

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



Accredited to  
ISO 15189:2022

### Sheffield Teaching Hospitals NHS Foundation Trust

Issue No: 015 Issue date: 03 December 2025

Department of Cellular and  
Infectious Sciences  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
S10 2JF

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Testing performed by the Organisation at the locations specified below

#### Locations covered by the organisation and their relevant activities

##### Laboratory locations:

Location details	Activity	Location code
<b>Address</b> Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF	<b>Local contact</b> Stephanie Parr stephanie.parr3@nhs.net  Histopathology Diagnostic Cytopathology	A
<b>Address</b> Laboratory Medicine Centre (North Lane) Northern General Hospital Herries Road Sheffield S5 7AU	<b>Local contact</b> Stephanie Parr stephanie.parr3@nhs.net  Leeanne Tovey leeanne.tovey@nhs.net  Rapid frozen section for intraoperative reporting Microbiology Department	B
<b>Address</b> Department of Histopathology Chesterfield Royal Hospital Calow S44 5BL	<b>Local contact</b> Greg Zardin greg.zardin2@nhs.net  Histopathology Department	C

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

Location details	Activity	Location code
Dermatology Clinic, Royal Hallamshire Hospital	Mohs rapid frozen section service	D



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**DETAIL OF ACCREDITATION**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS	<u>Histopathology</u>		
Formalin fixed tissues	Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)  Macroanalysis and dissection: Manual method using: HIRD 015 and 017  Decalcification: Manual method using HIRD 027  Tissue Processing: Automated method using HIML086 and Sakura VIP5 & 6, and Leica Peloris tissue processors  Embedding: Manual method using HIML075 and Sakura, Leica and Thermo embedding centres.  Microtomy: Manual method using HIML093 and Leica RM2235 and Microm HM 325 microtomes	A
Tooth		Preparing ground tooth sections using EXACT 300/30 Diamond Band Saw and HIML125	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	
Fresh and frozen tissue	Intraoperative diagnosis	Rapid frozen section: Cryotomy and manual H&E staining using Leica CM1950 Cryostat and HIMAL 131, HIMED067, HISL003, HIMAL 077, HISL007	A, B
Stained tissue section on glass slide	Intraoperative diagnosis	Scanning of glass slides using Hamamatsu Nanozoomer 2.0RS Scanner and HISL003, HIMED056	B
Scanned image of frozen section on glass slide	Intraoperative diagnosis	Viewing slide image using Dell monitor and primary reporting using HIMED067, Reporting for Primary Digital Reporting	A
Fresh and frozen tissue	Intraoperative diagnosis	Rapid frozen section Moh's micrographic technique: Cryotomy and manual H&E using Leica CM1950 Cryostat and HIMAL048	D
Skin	Detection of inflammatory skin disease	Direct Immunofluorescence using Bright cryostat and HIMAL039, 036	A
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides	Basophilic and eosinophilic tissue structures	Routine Haematoxylin and eosin (H&E) staining and coverslapping: Automated method using HIMAL090 Leica HistoCore Spectra ST autostainers, Leica HistoCore Spectra CV coverslippers	A
Formalin fixed paraffin embedded (FFPE) tissue	Detection of the following:  Acid mucins	Special staining: Manual methods and the following stains  Alcian Blue HISM006	A



