


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9100 Accredited to ISO 15189:2012	Northern Devon Healthcare NHS Trust	
	Issue No: 006 Issue date: 26 March 2021	
	Pathology Department North Devon District Hospital Raleigh Park Barnstaple EX31 4JB United Kingdom	Contact: Bruce Seymour Tel: +44 (0)1271 335758 E-Mail: bruce.seymour@nhs.net Website: www.northdevonhealth.nhs.uk/pathology/
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)
Tyrell Hospital – Lantern Suite St. Brannocks Park Road Ilfracombe Devon EX34 8JF	Blood storage & issue Fridge managed by laboratory
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



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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:
Serum	Quantitative determination of:	
Serum & urine	Chloride	Roche c501 analyser using Ion Selective Electrodes:
Serum & urine	Potassium	B-SOP-COB-38
Serum	Sodium	
	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
	LDH	B-SOP-COB-15
	Gentamicin	B-SOP-COB-23
	Theophylline	B-SOP-COB-16
	Vancomycin	B-SOP-COB-31
		B-SOP-COB-33
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
Serum	CRP IgA IgG IgM Rheumatoid Factor	Roche c501 analyser using immuno-turbidimetric assays 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 Paracetamol Salicylate	B-SOP-COB-9 B-SOP-COB-13 B-SOP-COB-37 B-SOP-COB-28
	Bile Acids	B-SOP-COB-67



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Calculation as above</p>	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):</p> <p><u>Calculated tests</u></p> <p>AKI - Calculation of risk of acute kidney injury</p> <p>AST/ALT ratio</p> <p>Blood Gas – Bicarb, total CO₂ & base excess</p> <p>Adjusted Calcium</p> <p>Estimated glomerular filtration rate</p> <p>Free androgen index</p> <p>LDL - Low Density Lipoprotein</p> <p>Non HDL</p> <p>CHOL/HDL ratio</p> <p>Macroprolactin</p> <p>Urine albumin/creatinine ratio</p> <p>Urine T Protein/Creatinine ratio</p> <p>U. Porphyrin/creat ratio</p> <p>24hr urine: sodium, potassium, urea, creatinine, phosphate, calcium, urate & protein.</p> <p>Creatinine clearance</p> <p>Bioavailable Testosterone</p> <p>Free Testosterone</p> <p>Anion gap</p>	<p>Documented in house methods and manufacturers instructions for:</p> <p>B-RECORD-SHEET-194</p> <p>LIMS algorithm based on time and previous creatinine values</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rules in blood gas analyser software</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Manual calculation</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>Calculated by rule in LIMS</p> <p>B-RECORD-ARCHIVE-20</p> <p>Calculated by rule in LIMS</p> <p>B-RECORD-ARCHIVE-20</p> <p>Calculated by rule in LIMS</p> <p>B-RECORD-ARCHIVE-20</p>



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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 (β HCG) LH NT-proBNP Oestradiol Progesterone Prolactin PSA (total) PTH SHBG Testosterone Troponin (high sensitive) TSH Vitamin D	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
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, measurement and typing	Electrophoresis platform used for typing of cryoglobulin by immunofixation using Sebia Hydrasys 2: B-SOP-MAN-19 B-SOP-MAN-33 B-SOP-MAN-8
Blood & urine	Osmolality	Vitech Advanced Micro-osmometer 3320 using depression of freezing point B-SOP-MAN-24
CSF	Haem pigments	North Star Uvikon XS spectrophotometer B-SOP-MAN-9
Urine	Porphyryns (PBG)	North Star Uvikon XS spectrophotometer B-SOP-MAN-31
Urine	<u>Miscellaneous</u> Human Chorionic Gonadotrophin (HCG)	BioSign® hCG—One Step Pregnancy Test - immunometric B-SOP-MAN-32



