

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<b>Royal Devon University Healthcare NHS Foundation Trust</b>	
	<b>Issue No: 014</b>	<b>Issue date: 27 September 2023</b>
	<b>Pathology Department</b> North Devon District Hospital Raleigh Park Barnstaple EX31 4JB United Kingdom	<b>Contact David Lea</b> Tel: +44 (0)1271 335758 E-Mail: davidlea@nhs.net Website: <a href="https://www.royaldevon.nhs.uk/services/pathology/">https://www.royaldevon.nhs.uk/services/pathology/</a> <a href="https://pathologylaboratory.co.uk/pathology-2/">https://pathologylaboratory.co.uk/pathology-2/</a>
Testing performed at the above address only		

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

Location details	Activity
On-site Mortuary and Body Store Mortuary, Level 1 North Devon District Hospital Barnstaple EX31 4JB	Storage of bodies Record keeping (body identification and audit trail)
South Molton Hospital – Room off of Hugh Squire Ward Widgery Drive South Molton Devon EX36 4DP	Blood storage & issue Fridge managed by laboratory
Torrington Hospital – Treatment Room Calf Street Torrington Devon EX38 7BJ	Blood storage & issue Fridge managed by laboratory
Holsworthy Hospital – Room off of the Ward Dobles Lane Holsworthy EX22 6JQ	Blood storage & issue Fridge managed by laboratory
North Devon District Hospital Main Theatres	Blood storage & issue Fridge managed by laboratory
North Devon District Hospital Labour Ward Maternity	Blood storage & issue Fridge managed by laboratory
North Devon District Hospital Pathology Corridor	Blood storage & issue Fridge managed by laboratory



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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>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for:
	Quantitative determination of:	
Serum	Chloride	Roche c501 analyser using Ion Selective Electrodes:
Serum & urine	Potassium	B-SOP-COB-38
Serum & urine	Sodium	
Serum	ALP	Roche c501analysers using kinetic assays:
	ALT	B-SOP-COB-2
	Amylase	B-SOP-COB-3
	AST	B-SOP-COB-4
	CK (NAC)	B-SOP-COB-5
	GGT	B-SOP-COB-8
	Theophylline	B-SOP-COB-15
	Vancomycin	B-SOP-COB-31
	Procalcitonin	B-SOP-COB-33
	Gentamicin	B-SOP-COB-75
	Lactate Dehydrogenase (IFCC)	B-SOP-COB-16
		B-SOP-COB-23
Serum	Albumin	Roche c501 analyser using colorimetric assays
	Ammonia	B-SOP-COB-1
	Bicarbonate	B-SOP-COB-26
	Direct Bilirubin	B-SOP-COB-12
	Total Bilirubin	B-SOP-COB-39
	Cholesterol	B-SOP-COB-6
	HDL-Cholesterol	B-SOP-COB-11
	Iron	B-SOP-COB-17
	Lithium	B-SOP-COB-21
	Magnesium	B-SOP-COB-24
	Total Protein	B-SOP-COB-25
	Triglyceride	B-SOP-COB-29
		B-SOP-COB-30



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented in house methods and manufacturers instructions for:
Serum and urine	Calcium	Roche c501 analyser using colorimetric assays continued: B-SOP-COB-7
	Inorganic Phosphate	B-SOP-COB-27
	Urea	B-SOP-COB-34
	Uric Acid	B-SOP-COB-32
Serum, Plasma and CSF	Glucose	B-SOP-COB-14
Plasma and CSF	Lactate	B-SOP-COB-22
Urine & CSF	Urinary/CSF Protein	B-SOP-COB-36  Roche c501 analyser using immuno-turbidimetric assays
Serum	CRP IgA IgG IgM Rheumatoid Factor	B-SOP-COB-10 B-SOP-COB-18 B-SOP-COB-19 B-SOP-COB-20 B-SOP-COB-66
Urine	Microalbumin	B-SOP-COB-35  Roche c501 analyser using enzymatic assays
Serum and urine Serum	Creatinine Ethanol Salicylate Paracetamol Bile Acids	B-SOP-COB-9 B-SOP-COB-13 B-SOP-COB-28 B-SOP -COB-37 B-SOP-COB-67