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HUMAN TISSUES AND FLUIDS (cont'd)  Formalin fixed paraffin embedded (FFPE) tissue (cont'd)	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)  Detection of the following: (cont'd)  Acid and neutral mucopolysaccharides  Calcium deposits  Amyloid  Acid and neutral mucopolysaccharides  Basement membranes, neutral mucins  Differentiation of haematopoietic cell lineages and mast cells  Helicobacter pylori  Reticulin  Gram positive and Gram negative bacteria  Glomerular basement membrane  Fungi  Myelin	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)  Special staining: Manual methods and the following stains  Alcian Blue PAS HISM006  Alizarin Red HISM076  Congo Red HISM007  Diastase Alcian Blue PAS HISM006  Diastase PAS HISM011, 034  Giemsa (Lennert's) HISM001  Giemsa (Modified) HISM015  Gordon and Sweets Reticulin HISM008  Gram Twort HISM061  Grocott's Methenamine Silver for renal basement membranes HISM027  Grocott's Methenamine Silver HISM025  Luxol Fast Blue HINP030	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)  Detection of the following: (cont'd)  Myelin Melanin Collagen Collagen Elastin and collagen Acid glycoproteins Fibrin deposits Acid mucins Hepatitis B surface antigen Basement membranes, neutral mucins, glycogen Fungi Iron Amyloid	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)  Special staining: Manual methods and the following stains  Luxol Fast Blue/Cresyl Fast Violet HINP030  Masson Fontana HSMP030  Masson Trichrome HISMP010  Masson Trichrome (Goldner's) HISMP063  Miller's Elastic Van Gieson HISMP031  MILAB HISMP066  MSB HISMP004  Mucicarmine HISMP022  Orcein (Shikata) HISMP067 (A) and CRHHIS-HIST022 (C)  Periodic Acid Schiff (PAS) HISMP011 (A) and CRHHIS-HIST022 (C)  PAS for fungi HISMP011 (A) and CRHHIS-HIST022 (C)  Perls' Prussian Blue HISMP005(A) and CRHHIS-HIST022 (C)  Sirius Red HISMP019 (A) and CRHHIS-HIST022 (C)	
Formalin fixed paraffin embedded (FFPE) tissue (cont'd)			A
			A
			A
			A
			A
			A
			A
			A, C



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)  Detection of the following: (cont'd)  Neutral triglycerides Mast cells Calcium salts Acid fast bacilli Spirochetes Acid fast bacilli Elastin and Copper Protein Reticulin  Cytology cell blocks  Frozen sections only	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)  Special staining: Manual methods and the following stains  Sudan Black HISM041 Toluidine Blue HISM048 Von Kossa HISM020 Wade Fite HISM055 Warthin Starry HISM024 Ziehl-Neelsen HISM021 Orecin (Shikata) CRHHIS-HIST022 Reticulin CRHHIS-HIST022 Papanicolaou CRHHIS-HIST022 Oil Red O Toluidine Blue Von Kossa Wade Fite Warthin Starry	
Formalin fixed paraffin embedded (FFPE) tissue (cont'd)		A	A
		A	A
		A	A
		A	A
		A	A, C
		C	C
		C	C
		C	C



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HUMAN TISSUES AND FLUIDS (cont'd)  Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)  Detection of the following:  Extra cellular beta-amyloid Corticotrophs Squamous and columnar epithelium Hepatocytes ALK protein Myeloid cells, macrophages Lewy bodies Androgen Receptors Phosphatase sensitive epitope Marker of Alzheimer's disease	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)  Immunohistochemistry:  Manual staining*** Leica ST5020 stainer and CV5030 coverslipper HIIC028  Automated methods using Ventana Benchmark Ultra**** Dako Omnis autostainer* Dako 48 Link Autostainer** and SOPs HIIC002, HIIC003, HIIC009, HIIC010, HIIC015, HIIC016, HIIC017, HIIC018, HIIC019, HIIC041, HML036, HIIC046  Dako Auto immunostainer and DAKO PT link machines as relevant CRHHIS-HIST042^  A4 (beta amyloid) ** ACTH** AE1/AE3*/^ AFP* ALK-1*, **** Annexin* Alpha-Synuclein*** AR**** AT8** BAPP*	A A C A A A, C A A A A A A A A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Benign melanocytic nevi	BAP1	A
	Desmoid tumour, colorectal cancer	Beta-Catenin*	A
	Lymphocytes	BCL-2*/^	A, C
	Lymphoma	BCL-6*	A
	Adenocarcinoma	BEREP4*/^	A, C
	Trophoblasts	Beta HCG	A
	Renal allograft rejection	C4d, ****	A
	Ovarian carcinoma	Ca125*	A
	Gastrointestinal cancer	Ca19.9*	A
	C-cell hyperplasia	Calcitonin*	A
	Malignant mesotheliomas	Calretinin*/^	A, C
	Lymphomas	c-MYC****	A
	Malignant epithelial cells	CAM 5.2*	A
	Burkett lymphoma	CD10*/^	A, C
	Multiple myelomas	CD138*	A
	Kit Protein Receptors	CD117 (CKIT)**	A
	Hodgkin's lymphoma	CD15*/^	A
	Thyomas	CD1a*	A
	T-cell lymphoma	CD2*	A



