Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8429

Accredited to ISO 15189:2022

Milton Keynes University Hospital NHS Foundation Trust

Issue No: 018 **Issue date:** 18 August 2026

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Testing performed at the above address only

Location details	Activity
Blood issue room outside of Pathology	Blood product storage
Blood fridge theatre 1	Blood product storage
Blood fridge theatre 2	Blood product storage
Pathology Service Unit (PSU)	Booking in of all pathology specimens
On site Mortuary and body store	Storage of bodies Record keeping (body identification and audit trail)

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Testing performed at main address only	

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS	Histopathological examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue samples	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection: Cut –up procedures Using SOP: HIS112 for category A-E specimens and SOP: Decalcification: Decalcification of Femoral Heads and other Bony Tissue using SOP: HIS170
Tissue samples		Tissue processing: Leica ASP300S and Leica Peloris 3 Dual retort processors using SOP: HIS026 Embedding Thermohistostar embedding station using using SOP: HIS060
Formalin Fixed Paraffin Embedded Tissue (FFPE)		Microtomy : Leica RM2245 x 2 Leica RM2235 Histocore Biocut x2 Using SOP: HIS041 and SOP: HIS040

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) on glass slides	Routine morphological staining For the detection of:	Haematoxylin and Eosin staining including frozen sections Sakura Tissue Tek Prisma Staining and Cover Slipper
	tissue architecture and nuclear detail (Identification of basophilic and eosinophilic structures)	Sakura Tissue Tek Prisma Staining and Cover Slipper : Staining and Maintenance. SOP: HIS042
		Interpretive/diagnostic microscopy using Olympus BX53 Microscopes HIS513
	Special stains for the detection of:	Documented in-house procedures for manual special stains using SOP: HIS050
FFPE sections on glass slides	Acid Mucins	Alcian Blue
	Acid and neutral mucins	Alcian Blue PAS
	Amyloid	Congo Red
	Helicobacter/Microorganisms	Giemsa
	gram positive and gram negative bacteria	Gram
	Fungus	Grocott
	connective tissue	HVG
	melanin	Masson Fontana
	elastic fibres	Miller's Elastic Stain
	fibrin	MSB

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains using SOP: HIS050 and SOP: HIS220
FFPE sections on glass slides	glycogen, mucins	PAS
	mucin	PAS Diastase
	Fungus	PASF
	Fungus	PAS Diastase
	Iron	Perls Prussian Blue
	Reticulin	Reticulin
	Hepatitis B surface antigen/Copper associated protein	Shikata's Orcein
	Mast Cells	Toluidine Blue
	Acid fast bacilli	Ziehl Neelsen
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Immunohistochemistry to detect the following:	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	High molecular weight cytokeratin in epithelial derived tumours	34BE12
	Low molecular weight cytokeratin in epithelial derived tumours	5D3
	Epithelial cell types	AE1/AE3

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Embryonic cell in normal tissues and germ cell tumours	Alpha-fetoprotein
	Anaplastic lymphoma kinase gene for lung cancer and lymphomas	ALK-1
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.	bcl-2
	Oncoprotein expressed in normal germinal centre B cells and related lymphomas	bcl-6
	Epithelial cell types	Ber EP4
	Placental trophpblasts	B-HCG
	Ovarian epithelial malignancies	CA125
	Gastrointestinal and pancreatic cancers	CA19.9
	Parafollicular cells in thyroid and medullary thyroid carcinomas	Calcitonin
	T cells	CD3
	T cells (helper+mature)	CD4
	Mature T cells, T cell lymphomas	CD5
	T cells (suppressor, cytotoxic)	CD8

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin
	Mature B cells, follicular dentritic cells, CALLA	CD10
	Granulocytes, Reed-Sternberg cells	CD15
	B cells	CD20
	Mature B cells, Follicular dentritic cells	CD21
	Lymphoid/lymphoma cell types	CD23
	Granulocytes, plasma cells, RS Cells and other lymphomas.	CD30
	Endothelial cells	CD31
	Haematopoietic progenitor cells and endothelial cells.	CD34
	T cells and myeloid cells	CD43
	Haematopoietic cells (except erythrocytes and platelets)	CD45
	Natural killer cells, neuroendocrine tissues	CD56
	Macrophages, monocytes, myeloid cells	CD68
	B cells	CD79a

