


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8628</b> <b>Accredited to ISO 15189:2012</b>	<b>Wye Valley NHS Trust</b>  <b>Issue No: 011    Issue date: 10 April 2025</b>	
	<b>Pathology Department</b> <b>Hereford County Hospital</b> <b>Union Walk</b> <b>Hereford</b> <b>HR1 2ER</b>	<b>Contact: Nicola Edmunds</b> <b>Tel: +44 (0) 1432 364040</b> <b>Fax: +44 (0) 1432 364196</b> <b>E-Mail: Nicola.Edmunds2@wvt.nhs.uk</b> <b>Website: www.wyevalley.nhs.uk</b>
<b>Testing performed at the above address only</b>		

### 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	<p>Full Blood Count</p> <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> <p>Blood Film staining</p> <p>Blood Film reporting of normal and abnormal morphologies including White Blood Cell Differential (% and absolute count)</p> <p>Erythrocyte Sedimentation Rate (ESR)</p>	<p>Sysmex XN1000 Analysers SOP XN1000</p> <p>SLS Haemoglobin detection method</p> <p>Flow cytometry method using semiconductor laser</p> <p>Hydrodynamic Focusing (DC method) HA/HA/SOP/040</p> <p>Hydrodynamic Focusing (DC method)</p> <p>Flow cytometry method using semiconductor laser</p> <p>Calculated from RBC, HCT and HB</p> <p>RBC cumulative pulse height detection method</p> <p>SOP RAL RAL automated slide stainer</p> <p>Manual microscopy SOP BFEXAM</p> <p>Starrsed ST ESR analyser using modified Westergren Method SOP ESR</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations to assist in clinical diagnosis</u> (cont'd)	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	Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia Antenatal screening programme as defined in the laboratory QA evidence requirements  Sebia Capillarys 3 Tera – capillary zone electrophoresis HAEM 44 - Capillary Zone Electrophoresis for Variant Haemoglobins
Citrated blood	Blood coagulation Studies	<b>Sysmex CS2500 Optical, turbidimetry–</b> DMMAPTT DMPT DMINR DMF LA DMFVIII
	Activated partial thromboplastin time. Prothrombin Time INR Fibrinogen Lupus anticoagulant D-Dimer FVIII Inhibitor Screen	
	INR Activated partial thromboplastin time	KC4 coagulometer - mechanical end point detection)
	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</u> (cont'd)	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	Immunochromatographic assay using Core Malaria Pan/Pv/Pf Kit SOP MALP
	Detection of Malaria Parasites	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 Trephines	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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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous blood EDTA; Red cells	Blood Grouping by antigen detection:  A, B and O groups Rh D grouping	Processing samples for blood grouping and antibody screening on Ortho <b>Vision</b> – BTAGS Protocol for processing Antenatal samples SOP BTAN
Venous blood EDTA; plasma	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	Or Manual blood grouping by Ortho SOP BTMBG Tube blood group SOP BTRTG
	Detection and identification of the following Antibodies:	Red Cell Phenotyping using Ortho Technology BTPHEN
	ABO blood group antibodies: anti-A, anti-B	Processing samples for blood grouping and antibody screening on Ortho Vision– SOP BTAGS
	Rh blood group antibodies: anti-Cw, anti-C, anti-c, anti-E, anti-e, anti-D	Or Manual blood grouping by Ortho SOP BTMBG
	Kell blood group antibodies: anti-K, anti-k, anti-Kpa	Manual Antibody screening by Ortho SOP BTAS
	MNSs blood group antibodies: anti-M, anti-N, anti-S, anti-s	SOP Antibody Investigation by Ortho SOP BTABID
	Duffy blood group antibodies: anti-Fya, anti-Fyb	
	Kidd blood group antibodies: anti-Jka, anti-Jkb	



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	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	Lactate Dehydrogenase	Roche c501 UV enzymatic assay SOP CHEM 28-Serum Plasma Lactate Dehydrogenase
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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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 and plasma	Quantification of:  Total Protein Albumin Bile Acids Cholesterol Direct (conjugated) Bilirubin  Iron Gamma GT HDL Cholesterol (LDL Calculated) Paracetamol Total Bilirubin Triglycerides  Alcohol  Alkaline Phosphatase ALT AST Creatine Kinase Theophylline  Salicylate  Angiotensin Converting Enzyme  Gentamicin Vancomycin Hydroxybutyrate  Fructosamine	Roche c501 Analyser  SOPCMOD020 - Biuret SOP CMOD024 - BCG SOP CMOD002 – CLS Enzymatic SOP CMOD006 – Chol. Oxidase SOP CMOD008 – <b>Vanadate Oxidation</b>  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  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





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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
Urine	Detection of 5HIAA (Screening Method)	Manual method – Nitrosonaphthol SOP CMAN011
Urine & faeces	Urinary and Faecal Reducing Substances (semi-quantitative)	Manual Method – Benedicts Reagent SOP CMAN006
Serum, Plasma & Urine	Quantification of:  Osmolality	  Advanced Instruments OSMO1 Depression SOP CEMERG002
Venous Whole Blood: EDTA/Fluoride	HbA1c	Sebia Capillarys 3 Tera – capillary zone electrophoresis CHEM 118 – HbA1c Analysis on Sebia Calillary 3 Tera Systems



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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 Parathyroid Hormone BNP	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 SOP CME 020 PTH SOP CHEM 49
Serum	Plasma Protein Paraprotein Quantification Detection of Cryoglobins	SOP CPP003 SOP CPP004 SOP CPP006
Plasma	Ammonia	SOP CHEM 1