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HUMAN TISSUES AND FLUIDS (cont'd)  Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	<p><u>Histopathology</u> (cont'd)</p> <p>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Detection of the following: (cont'd)</p> <p>Renal cell carcinoma</p> <p>S100 positive neoplasms</p> <p>Leiomyomas, leiomyosarcomas and pleomorphic adenovirus</p> <p>Labels myoepithelial cells in breast</p> <p>Melanocytes and myoepithelial cells</p> <p>Mantle cell lymphoma</p> <p>Solitary fibrous tumours</p> <p>Polyoma virus</p> <p>Neuroendocrine neoplasms</p> <p>Differentiation of frontotemporal dementia</p> <p>Thymic and Bone marrow cortical lymphocytes</p> <p>Vascular tumours, mesothelial cells and peripheral nerves</p> <p>Tumours of thyroid origin</p> <p>T cell lymphomas</p> <p>Classification of pituitary tumours</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Immunohistochemistry:</p> <p>RCC*</p> <p>S100*/^</p> <p>SMA*/^</p> <p>SMM**</p> <p>SOX10****</p> <p>SOX11****</p> <p>STAT6****</p> <p>SV40*</p> <p>SYNAP*/^</p> <p>TDP43**</p> <p>TDT*</p> <p>Thrombomodulin**</p> <p>Thyroglobulin*</p> <p>TIA1*</p> <p>TSH**</p>	A A, C A, C A A A A A A, C A A A A A A A A A A



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HUMAN TISSUES AND FLUIDS (cont'd)  Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)  Slides produced from location C processes listed above	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)  Detection of the following: (cont'd)  Tumours from lung and thyroid  B-cell chronic lymphocytic leukaemia/small lymphocytic lymphoma  Labels nucleus of ovary and kidney cells  Microscopic Examination for the purposes of clinical diagnosis	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)  Immunohistochemistry:  TTF1*/^  VIMENTIN*  WT1**, ****  <u>Interpretive Microscopy (qualitative analysis)</u> CRH-PATH001 and CRH-PATH018. Light microscopy using Nikon microscopes	A, C  A  A  C