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented in house methods and manufacturers instructions for:
Calculation as above	<u>Calculated tests</u>	B-RECORD-SHEET-194
	AKI - Calculation of risk of acute kidney injury	LIMS algorithm based on time and previous creatinine values
	Adjusted Calcium	Calculated by rule in LIMS
	Estimated glomerular filtration rate	Calculated by rule in LIMS
	Free androgen index	Calculated by rule in LIMS
	LDL - Low Density Lipoprotein	Calculated by rule in LIMS
	Non HDL	Calculated by rule in LIMS
	CHOL/HDL ratio	Calculated by rule in LIMS
	Macroprolactin	Manual calculation
	Urine albumin/creatinine ratio	Calculated by rule in LIMS
	Urine T Protein/Creatinine ratio	Calculated by rule in LIMS
	24hr urine: sodium, potassium, urea, creatinine, phosphate, calcium, urate & protein.	Calculated by rule in LIMS
	Creatinine clearance	Calculated by rule in LIMS
	Bioavailable Testosterone	Calculated by rule in LIMS B-RECORD-ARCHIVE-20
	Free Testosterone	Calculated by rule in LIMS B-RECORD-ARCHIVE-20
	Anion gap	Calculated by rule in LIMS B-RECORD-ARCHIVE-20
	Pre-Eclampsia Toxaemia Ratio	Calculation based on soluble fms-like tyrosine kinase-1 and placental growth factor results



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):  Quantitative determination of:	Documented in house methods and manufacturers instructions for:
Serum	AFP ATP B12 CA125 CEA Cortisol Digoxin Ferritin Folate FSH FT3 FT4 HCG ( $\beta$ HCG) LH NT-proBNP Oestradiol Progesterone Prolactin PSA (total) PTH SHBG Testosterone Troponin (high sensitive) TSH Vitamin D Fms-like Tyrosine Kinase-1 Placental growth factor	Roche e601immunoanalyser using ECLIA (electroelectrochemiluminescent immunoassays) B-SOP-COB-41 B-SOP-COB-42 B-SOP-COB-63 B-SOP-COB-43 B-SOP-COB-44 B-SOP-COB-45 B-SOP-COB-46 B-SOP-COB-47 B-SOP-COB-65 B-SOP-COB-48 B-SOP-COB-49 B-SOP-COB-50 B-SOP-COB-51 B-SOP-COB-52 B-SOP-COB-54 B-SOP-COB-53 B-SOP-COB-55 B-SOP-COB-56 B-SOP-COB-57 B-SOP-COB-58 B-SOP-COB-59 B-SOP-COB-60 B-SOP-COB-61 B-SOP-COB-62 B-SOP-COB-64 B-SOP-COB-74 B-SOP-COB-73
Urine	Bence Jones protein confirmation and typing	Immunofixation using Sebia Hydrasys 2 B-SOP-MAN-3
Serum	Paraprotein bands identification and classification	Immunofixation using Sebia Hydrasys 2 B-SOP-MAN-19
Serum & Urine	Protein abnormalities screening	Electrophoresis using Sebia Hydrasys 2 B-SOP-MAN-33



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented in house methods and manufacturers instructions for:
Serum	Cryoglobulin detection,	Visual inspection B-SOP-MAN-8
CSF	Haem pigments	North Star Uvikon XS spectrophotometer B-SOP-MAN-9
Blood & Urine	Osmolarity	Osmometer B-SOP-MAN-52



