


# 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>	<h3>Northern Devon Healthcare NHS Trust</h3> <p>Issue No: 003 Issue date: 23 October 2019</p>	
	<p><b>Pathology Department</b> North Devon District Hospital Raleigh Park Barnstaple EX31 4JB United Kingdom</p>	<p><b>Contact: Bruce Seymour</b> Tel: +44 (0)1271 335758 E-Mail: bruce.seymour@nhs.net Website: <a href="http://www.northdevonhealth.nhs.uk/pathology/">www.northdevonhealth.nhs.uk/pathology/</a></p>
<p>Testing performed at the above address only</p>		

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

Location details	Activity
<p>Tyrell Hospital – Lantern Suite St. Brannocks Park Road Ilfracombe Devon EX34 8JF</p>	<p>Blood storage &amp; issue Fridge managed by laboratory</p>
<p>South Molton Hospital – Room off of Hugh Squire Ward Widgery Drive South Molton Devon EX36 4DP</p>	<p>Blood storage &amp; issue Fridge managed by laboratory</p>
<p>Torrington Hospital – Treatment Room Calf Street Torrington Devon EX38 7BJ</p>	<p>Blood storage &amp; issue Fridge managed by laboratory</p>
<p>Holsworthy Hospital – Room off of the Ward Dobles Lane Holsworthy EX22 6JQ</p>	<p>Blood storage &amp; issue Fridge managed by laboratory</p>
<p>North Devon Hospice – Room off the Treatment Area of the Bedded Unit Deer Park Newport Barnstaple Devon EX32 0HU</p>	<p>Blood storage &amp; issue Fridge managed by laboratory</p>
<p>Stratton Hospital – Room off the Ward Stratton Bude Cornwall EX23 9BR</p>	<p>Blood storage &amp; issue Fridge managed by laboratory</p>



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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)



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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:	Roche c501 analyser using Ion Selective Electrodes:
Serum & urine	Chloride	B-SOP-COB-38
Serum & urine	Potassium	
	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
	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 (cont'd):</u>	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	Roche c501 analyser using immuno-turbidimetric assays B-SOP-COB-10
	IgA	B-SOP-COB-18
	IgG	B-SOP-COB-19
	IgM	B-SOP-COB-20
	Rheumatoid Factor	B-SOP-COB-66
Urine	Microalbumin	B-SOP-COB-35
Serum and urine Serum	Creatinine	Roche c501 analyser using enzymatic assays B-SOP-COB-9
	Ethanol	B-SOP-COB-13
	Paracetamol	B-SOP-COB-37
	Salicylate	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 (cont'd):</u></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 CO<sub>2</sub> &amp; 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 &amp; protein.</p> <p>Creatinine clearance</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>



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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	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
Whole Blood	Blood gas analysis pH pCO <sub>2</sub> pO <sub>2</sub> tHb Oxygen saturation Carboxyhaemoglobin Methaemoglobin Lactate	Radiometer ABL90 Flex - blood gas, oximetry and metabolite using manufacturer sensor & reagent pack B-SOP-MAN-43 B-SOP-MAN-5 B-SOP-MAN-22
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	Porphyrins (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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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue: biopsy, excision, resection and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection CP-SOP-23 CP-SOP-21 CP-METHOD-CUT-1-24
Formalin Fixed paraffin embedded (FFPE) tissue		Tissue Processing using Thermo Excelsior AS tissue processors CP-SOP-19
		Tissue Embedding using Thermo Histostar embedding centre CP-SOP-6
		Tissue Sectioning using Leica microtomes (RM2235 and RM2245) CP-SOP-12
		Frozen sections using Thermo Cytotome CP-SOP-8
FFPE sections and frozen sections	Routine morphological staining for the detection of: Basophilic and eosinophilic structures	Routine morphological staining using Leica ST5020 multistainer using Haematoxylin and Eosin (H&E) and coverslipped using Leica CV5020 and manual method CP-SOP-14 CP-SOP-24 CP-METHOD-SPEC-10 H&E
FFPE sections	Special stains for the detection of:	Automated staining using Leica ST5020 multistainer
	Neutral Mucins, fungi, glycogen	PAS
	Acid/neutral mucins	ABPAS