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed paraffin embedded tissue samples	Detection of the following:  EGFR mutation analysis in lung. BRAF for melanoma KRAS for colorectal cancer NRAS/BRAF mutations in colorectal cancer KRAS for lung cancer Braf for lung cancer Non-Small Cell Lung Cancers MSI mutations for 1 <sup>st</sup> line screening in Lynch syndrome NRAS/BRAF in second line Lynch screening	Using in-house procedures in conjunction with manufacturer's instructions (where relevant) Real-time PCR using the Biocartis Idylla™ SOP HIIC048 and HIMED074  EGFR Mutation Test BRAF Mutation Test KRAS Mutation Test NRAS-BRAF Mutation Test KRAS Mutation Test BRAF Mutation Test Gene Fusion PCR based Test MSI Test NRAS-BRAF Mutation Test	A  A A A, C A, C A A A A, C A
Post-mortem lung tissue	Microscopic analysis and counting of asbestos fibres	Manual in-house procedure using HIML114	A
Lymph node tissue	Detect the expression level of Cytokeratin 19 normally not present in lymph node tissue.	One Step Nucleic Acid Amplification (OSNA) using Sysmex RD210 analyser and HIML114	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Neuropathology examination activities to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
Nerve biopsy	<u>Detection of myelinated nerve fibres</u>	Nerve Tease preparation using the Olympus SZX12 dissection microscope and KL1500 LCD light source, HINP032	
Tissue samples, predominantly from the central nervous system on FFPE slides (Formalin fixed paraffin embedded)	Detection of the following:  Neuronal architecture or the Nissl Substance  Senile plaques and neurofibrillary tangles  Senile plaques and neurofibrillary tangles  Myelin  Myelin	Manual staining using the following stains:  Cresyl Fast Violet, HINP023  Gallyas, HINP009  Modified Bielschowsky, HINP048  Luxol Fast Blue, HINP030  LFB/Cresyl Fast Violet, HINP030	
Frozen sections of muscle tissue	Detection of the following:  Basophilic and eosinophilic structures  Acid phosphatase activity  Fibre types  Cytochrome oxidase activity	Cryotomy using the Leica CM3050S Cryostat and HIN035 followed by manual staining using the following:  Rapid H&E HINP052  Acid Phosphatase HINP027  ATPase at pH 4.3, 4.6, 9.4 HINP036  Cytochrome oxidase HINP028	