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<p><b>HUMAN BODY TISSUE</b></p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>Formalin Fixed paraffin embedded (FFPE) tissue</p> <p>Formalin Fixed paraffin embedded (FFPE) tissue</p> <p>FFPE sections and frozen sections</p> <p>FFPE 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>Routine morphological staining for the detection of: Basophilic and eosinophilic structures</p> <p>Special stains for the detection of:</p> <p>Neutral Mucins, fungi, glycogen</p> <p>Acid/neutral mucins</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Specimen dissection CP-SOP-23 CP-SOP-21 CP-METHOD-CUT-1-24</p> <p>Decalcification Manual method using: CP-SOP-21</p> <p>Tissue Processing using Thermo Excelsior AS tissue processors CP-SOP-19</p> <p>Tissue Embedding using Thermo Histostar embedding centre CP-SOP-6</p> <p>Tissue Sectioning using Leica microtomes (RM2235 and RM2245) CP-SOP-12</p> <p>Frozen sections using Thermo Cryotome CP-SOP-8</p> <p>Routine morphological staining using the Thermo Gemini stainer and Haematoxylin and Eosin (H&amp;E) and coverslipped using ClearVue Stainer.Coverslipper and manual method CP-SOP-14 CP-SOP-24 CP-METHOD-SPEC-10 H&amp;E</p> <p>Automated staining using Thermo Gemini and ClearVue Stainer/Coverslipper</p> <p>PAS</p> <p>ABPAS</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:
FFPE sections (cont'd)	Special stains for the detection of: (cont'd)	Documented in house procedures for manual special stains CP-SOP-2
	Acid mucins	CP-METHOD-SPEC-1 Alcian Blue(AB)
	Acid/neutral mucins, fungi	CP-METHOD-SPEC-2 AB/PAS+/-D
	Amyloid	CP-METHOD-SPEC-3 Congo Red
	Micro organisms	CP-METHOD-SPEC-4 CVA
	Elastic fibres	CP-METHOD-SPEC-5 Elastic Van Gieson
	Azuophilic & eosinophilic granules	CP-METHOD-SPEC-6 Giemsa (BMT)
	Gram +/- organisms	CP-METHOD-SPEC-7 Gram Stain
	Fungi	CP-METHOD-SPEC-9 Grocott
	Melanin	CP-METHOD-SPEC-11 Masson Fontana
	Fibrin, collagen	CP-METHOD-SPEC-12 Masson Trichrome
	Fibrin and connective tissues	CP-METHOD-SPEC-13 MSB
	Ferric iron (haemosiderin)	CP-METHOD-SPEC-16 Perls Stain
	Reticulin fibres	CP-METHOD-SPEC-17 Reticulin Stain
	Connective tissues	CP-METHOD-SPEC-19 Van Gieson





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HUMAN BODY TISSUE (cont'd)	Histopathological examination <u>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:
FFPE sections (cont'd)	Special stains for the detection of: (cont'd)	Documented in house procedures for manual special stains CP-SOP-2
	Spirochaetes	CP-METHOD-SPEC-20 Warthin Starry
	Mycobacterium tuberculosis	CP-METHOD-SPEC-21 Ziehl Neelsen (ZN)
	Neutral mucins, fungi, +/- glycogen	CP-METHOD-SPEC-22 PAS +/- diastase
	Mycobacterium leprae	CP-METHOD-SPEC-24 Wade Fite
	Mast cell granules	CP-METHOD-SPEC-25 Toluidine Blue
FFPE sections	Immunohistochemistry to detect the following:	Automated method using Dako Omnis Immunostainer CP-SOP-1
	Epithelial cells, mesothelioma panel	34Be12
	Epithelial cells	AE1/3
	Germ cell tumours	AFP
	B Cells	BCL2
	B Cells	BCL6
	Ovarian tumour	Ca125
	Mesothelial derived cells	Calretinin



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HUMAN BODY TISSUE (cont'd)	Histopathological examination <u>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:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using Dako Omnis Immunostainer CP-SOP-1
	Langerhans cells	CD1a
	T cells in mantle zone	CD3
	T cells	CD4
	T and B cells-leukaemia	CD5
	T cells	CD8
	Lymphoma, brush border of gut epithelium	CD10
	Granulocytes, Reed Sternberg (RS) cells, mesothelioma panel	CD15
	B cells	CD20
	B cells	CD23
	RS cells	CD30
	Endothelial cells	CD31
	Endothelial cells	CD34
	T cells	CD43
	T cells	CD44
	White blood cells	CD45 (LCA)
	Macrophages	CD68
	B cells	CD79a
	Gastrointestinal stromal tumour	CD117



