procedures





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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities performed for the purpose of clinical diagnosis- Cont'd</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Sputum, fluid, urine, tissue and swabs	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Liquid TB culture using BacTAlert system, auramine phenol staining and microscopy and confirmation ZN staining using light microscopy using: MIM21 Staining procedures MIM10 Investigation of specimens for Mycobacterium
Urine	Detection of Legionella pneumophila serotype 1 antigen	Immunochromatographic assay using TRU Meridian Launch MIM 2 Detection of Legionella and pneumococcal antigen in urine samples
Urine	Detection of Streptococcus pneumoniae soluble antigen	Immunochromatographic assay using TRU Meridian Launch MIM 2 Detection of Legionella and pneumococcal antigen in urine samples
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular examination activities performed for the purpose of clinical diagnosis</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Genital samples and Urine	Detection of Chlamydia trachomatis and Neisseria gonorrhoea DNA	Automated real-time PCR using Roche Cobas 4800 – following SOP MSIM 10 CT/NG DNA Detection by PCR  Real time qualitative PCR Confirmation assay on Gene Xpert using SOP MIM14 Cepheid Gene Xpert test procedures
NPA, nose/throat swabs	Detection of influenza virus A&B & RSV RNA/DNA	GeneXpert analyser-PCR using SOP MIM14
Faeces	Detection of Norovirus and Clostridium difficile RNA/DNA	Real-time qualitative PCR assay using Gene Expert analyser and SOP MIM14 Cepheid Gene Xpert test procedures



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Mycobacterial culture isolates	Detection of Mycobacteria tuberculosis DNA and rifampicin resistance gene	Real-time qualitative PCR GeneXpert SOP MIM14 - Cepheid GeneXpert test
Serum/Plasma	Detection of Hepatitis C DNA (viral load)	RT-PCR (Quantitative) - Gene Xpert SOP MIM14 - Cepheid Gen Xpert test
Nose and throat swabs collected into VTM	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences ORF1 and ORF8	AusDiagnostics MT-PREP (automated RNA extraction), MT-Processor and MT-analyser (for liquid handling and PCR) Detection of viral RNA and semi-quantitative analysis. SOP: MIM23 Coronavirus Typing Assay
	<u>Serological examination activities performed for the purpose of clinical diagnosis</u>	
Serum/Plasma (unless stated)	Antistreptolysin O	Rheumajet ASO, latex agglutination. Quantitative & Qualitative MSIM2-Detection of ASO
	Syphilis Total (IgG/IgM) and IgM only	DS2 ELISA MSIM12 Use of DS2® automated ELISA system (serology testing on the DS2) Manual EIA for confirmation MSIM7 Test procedure for Syphilis IgM manual EIA
	Treponema pallidum antibodies	Positive particle agglutination confirmation test using SOP MSIM8 Test procedure for Serodia TPPA
	Reagin antibody	Flocculation, qualitative & semi-quantitative confirmation test using SOP MSIM6 Test procedure for RPR Reditest
	Mycoplasma pneumoniae antibodies	Particle agglutination SOP MSIM 4 Test procedure for Mycoplasma pneumoniae



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Serum	Cytomegalovirus IgM Cytomegalovirus IgG EBV Nuclear antigen/antibody EBV Capsid IgM antibody EBV Capsid IgM antibody Hepatitis A IgM antibody Hepatitis B surface antibody Hepatitis B Anti HBc Hepatitis C antibody Hepatitis E IgG/IgM Toxoplasma IgG/IgM Varicella-Zoster IgG	VIDAS using Enzyme linked fluorescent immunoassay (ELFA) MSIM11 - Serology Testing on the VIDAS
Serum	Hepatitis B surface antigen	VIDAS using ELFA MSIM11 Serology Testing on the VIDAS OR DS2 ELISA for confirmatory and primary diagnosis) MSIM12 Use of DS2® automated ELISA system (serology testing on the DS2) for antenatal screening)
Serum	HIV 1 and 2	VIDAS using ELFA MSIM11 Serology Testing on the VIDAS DS2 EIA MSIM12 Use of DS2® automated ELISA system (serology testing on the DS2) Alere Combo – lateral flow MSIM3 Test procedure for HIV Combo
Serum	Parvovirus IgM Parvovirus IgG	Manual ELISA MSIM5 Test procedure for Parvovirus
END		