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HUMAN TISSUES AND FLUIDS (cont'd)	<p><u>Neuropathology (cont'd)</u></p> <p>Preparation and examination to identify or exclude morphological and cytological abnormalities</p> <p>Detection of the following:</p> <p>Cytochrome oxidase positive fibres and Cytochrome oxidase negative fibres</p> <p>Nuclei, muscle fibres, mitochondria, sarcoplasmic reticulum, connective tissue, sarcolemma.</p> <p>Myoadenylate deaminase activity</p> <p>Phosphorylase activity</p> <p>Mitochondria and sarcoplasmic reticulum</p> <p>Glycogen</p> <p>Phosphofructokinase activity</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Cryotomy using the Leica CM3050S Cryostat and HIN035 followed by manual staining using the following:</p> <p>Cytochrome oxidase/SDH HINP033</p> <p>Engels Gomori Trichrome HINP031</p> <p>Myoadenylate Deaminase HINP043</p> <p>Myophosphorylase HINP010</p> <p>NADH-TR HINP024</p> <p>PAS/DPAS HINP034</p> <p>Phosphofructokinase HINP042</p> <p>Succinate Dehydrogenase HINP019</p> <p>Sudan Black HINP042</p>	A
Fresh brain tissue	<p>Detection of the following</p> <p>Basophilic and eosin structures</p> <p>Nuclei cytoplasm</p>	<p>Brain smear preparation HINP004 and manual staining using the following:</p> <p>Rapid H&amp;E HIM105</p> <p>Rapid Toluidine blue HINP053</p>	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
Urine, fluids, aspirates, sputum	Examination of cellular material to identify or exclude morphological and cytological abnormalities	TriMat class1 microbiological safety cabinet, HIHID062, HISC037.  Thermo IEC CL30 centrifuge Boeco U-320 centrifuge, Thermo scientific Cytospin 4, Thermo scientific HISC040.	A
Body fluids, Aspirates, FNA, brushings, washings	Detection of abnormal cells	Papanicolaou stain HISC020, May-Grunwald stain HISC018 and, H&E stain HISC008 performed on the MYREVA SS-30 autostainer SOP HISC047	A
Slides produced from processes listed above	Microscopic Examination for the purposes of clinical diagnosis	Using Leica stainer and cytospin stains used are PAP, H&E and Romanowsky -SOP: CRHHIS-NGY013	C
Slides produced from processes listed above	Interpretive Light microscopy using: Nikon microscopes (qualitative analysis) SOPs: CRH-PATH001 and CRH-PATH018		C
Stained tissue section on glass slide	Pathologist reporting of Histopathology slides HIMED066 Final Authorisation of Reports HIMED051	Pathologist reporting of Histopathology slides HIMED066 Final Authorisation of Reports HIMED051	A
	Scanning and Primary reporting from Digital images of Upper & Lower GI, Skin, Urology, Breast, Gynae using 3DHistech P1000 digital slide scanner SOP HIML137 and HIML136, HIMED067, HIMED069	Scanning and Primary reporting from Digital images of Upper & Lower GI, Skin, Urology, Breast, Gynae using 3DHistech P1000 digital slide scanner SOP HIML137 and HIML136, HIMED067, HIMED069	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis</u>	Documented in-house methods based on related UK SMIs and equipment manuals as relevant to meet the requirements of the IDPS screening programme as defined in the laboratory QA evidence requirements	
Serum and Plasma	Detection of the following: Hep A IgM Antibody Hep A Total Antibody	Roche Cobas 8000 immunoassay, and SOP VIAS044	B
Serum and Plasma	Hep B Total Core Antibody		
Serum and Plasma	Hep B Core IgM Antibody		
Serum and Plasma	Hep B Surface Antibody		
Serum and Plasma	Hep B s Antigen Neutralisation		
Serum, Dry Blood Spot and Plasma	Hep B Surface Antigen		
Serum, Dry Blood Spot and Plasma	Hep C Antibody		
Serum, Dry Blood Spot and Plasma	HIV Ag/Antibody combo		
Serum and Plasma	Rubella IgG Antibody		
Serum and Plasma	Syphilis Antibody IgG		
Oral fluid samples	HIV Ab		
Serum and plasma	COVID-19 Antibody testing - Anti SARS CoV 2 total antibody (qualitative)	Roche Cobas 8000 Immunoassay and SOP VIAS044	B
Serum and plasma	Anti SARS CoV 2 spike antibody (qualitative)		
Serum and plasma	Detection of the following : HBe Ag HBe Ab HBsAg (2nd line) HBsAg Quantitative Hepatitis C Antibody (2nd line) HIV Ab/Ag (2nd Line) Borrelia IgG CMV IgG CMV IgM CMV Avidity EBV IgM (Clinical) EBV VCA IgG	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