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Urine	Paraprotein Typing  Detection, quantification and typing of:  Bence Jones Protein	Sebia Hydrasys Immunofixation Electrophoresis SOP CPP001  Sebia Hydrasys - Gel electrophoresis SOP CPP002
Urine & Faeces	Detection of: Xylose Glucose Galactose Lactose Fructose Sucrose  Quantification of:	Manual method – Thin Layer Chromatography SOP CMAN007
CSF	CSF Xanthochromia	Northstar Bio-UV Spectrophotometer SOP CMSP001
Venous Whole Blood: EDTA	Ammonia	Arkray PocketChem Blood Ammonia Meter SOP CEMERG015
Serum / Plasma/ Urine/ Sweat	Chloride	Corning/Sherwood 925 Chloride Analyser – Coulometry SOP CEMERG001
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:  Detection and Quantification of:  Double Stranded DNA Antibodies Anticardiolipn 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	Phadia ImmunoCap 250 Analyser – ELISA method SOP CIMM022 Combi ELISA Kit SOP CIMM009



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum / Plasma	Quantification of Allergen Specific IgE:  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	Phadia Immucap 250 Analyser Immunoassay: SOP CICAP001
Serum / Plasma	Quantification of Cyclic Citrillunated Peptide (CCP) Antibodies	Phadia Immucap 250 Analyser Immunoassay: SOP CICAP002
	Extractable Nuclear Antibodies (ENA) Screen 1 test	Phadia Immucap 250 Analyser Immunoassay: SOP CICAP003
	(U1RNP (RNP 70, A, C), SS-A/Ro (60kDa, 52kDa), SS-B/La, Centromere B, Scl-70, Jo-1 proteins, Sm proteins)	



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



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	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  Polysaccharides including glycogen  Polysaccharides excluding glycogen  Haemosiderin  Melanin  Mast cells  Calcium salts	Orcein (Shikata's)  Papanicolaou  Periodic acid Schiff (PAS)  Periodic acid Schiff after diastase digestion  Perl's Prussian blue  Schmorl's technique  Toluidine blue  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</u> (cont'd)</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>Cells containing carcinoembryonic antigen, principally in the gastrointestinal tract</p> <p>Endometrial glands, appendix, ovary, cervix and luminal cells of the fallopian tube</p> <p>Low molecular weight keratins</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> <p>CEA (Monoclonal)</p> <p>Ca 125</p> <p>CAM5.2</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin fixed/ paraffin embedded tissue sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:
	T cells	CD3
	T cells and mantle zone B cells	CD5
	Immature and germinal centre B cells	CD10
	Immature B lymphocytes	CD15
	B cells	CD20
	Mature B cells and follicular dendritic cells	CD21
	Follicular dendritic cells and EBV transformed blasts	CD23
	Reed Sternberg and Hodgkin's cells	CD30
	Endothelial marker	CD34
	Pan leucocyte marker	CD45 (LCA)
	Marker of neural and peptide cells	CD56
	Macrophages	CD68 (KP1)
	B cell marker	CD79a
	Mast and gastro-intestinal stromal cells	CD117 (c-kit)
	Plasma cells	CD138
	Intestinal epithelium	CDX2
	Neuroendocrine cells	Chromogranin A



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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</u> (cont'd)	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:	Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:
	Squamous and myoepithelial cells	CK5/6
	Glandular and transitional epithelium	CK7
	Gastrointestinal epithelium	CK20
	Cells within squamous epithelium and mantle cell lymphoma	Cyclin D1
	Muscle intermediate filaments	Desmin
	Mast and gastrointestinal tumour cells	DOG-1
	Cell adhesion molecules and indicative of ductal carcinoma breast	E-CADHERIN
	Epithelial cells	EMA
	Breast and endometrium	Estrogen Receptor
	Trophoblasts	HCG
	Melanosomes	HMB 45
	Immunoglobulin producing cells eg plasma cells	IgM
	Leydig and Sertoli cells	Inhibin
	Cells producing kappa light chain immunoglobulin	Kappa lc
	Proliferation	Ki 67
	Melanocytes	MELAN-A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	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:	Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform SOP CP-VENT 49: Incorporating the following antibodies:
	Pan cytokeratin marker	MNF116
	mRNA/ p16 HPV biomarker	P16
	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><b>HUMAN BODY FLUIDS</b></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><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>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>
Thin layer preparations from body fluids	<p>Demonstration of:</p> <p>Cells (nuclei and cytoplasm) and micro organisms</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>
Joint fluids	Detection and identification of Crystals	Preparation and examination of Joint fluids for crystals using polarising microscopy SOP JFL 23: Centrifuge CP CEN 87: Leica microscope



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<b>HUMAN TISSUES AND FLUIDS</b>	<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 (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis</u> (cont'd)	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 from clinical samples)	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc and MIC gradient determination using DensiCHEK Plus Photometric device using EUCAST methodology SOP : MIM 25 : EUCAST 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 (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis</u> (cont'd)	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
	<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	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
Faeces, Rectal swabs, urine, wound swabs	Detection of Carba-R	MIM 14 Cepheid GeneXpert RT-PCR procedures
Mycobacterial culture isolates	Detection of Mycobacteria tuberculosis DNA and rifampicin resistance gene	Real-time qualitative PCR GeneXpert SOP MIM14 - Cepheid GeneXpert test





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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)
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
Serum/Plasma (unless stated)	<u>Serological examination activities performed for the purpose of clinical diagnosis</u>  Antistreptolysin O	Rheumajet ASO, latex agglutination. Quantitative & Qualitative MSIM2-Detection of ASO
END		