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using Dako Omnis Immunostainer CP-SOP-1
	Plasma cells	CD138
	Colonic adenocarcinoma	CDX2
	Colonic carcinoma	CEA
	Neuroendocrine cells	Chromogranin
	Epithelial cells/mesothelioma panel	CK 5
	Epithelial cells	CK 7
	Epithelial cells	CK 20
	Mantle cell lymphoma cells	Cyclin D1
	Muscle: Smooth/striated	Desmin
	Gastrointestinal stromal tumour	Dog-1
	Breast duct epithelial cells	E-Cadherin
	Epithelium/mesothelioma panel	EMA
	Epithelial cells, mesothelioma panel	EP4 (Ber EP4)
	Oestrogen receptors	ER
	Blood proenzyme- platelets, histocytes, megakaryocytes	F13a



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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:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using Dako Omnis Immunostainer CP-SOP-1
	Germ cell tumours, placenta	HCG
	Melanoma cells, melanocytes	HMB45
	Sertoli cells, granulosa cells, prostate, brain, adrenal	Inhibin
	Kappa light chains	Kappa
	Proliferating cells	Ki67 (MIB1)
	Lambda light chains	Lambda
	Melanoma cells, melanocytes	Mel A
	Epithelial cells	MNF 116
	Smooth muscle	Myosin (heavy chain) (SMM)
	Germ cell tumour	Oct 3/4
	Prostatic adenocarcinoma	P504S (Racemace)
	SCC of female genital tract, cervical neoplasms	p16
	Cell proliferation	p53
	Basal cells of glandular tissue	p63
	Placenta	PLAP
	Breast epithelium (Progesterone Receptors)	Progesterone Receptors (PR)
	Prostate	PSA
	Renal Cell Carcinoma	RCC



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using Dako Omins Immunostainer CP-SOP-1
	Nerve/Melanoma	S100
	Smooth muscle	SMA
	Nervous tissue	Synaptophysin
	Thyroid colloid	Thyroglobulin
	Primary lung cancer/thyroid, mesothelioma pane	TTF1
	Mesenchymal cells	Vimentin
	Wilm's tumour/Mesothelioma panel	WT1
	Prostate/prostate adenocarcinoma	Chromoplex (34Be12/P504S)
Frozen tissue sections	Direct Immunofluorescence for the identification of:  Immune deposits of IgA Immune deposits of IgG Immune deposits of IgM Immune deposits of C3	Immunofluorescence technique. Documented in-house procedures in conjunction with manufacturer's instructions for fluorescent microscope CP-SOP-5



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<p><b>HUMAN BODY FLUIDS</b></p> <p>Fine needle aspirates (FNA) – Breast, cyst, lung, lymph node, nasopharyngeal, parotid, thyroid. Urine, CSF, abdominal washings, cyst fluids/aspirates, bronchial brushings/washings, fluids, aspirates, needle washings, sputum</p> <p>FFPE and frozen sections stained as above</p>	<p><u>Cytological (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: Cells (nuclei and cytoplasm) and microorganisms</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</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 CP-SOP-22</p> <p>Automated Papanicolaou stain using the Thermo Gemini stainer. Manual May-Grunwald Giemsa stain CP-SOP-22 CP-SOP-14</p> <p>Interpretive/diagnostic microscopy using light microscopes; Olympus BX50, BX51 &amp; BX53 and Leica DM2600 CP-SOP-32 CP-SOP-26</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood – EDTA samples	<p>Full Blood Count (FBC) analysis of the following parameters:</p> <p>Haemoglobin White Blood Cell count Red Blood Cell count Platelets Mean Cell Volume Mean Corpuscular Haemoglobin Mean Corpuscular Haemoglobin Concentration Red Cell Distribution Width Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Nucleated Red Blood Cell count Reticulocyte count</p> <p>Optical Platelet Count</p>	<p>Automated using the Horiba Yumizen 2500 analysers Spectrophotometry Flow Cytometry Aperture impedance Aperture impedance &amp; fluorescence Calculated result Calculated result</p> <p>Calculated result Calculated result Flow Cytometry Flow Cytometry Flow Cytometry Flow Cytometry Aperture impedance Aperture impedance &amp; fluorescence Aperture impedance &amp; fluorescence SOP H-SOP-69 SOP H-EXT-28</p> <p>Flow Cytometry H-SOP-92</p>
Plasma Serum	Glandular Fever Screen	Monogen commercial kit, latex micro particle immunoassay SOP H-SOP-21
Whole Blood – EDTA samples	<p>Malaria screening for:</p> <p>P. falciparum P. vivax P. ovale P. malariae</p>	<p>Thick and thin films</p> <p>Fields and Giemsa stain and manual microscopy</p> <p>Binax Now Immunochromatographic test SOP H-SOP-22</p>