	Syphilis		
	Hepatitis E IgM		
	Hepatitis E IgG		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum and plasma	Detection of the following : EBV NA IgG HSV Immunity HTLV I + II Measles Immunity Mumps Immunity Parvovirus Immunity Parvovirus Clinical Rubella IgM Toxoplasma IgG Toxoplasma IgM VZV Immunity	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Faeces	Detection of <i>Helicobacter Pylori</i>	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Oral fluid samples	Detection of HIV Antibody	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045, and the HIV Genscreen EIA using SOP VISE035	B
Serum	Detection of Hepatitis E IgG and Hepatitis E IgM	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Serum	Detection of Hepatitis D	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Serum and plasma	Detection of the following: HIV Ag/Ab, HCV Ag/Ab, Syphilis total antibody Syphilis IgM Mycoplasma pneumonia IgG, IgA and IgM, VZV glycoprotein IgG	BioRad Evolis Twin Plus (ETP) Automated EIA platform, using the following kits and SOPs: BioRad Genscreen Ultra BioRad Genscreen Enzygnost Syphilis NMT Syphilis IgM Launch Virion/Serion ELISA Classic: Mycoplasma pneumonia IgG, IgA and IgM VaccZyme VZV glycoprotein IgG low level EIA. SOP VISE067	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum and plasma	Detection of VZV IgG	Manual ELISA using the following kit: VaccZyme VZV glycoprotein IgG low level EIA and SOP VISE058	B
Serum and plasma	Detection of the following: Mycoplasma IgA, IgM, IgG	Manual ELISA using Launch Virion/Sirion VISE060	B
Serum	Qualitative detection of the following: ASO	Latex agglutination using Rheumajet ASO and VISE046	B
Serum and CSF	Treponema pallidum IgG	Particle agglutination using Serodia TPPA and VISE019	B
Serum and CSF	Antibodies to VDRL antigen	Slide flocculation using Launch Diagnostics ASI RPR kit VISE017	B
Serum and Plasma	Detection of HIV antibody	Bio-Rad Geenius immunochromatographic and SOP VISE057	B
Serum	Qualitative detection of $\beta$ -D-Glucan	Cape Cod Fungitell Stat, a protease zymogen-based colorimetric assay SOP VIAS050	B
Faeces	Clostridioides GDH	RIDAQUICK lateral flow GDH BAEN002	B
Urine	Detection of Legionella urinary antigen	Sofia EIA and SOP BAUR011	B
Serum, CSF	Cryptococcal antigen	IMMY CrAg lateral flow assay (BASF014)	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Serum and plasma	Quantitative detection of HBV and HCV viral load	Quantitative PCR using the Hologic Panther Aptima and SOP VIMO0051	B
Dry blood spots	Qualitative detection of HCV	Qualitative PCR using Hologic Panther Aptima and SOP VIMO0051	B
Genital swabs and urine	Detection of DNA for Chlamydia trachomatis and Neisseria gonorrhoeae	Hologic Panther quantitative TMA and SOPVICH023	B
Presumptive Neisseria gonorrhoeae bacterial isolates from genital samples	Detection of Neisseria gonorrhoeae DNA	Hologic Panther quantitative TMA and SOPs BAGE001 and VICH023	B
Genital swabs	Detection of Trichomonas vaginalis DNA	Hologic Panther using quantitative TMA SOP VICH023	B
Throat swab and combined Nose/Throat Swabs in - Viral Transport Media - Universal Transport Media	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequence: ORF1ab	Hologic Aptima SARS-CoV-2 assay using the Hologic Panther system SOP VIVI004 and VICH023	B
Nasopharyngeal aspirate, Sputum			
Serum and plasma	Quantitative detection of HIV type 1 RNA	Quantitative assay using the Hologic Panther Aptima assay (VIMO051)	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
CSF	Identification of pathogens in nucleic acid extracts Detection of: CMV EBV HSV1 HSV2 Adenovirus Enterovirus Paraechovirus HHV6 HHV7 VZV	Hologic Panther using Aus-diagnostics Viral 12-well Panel; CSF Viral (12-well) semi-automated IVD. SOP VIMO078	B
Serum, plasma, Roche PCR product	Hep C genotyping	Autoblot 3000 Immunoblot assay and SOP VIMO003	B
Blood, plasma, dry blood spot, urine, CSF	Quantitative detection of: CMV viral load EBV viral load	Roche MagNAPure 96 extraction and Qiagen Rotorgene amplification using SOP VIMO035	B