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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
	HepB surface antigen and Copper Associated Protein	CP-METHOD-SPEC-15 Orcein
	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 Leica Bond III 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 Leica Bond III 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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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE sections (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Plasma cells</p> <p>Colonic adenocarcinoma</p> <p>Colonic carcinoma</p> <p>Neuroendocrine cells</p> <p>Epithelial cells/mesothelioma panel</p> <p>Epithelial cells</p> <p>Epithelial cells</p> <p>Mantle cell lymphoma cells</p> <p>Muscle: Smooth/striated</p> <p>Gastrointestinal stromal tumour</p> <p>Breast duct epithelial cells</p> <p>Epithelium/mesothelioma panel</p> <p>Epithelial cells, mesothelioma panel</p> <p>Oestrogen receptors</p> <p>Blood proenzyme- platelets, histocytes, megakaryocytes</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Automated method using Leica Bond III CP-SOP-1</p> <p>CD138</p> <p>CDX2</p> <p>CEA</p> <p>Chromogranin</p> <p>CK 5</p> <p>CK 7</p> <p>CK 20</p> <p>Cyclin D1</p> <p>Desmin</p> <p>Dog-1</p> <p>E-Cadherin</p> <p>EMA</p> <p>EP4 (Ber EP4)</p> <p>ER</p> <p>F13a</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)	Immunohistochemistry to detect the following: (cont'd)	Automated method using Leica Bond III 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 Leica Bond III 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><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><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 Leica Autostainer. 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><u>Andrology examination activities for the purpose of clinical diagnosis</u></p>	<p>Interpretive/diagnostic microscopy using light microscopes; Olympus BX50, BX51 &amp; BX53 and Leica DM2600 CP-SOP-32 CP-SOP-26</p>
<p>Seminal Fluid (Fertility investigation)</p>	<p>semen analysis:</p> <ul style="list-style-type: none"> <li>- pH</li> <li>- Volume</li> <li>- Concentration</li> <li>- Count</li> <li>- Motility</li> <li>- Morphology</li> </ul>	<p>Documented in house manual method for examination of direct wet prep based on WHO Manual 2010 (5<sup>th</sup> 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"> <li>- Absence/presence of semen</li> <li>- Motility</li> </ul>	<p>Documented in house manual method for examination of direct wet prep based on WHO Manual 2010 (5<sup>th</sup> 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 Pentra DX Nexus 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 Immunochromatographic 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 Pentra DX Nexus analysers for FBC and HPLC using the TOSOH G8 analysers SOP H-SOP-35



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**Northern Devon Healthcare NHS Trust**  
**Issue No:** 003    **Issue date:** 23 October 2019

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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:
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 Shandon Varistain 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 Shandon Varistain 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 Pentra DX Nexus 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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<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):
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	Isolation of micro-organisms of clinical significance	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 Mose/Mouth/Throat Swab SOP, M-SOP-38  Inoculation & Incubation of Culture Media for Bacteriology SOP, M-SOP-34 Urine Analysis SOP, M-SOP-14
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual inoculation of enrichment culture followed by culture using chromogenic culture media M-SOP-15
Blood	Isolation of micro-organisms of clinical significance	Liquid media culture of anaerobic, aerobic and paediatric culture broths using BD BacTec FX400 and FX40 M-SOP-8
Urine	Quantification of white blood cells	Manual examination using light microscopy M-SOP-14
CSF	Quantification of white and red blood cells and bacteria	Manual examination using light microscopy M-SOP-7
Respiratory samples	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Culture and microscopy, using auramine phenol (with fluorescence microscopy) and Ziehl Neelsen (with light microscopy). M-SOP-13



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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	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® <i>C. Diff</i> 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</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  Dynex Technologies DS2 analyser using ELISA M-SOP-82
Serum	Serology tests to detect the following:  Syphilis confirmation (Antibody to <i>treponema Pallidum</i> )  Hepatitis B surface antigen  HIV 1 and 2 antigen/antibody	Syphilis Bioelisa enzyme immunoassay kit  Bioelisa HBs Ag enzyme immunoassay  Genscreen ULTRA HIV Ag-Ab enzyme immunoassay
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
END		