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<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</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>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 Cytotome CP-SOP-8</p> <p>Routine morphological staining using the Thermo Gemini stainer and Haematoxylin and Eosin (H&E) and coverslipped using ClearVue Stainer.Coverslipper and manual method CP-SOP-14 CP-SOP-24 CP-METHOD-SPEC-10 H&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
	Azurophilic & 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)	<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
	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)	<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
	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)	<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) Plasma cells Colonic adenocarcinoma Colonic carcinoma Neuroendocrine cells Epithelial cells/mesothelioma panel Epithelial cells Epithelial cells Mantle cell lymphoma cells Muscle: Smooth/striated Gastrointestinal stromal tumour Breast duct epithelial cells Epithelium/mesothelioma panel Epithelial cells, mesothelioma panel Oestrogen receptors Blood proenzyme- platelets, histocytes, megakaryocytes	Automated method using Dako Omnis Immunostainer CP-SOP-1 CD138 CDX2 CEA Chromogranin CK 5 CK 7 CK 20 Cyclin D1 Desmin Dog-1 E-Cadherin EMA EP4 (Ber EP4) ER 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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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) Nerve/Melanoma Smooth muscle Nervous tissue Thyroid colloid Primary lung cancer/thyroid, mesothelioma pane Mesenchymal cells Wilm's tumour/Mesothelioma panel Prostate/prostate adenocarcinoma	Automated method using Dako Omins Immunostainer CP-SOP-1 S100 SMA Synaptophysin Thyroglobulin TTF1 Vimentin WT1 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>HUMAN BODY FLUIDS</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><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>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>FFPE and frozen sections stained as above</p>	<p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Interpretive/diagnostic microscopy using light microscopes; Olympus BX50, BX51 & BX53 and Leica DM2600 CP-SOP-32 CP-SOP-26</p>
<p>Seminal Fluid (Fertility investigation)</p>	<p><u>Andrology examination activities for the purpose of clinical diagnosis</u></p> <p>semen analysis:</p> <ul style="list-style-type: none"> - pH - Volume - Concentration - Count - Motility - Morphology 	<p>Documented in house manual method for examination of direct wet prep based on WHO Manual 2010 (5th edition) and British Andrology Society Guidelines (2012). M-SOP 16</p>
<p>Seminal Fluid (Post vasectomy)</p>	<p>semen analysis:</p> <ul style="list-style-type: none"> - Absence/presence of semen - Motility 	<p>Documented in house manual method for examination of direct wet prep based on WHO Manual 2010 (5th edition) and British Andrology Society Guidelines (2012). M-SOP 16</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	Full Blood Count (FBC) analysis of the following parameters: 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	Automated using the Horiba Yumizen 2500 analysers Spectrophotometry Flow Cytometry Aperture impedance Aperture impedance & fluorescence Calculated result Calculated result Calculated result Calculated result Flow Cytometry Flow Cytometry Flow Cytometry Flow Cytometry Aperture impedance Aperture impedance & fluorescence Aperture impedance & fluorescence SOP H-SOP-69 SOP H-EXT-28
Plasma	Plasma Viscosity	Benson BV200 Viscometer SOP H-SOP-45
Plasma Serum	Glandular Fever Screen	Monogen commercial kit, latex micro particle immunoassay SOP H-SOP-21
Whole Blood – EDTA samples	Malaria screening for: P. falciparum P. vivax P. ovale P. malariae	Thick and thin films Fields and Giemsa stain and manual microscopy Binax Now Immunochromographic test SOP H-SOP-22



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Serum	Intrinsic Factor Antibodies	Manual ELISA SOP H-SOP-26
Serum	Glucose 6 phosphate dehydrogenase screen (G6PD)	Visual qualitative fluorescence Trinity Biotech kit SOP H-SOP-28
Plasma	Routine Coagulation testing for:	Automated method using Stago Star Max analysers
	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	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
Whole blood - EDTA	Detection of Glycosylated Hb	HPLC Automated method using the TOSOH G8 analysers SOP H-SOP-58
Whole blood - EDTA	Antenatal Haemoglobinopathy Screening	Automated method using the Horiba Yumizen 2500 analysers for FBC and HPLC using the TOSOH G8 analysers SOP H-SOP-35



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Whole blood - EDTA	Detection of haemoglobin S (Hb-S)	Microgen Solubility test SOP H-SOP-35
Whole blood – EDTA Urine	Detection of iron	Light microscopy following Perl's Prussian Blue iron staining SOP H-SOP-15
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
Whole Blood – EDTA samples	CD4 Count	Pima analyser – cartridge based monoclonal antibodies to T cells H-SOP-70