Blood, plasma, swabs, CSF, NPA, sputum, BAL, urine	Quantitative detection of: BK virus HHV6	Roche MagNAPure 96 extraction and Qiagen Rotorgene amplification	B
Blood, swabs, tissue	Quantitative detection of: Parvovirus	Roche MagNAPure 96 extraction and Qiagen Rotorgene amplification	B
Blood, plasma, swabs, CSF, NPA, Sputum, BAL, faeces, vomit	Qualitative detection of the following:  Respiratory virus (Influenza A, B, RSV, Rhinovirus, Parainfluenza 1, 2, 3, 4, HMPV, Coronavirus, Adenovirus) Herpes simplex VZV Adenovirus Enterovirus Measles	Qualitative PCE using Roche MagNAPure 96 extraction and ABI 7500 amplification and SOPs: VIMO020  VIMO027 VIMO027 VIMO020 VIMO006 VIMO019	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Swabs, CSF, sputum, urine	Qualitative detection of Mumps	Qualitative PCR, using Roche MagNAPure 96 extraction and ABI 7500 amplification SOP VIMO048	B
Skin swabs, penile swabs, nose and throat swabs	Quantitative detection of Monkey Pox (DNA) virus, specifically, G2R, F3L and C3L genes	Qualitative PCR using Roche MagNAPure extraction and qualitative PCR by ABI 7500 following SOPs VIVO026 and VIMO073.	B
Nose swabs, throat swabs, nose/throat swabs	Detection of Mers CoV (RNA) virus specifically genes E (upE) and 1a (orf1a)	Qualitative PCR using Roche MagNAPure extraction and ABI 7500 with Realstar MERS CoV RT PCR kit Altona following SOPs VIVO026 and VIMO056	B
Blood, plasma	Hepatitis E	Quantitative PCR using Qiacube Extraction and ABI 7500. SOP VIVI023 & VIMO042	B
Swabs, sputum, BAL	Detection of Atypical respiratory organisms (Mycoplasma pneumoniae, Chlamydia pneumoniae & Chlamydia psittaci)	PCR and Extraction using the Roche MP96 and Amplification and Detection using the ABI7500 SOP VIMO046 and VIMO047	B
Sputum, BAL	Detection of Pneumocystis jirovecii (PCP)	PCR and extraction using the Roche MP96 and amplification and detection using the ABI7500 SOP VIMO071	B
All respiratory samples (swabs, BAL, NPA, ETS)	Detection of respiratory viruses: Parainfluenza 1-4, Rhinovirus, Coronavirus , RSV A/B , Human Metapneumovirus Adenovirus	PCR using the Roche FLOW system and MagnaPure 96 extraction system SOP VIMO052 and VIMO053	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Nose swab, throat swab and combined Nose/Throat Swabs in - Viral Transport Media - Universal Transport Media	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: RdRp gene and E gene	In-house real-time PCR assay using QuantaBio Custom XLT mastermix facilitated by MagNa Pure Extraction and the Hamilton PSH Liquid Handling Unti and ABI 7500, SOP VIVI004, VIVI026, VIMO052 and VIMO064. Thermal extraction followed by ABI 7500 SOP VIVI004, VIMO052 and VIMO064.	B
Nasopharyngeal aspirate, Sputum, Bronchoalveolar lavage			B
Nose swab, throat swab and combined Nose/Throat Swabs in Viral Transport Media Universal Transport Media	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: N and E gene	PCR using the Roche FLOW system and MagnaPure 96 extraction system	B
Combined nose/throat swabs	Detection of SARS CoV-2 virus RNA (COVID-19)	SAMBA II SARS-CoV-2 test following SOP, VIM068a	B
		Abbott ID following SOP, POCT23	A, B
Respiratory tract secretions	Detection of Mycobacterium tuberculosis (MTB) complex DNA and rifampicin-resistance associated mutations of the rpoB gene.	PCR and Cepheid GeneXpert System SOP BARE039	B
Rectal and perirectal swabs Bacterial isolates	Detection of Carbapenem Resistant Organisms	Cepheid GeneXpert System and SOP BAIC016	B
Nose swab, throat swab and combined Nose/Throat Swabs	Detection of SARS CoV2 PCR (qualitative) target genes N2 and E	Cepheid GeneXpert real-time PCR and SOP VIMO065	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Faeces	<u>Detection of the following faecal pathogens:</u>  <i>Campylobacter</i> species <i>Salmonella</i> species <i>Shigella</i> species Toxin producing <i>Escherichia coli</i> (including O157)  Rotavirus Adenovirus Norovirus Astrovirus  Giardia lamblia <i>Cryptosporidium</i> species <i>Entamoeba histolytica</i>  <i>Clostridioides difficile</i> toxin A/B	PCR using the Roche FLOW system, and MagnaPure 96 extraction system, SOP BAEN027, and the following:  R-Biopharm RIDAGENE bacterial stool panel I  R-Biopharm RIDAGENE viral stool panel I  R-Biopharm RIDAGENE parasite stool panel II  R-Biopharm RIDAGENE <i>Clostridioides</i> toxin A/B stool panel	B