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Serum	Glucose 6 phosphate dehydrogenase screen (G6PD)	Visual qualitative fluorescence Trinity Biotech kit SOP H-SOP-28
Plasma	Routine Coagulation testing for:  INR / Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Clauss) Factor Assays Factor VIII inhibitor assay Heparin Assay Thrombophilia screen (Protein C, Antithrombin 3, Free Protein S antigen Lupus anticoagulant Screen Abnormal coagulation screen	Automated method using Stago Star Max analysers  Photo optical method H-SOP-81 SOP H-SOP-82  SOP H-SOP-83  SOP H-SOP-76 & H-SOP-77 SOP H-SOP-85 SOP H-SOP-78 SOP H-SOP-10 SOP H-SOP-79 SOP H-SOP-55
Plasma	D Dimer assays	Automated method using Stago Star Max analysers Latex agglutination method SOP H-SOP-84





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Whole blood – EDTA	Detection of iron	Light microscopy following Perl's Prussian Blue iron staining SOP H-SOP-15
Urine		
Whole blood – EDTA	Blood film analysis: Identification of normal and abnormal morphologies including WBC differential count	May Grunwald-Giemsa semi automated staining using IUL Polystainer G2 followed by manual light microscopy SOP H-SOP-61 SOP H-SOP-19 SOP H-SOP-16
Bone marrow aspirate slides	Reporting of normal and abnormal morphologies	Semi automated MGG stain using IUL Polystainer G2 and Manual iron stain followed by manual light microscopy SOP H-SOP-49
Calculation as above	Calculated tests MCV MCH MCHC RCDW INR APTR Lupus Anticoagulant	Results produced by automated calculations using Horiba Yumizen 2500 Analyser  Results produced by automated calculations using Stago Star Max 2 Analyser  Documented -in-house methods to meet the requirements of the Sick cell and Thalassaemia (SCT) screening programme screening programme(s) as defined in the 'NHS Sick Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements
Whole blood - EDTA	Detection of haemoglobin S (Hb-S)	Sickledex Solubility test SOP H-SOP-35
Whole Blood – EDTA	Detection of haemoglobin variants and thalassaemia	Sebia Capillarys 3, by capillary electrophoresis H-SOP-35v8 H-SOP-96v2



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**Issue No: 014    Issue date: 27 September 2023**

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY FLUIDS AND TISSUES</b></p> <p>Routine samples: Aspirates Cellular and fluid material contained on swabs, catheter tips and intra-uterine contraceptive devices Fluids Genital samples Pus Samples from sterile sites Tissues Urine</p> <p>Cellular and fluid material contained on swabs</p> <p>Blood</p> <p>Urine</p> <p>CSF</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation of micro-organisms of clinical significance</p> <p>Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)</p> <p>Isolation of micro-organisms of clinical significance</p> <p>Quantification of white blood cells</p> <p>Quantification of white and red blood cells and bacteria</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):</p> <p>Manual inoculation followed by culture using the following procedures: Genital swabs &amp; associated specimens SOP (M-BSOP-1). Wound swab and associated specimens SOP (M-BSOP-3). Sterile fluids SOP (M-SOP-83)</p> <p>Inoculation &amp; Incubation of Culture Media for Bacteriology SOP, M-SOP-34 Urine Analysis SOP, M-SOP-14</p> <p>Direct inoculation chromogenic culture media M-SOP-15</p> <p>Liquid media culture of anaerobic, aerobic and paediatric culture broths using BD BacTec FX400 and FX40 M-SOP-8</p> <p>Manual examination using light microscopy M-SOP-14</p> <p>Manual examination using Fuchs Rosenthal chamber and light microscopy M-SOP-83</p>