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Northern Devon Healthcare NHS Trust
Issue No: 006 Issue date: 26 March 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS AND TISSUES</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>Respiratory samples</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>Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)</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: Swab SOP, M-SOP-7 Wound Swab SOP, M-SOP-35 Ear Swab SOP, M-SOP-31 Eye Swab SOP, M-SOP-32 Nose/Mouth/Throat Swab SOP, M-SOP-38</p> <p>Inoculation & Incubation of Culture Media for Bacteriology SOP, M-SOP-34 Urine Analysis SOP, M-SOP-14</p> <p>Manual inoculation of enrichment culture followed by culture using 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 light microscopy M-SOP-7</p> <p>Culture and microscopy, using auramine phenol (with fluorescence microscopy) and Ziehl Neelsen (with light microscopy). M-SOP-13</p>



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HUMAN BODY FLUIDS AND TISSUES	<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	Automated using the Vitek 2 M-SOP-26
Cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc diffusion and/or automated method using the Vitek 2 and EUCAST methodology Vitek SOP, M-SOP-26 EUCAST SOP, M-SOP-42 Gradient MIC determination by E-test M-SOP-3
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis (Hays criteria)	Gram stained microscopic examination M-SOP-36
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	Fluorecent microscopy using Auramine-phenol immunofluorescent stain and light microscopy using modified ZN stain M-SOP-11



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Faeces	Detection and confirmation of Helicobacter pylori antigen	Detection by Immunochromatographic assay using RAPID Hp StAR kit and confirmation using ELISA with the Oxoid Amplified IDEIA™ Hp StAR kit M-SOP-11 and M-SOP-24
Faeces	Detection of Rotavirus and Adenovirus	One step immunochromatographic test using Biorapid ROTA-ADENO kit. M-SOP-11 Roche Cobas 4800 Automated Nucleic acid extraction, PCR amplification and detection
Male: Urine Female: Endocervical sample – self taken vaginal swab	Detection of <i>Chlamydia trachomatis</i> an <i>Neisseria gonorrhoeae</i> DNA	M-SOP-25
Skin and anogenital swab	Detection of Herpes Simplex Virus	M-SOP-45
Urine	Detection of Legionella (serogroup 1 antigen) and Pneumococcal urinary antigen	Rapid lateral flow immunoassay by Meridian TRUTM M-SOP-14



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Nasal swab or nasal pharyngeal aspirate	Detection of Influenza A/B and RSV	Automated nucleic acid extraction, PCR amplification and detection using the Cepheid GeneXpert analyser M-SOP-43
Faeces	Detection of Norovirus	M-SOP-40
Male: Urine Female: Urine or endocervical sample – self taken vaginal swab	Detection of Neisseria gonorrhoeae DNA	M-SOP-44
	<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 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 using Immucor Galileo Echo Lumena analyser and manual using Diamed 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 ^w Kell system blood group antibodies: K, k, Kp ^a , Kp ^b , Js ^a and Js ^b Duffy blood group antibodies: Fy ^a , Fy ^b Kidd blood group antibodies: Jk ^a and Jk ^b Lewis blood group antibodies: Le ^a and Le ^b P blood group antibodies P ₁ MNS blood group antibodies: M, N, S and s Lutheran blood group antibodies: Lu ^a and Lu ^b Xg blood group antibodies: Xg	Automated using Immucor Galileo Echo Lumena analyser and manual using Diamed Column Agglutination Technique SOP T-SOP-17 SOP T-SOP-4
Whole Blood – EDTA samples	Antigen phenotyping: Rh K	Tube agglutination technique.SOP T-SOP-47
Whole Blood – EDTA samples	Direct Antiglobulin Test (DAT)	Automated using Immucor Galileo Echo and manual using Diamed 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	Automated using Immucor Galileo Echo and manual cross matching using Diamed Column Agglutination technology SOP T-SOP-10
Whole Blood – EDTA samples	Foetal Maternal Haemorrhage	Manual method: Kleihauer Betke using the Guest Medical Kleihauer kit. SOP T-SOP-18 SOP T-SOP-15 SOP T-SOP-31
END		