AAFB positive cultures	Identification of <i>Mycobacterium tuberculosis</i> complex	HAIN TB Check MPT64	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)  Swabs from wounds, ulcers, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, faeces, sterile fluids, pus,	<u>Microbiology examinations for the purposes of clinical diagnosis</u>  Isolation and identification of microorganisms of clinical significance	In-house documented procedures based on equipment manuals as relevant  Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs: Wound swabs (inc. T/S, N/S, etc), fluids and tissues from sites not expected to be sterile and Neonate screens [BAWS001, BAWS002 &BAWS003] Genital tract swabs [BAGE001] N.gonorrhoeae [BAGE001] CSF culture and shunts [BASF003] Fluid from sites expected to be sterile CAPD fluid [BASF011] Corneal scrape and anterior chamber and vitreous taps [BAMI002] Contact lenses and fluid and corneal grafts [BAMI001] Heart valve culture [BAMI010] intra-venous lines and pacing wire tips [BAMI003] Faecal culture [BAEN001] H pylori culture [BAEN012] Orthopaedic tissue culture [BATI002] MSSA by culture [BAIC004] Multi-resistant Gram Negatives by culture [BAIC001] MRSA by culture [BAIC006] Vancomycin resistant enterococci (VRE) [BAIC002] Respiratory bacterial pathogens by culture [BARE003, BARE006] Cystic fibrosis respiratory culture [BARE001]	B
Skin, hair, nails Urine		Mycology by culture [BAMY001] Urine culture (BAUR001)	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Respiratory fluids, CSF, sterile fluids, pus, tissue, urine	Isolation and identification of microorganisms of clinical significance	Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs:	B
Urine	Detection of WBC, RBC, epithelial cells, casts	IQ Sprint urine analyser using automated microscopy and BAUR003	B
	Microscopic examination of for qualitative detection of the following:		
Urine	White and red blood cells, casts, epithelial cells	Light microscopy using inverted microscope and SOP BAUR001	B
CSF	Cell count and differential cell count	Manual cell count using SOP BASF003	B
Faeces	Ova, cysts and parasites	Wet preparation using light microscopy and concentration using Parasep(BAEN022)	B
Skin, hair, nails	Fungal elements	Wet preparations on microscope slides using epi-fluorescent microscopy and SOP BAMY001	B
Vaginal swabs	Clue cells	Stained slides by epi-fluorescent microscopy and SOP BAGE004	B
Respiratory samples, fluids, tissues	Acid fast bacilli	Stained auramine slides and epi-fluorescent microscopy, BAGP002	B
Blood	Detection of microbial growth	BD FX analyser using SOP BABC016	B
Blood	Detection and presumptive identification of acid fast bacilli, including Mycobacterium species	Bactec BDFX40 using SOP BARE037	B



**Schedule of Accreditation**  
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**Sheffield Teaching Hospitals NHS Foundation Trust**

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**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Sputum, tissues, urine, fluids	Detection and presumptive identification of acid fast bacilli, including Mycobacterium species	BD MGIT analyser using SOP BARE05	B
		Mycobacterium culture using LJ media and SOP BARE005	B
Isolates of bacteria and yeasts	Identification of bacteria and yeast	Bruker Maldi-ToF Biotyper using mass spectrometry, and Bruker MALDI-SMART SOP BAAS024	B
Isolates of bacteria	Determination of antimicrobial susceptibility	Disc diffusion using EUCAST method and SOP BAAS001	B
		MIC by strip diffusion using E test and MICE, SOP BAAS003	B
		Breakpoint method using EUCAST breakpoints and multipoint inoculation SOP BAAS001	B
Isolates of yeast		MIC using Oxoid Yeastone Sensititre and SOP BAAS029	B
Isolates of bacteria	Detection of carbapenemases OXA-48, KPC, VIM, IMP and NDM	NG-Test CARBA 5 kit, EUCAST method and SOP BAAS055	B

END