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<b>HUMAN BODY FLUIDS AND TISSUES</b>	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Skin, nail	Isolation and characterisation of clinically significant fungi	Manual culture and microscopy using KOH wet prep M-SOP 17
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual: Biochemical identification, (Staph latex agglutination kit, strep grouping kit, oxidase test, API) M-SOP-26
Cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc diffusion and EUCAST methodology  EUCAST SOP, M-SOP-42
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis (Hays criteria)	Gram stained microscopic examination M-BSOP-1
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination using in-house procedures M-SOP-14
Faeces	Detection of ova, cysts and parasites (OCP)	Concentration and light microscopic examination using Parasep method M-SOP-11
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Fluorescent microscopy using Auramine-phenol immunofluorescent stain and light microscopy using modified ZN stain M-SOP-11
Faeces	Detection of <i>C. Difficile</i> GDH antigen	Qualitative immunoassay using Proflo GDH kit M-SOP-11
Faeces	Detection of <i>C. difficile</i> enterotoxin A, cytotoxin B and Glutamate dehydrogenase antigen	Lateral flow using Techlab® C.Diff Quick Chek Complete kit M-SOP-11



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood – EDTA samples	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Automated solid phase method using Immucor Galileo Echo Lumena analyser and manual using Tube Agglutination method SOP T-SOP-17 SOP T-SOP-42
Whole Blood – EDTA samples	Antibody Screen by detection of antibodies to red cell antigens expressed on the screening cells:	Automated solid phase indirect antiglobulin method using Immucor Galileo Echo Lumena analyser and manual using BioRad antibody screening with the Column agglutination technique. SOP T-SOP-17



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood – EDTA samples	Antibody investigation by detection and identification of:  Rhesus blood group antibodies: D, C, c, E, e, V and C <sup>w</sup> Kell system blood group antibodies: K, k, Kp <sup>a</sup> , Kp <sup>b</sup> , Js <sup>a</sup> and Js <sup>b</sup> Duffy blood group antibodies: Fy <sup>a</sup> , Fy <sup>b</sup> Kidd blood group antibodies: Jk <sup>a</sup> and Jk <sup>b</sup> Lewis blood group antibodies: Le <sup>a</sup> and Le <sup>b</sup> P blood group antibodies P <sub>1</sub> MNS blood group antibodies: M, N, S and s Lutheran blood group antibodies: Lu <sup>a</sup> and Lu <sup>b</sup>	Automated solid phase indirect antiglobulin method using Immucor Galileo Echo Lumena analyser and manual using BioRad Column Agglutination Technique SOP T-SOP-17 SOP T-SOP-4 SOP T-SOP-73
Whole Blood – EDTA samples	Direct Antiglobulin Test (DAT)	Manual BioRad Column Agglutination technology SOP T-SOP-16



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood – EDTA samples	Compatibility testing of patients plasma with donor cells	Manual cross matching using BioRadColumn Agglutination technology SOP T-SOP-10  Electronic issue of red cells via LIMS  SOP T-SOP-57  Rapid release – group specific SOP T-SOP-30
Whole Blood – EDTA samples	Foetal Maternal Haemorrhage	Manual method by acid elution: Kleihauer Betke using the Guest Medical Kleihauer kit. SOP T-SOP-18 SOP T-SOP-31  Manual technique using BioRAD column agglutination
	Rh/K phenotyping	SOP T-SOP-47
END		