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Mast cells haematopoetic stem cells, melanocytes, germ cells, interstitial cells of Cajal, GIST tumours	CD117
	Differentiating B cells	CD138
	Intestinal epithelial cells, colorectal + other adenocarcinomas	CDX2
	CEA glycoproteins	CEA
	Tissues of neuroendocrine origin	Chromogranin A
	Normal and neoplastic epithelial cells with restricted expression compared to CK20	Cytokeratin 7
	Epithelial basal cells and SCC	Cytokeratin 14
	Epithelial cells of the GI tract	Cytokeratin 19
	Normal and neoplastic epithelial cells with restricted expression compare to CK7	Cytokeratin 20
	Cells infected with cytomegalovirus	CMV
	Expressed in variety tumours including mantle cell lymphoma	Cyclin D1
	Striated and smooth muscle cells	Desmin
	Gastrointestinal tumours (GIST)	DOG-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal and neoplastic epithelium	EMA
	Breast and urothelial Ca marker	GATA3
	H.Pylori Antibody	Helicobacter Pylori
	Melanoma, melanocyte differentiation	HMB45
	Hepatocyte specific antigen for normal hepatocytes	HSA
	Sex chord stromal tumours	Inhibin alpha
	B cells and plasma cells	Kappa chains
	Proliferating Cells	Ki-67
	B cell follicles	Lambda chains
	Melanoma marker	Melan A
	Embryonic stem cells and germ cells	OCT34

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Mismatch Repair protein	Mismatch Repair Protein
	Neutrophil granulocytes, monocytes	Myeloperoxidase
	Panel marker to aid diagnosis of B-Cell lymphoma	Mum1
	Positively identifies lung adenocarcinoma	Napsin A
	Nuclei of cells containing a high level of oestrogen	Oestrogen
	Mesothelioma	P16
	Highly specific basal cell marker	P40
	P53 protein for growth arrest and apoptosis	P53
	Prostate basal cells, proliferative cells	P63
	Prostate Ca marker	P63/Racemase cocktail
	Combination of cytokeratins for epithelial derived tumours	Pan CK

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Hodgkins lymphoma	Pax5
	Confirmatory of female genital tract and urological Ca	Pax8
	Germ cell tumours	PLAP
	Lymphatic endothelial marker	Podoplanin (D2-40)
	Nuclei of cells showing expression of Progesterone	Progesterone
	Normal and neoplastic prostatic tissue	PSA
	Normal and neoplastic prostatic tissue (and other tissues).	PSAP
	Elevated expression in prostatic carcinomas and other tumours	Racemase
	Normal and neoplastic neural tissues and melanoma.	S100
	Smooth muscle cells, myoepithelial cells	SMA

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Smooth muscle cells, myoepithelial cells	SMM
	Neuroendocrine cells	Synaptophysin
	Thyroglobulin containing cells	Thyroglobulin
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1
	Cells of mesenchymal origin	Vimentin
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	Wilms tumour

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BIOLOGICAL FLUIDS	Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Serous body fluids FNA specimens Cyst fluid specimens Bronchiolar Lavage specimens Brushings from bronchus, oesophagus, bronchus, bile duct Sputum samples	Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	Papanicolau (PAP) and Rapid Romanowsky stain using Lecia st5020 HIS 172
Endobronchial ultrasound lymph node FNA	Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	Direct smears, Romanowsky and PAP stain using using Leica Jung autostainer XL, Leica Dialux microscope and procedures for EBUS Clinic specimens SOP: CYT 508
FNA specimens including Breast Cyst fluid specimens	Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	Papanicalou and Rapid Romanowsky stain using Lecia st5020 HIS 172
Synovial fluid	Crystal identification Sodium urate Calcium pyrophosphate	Wet preparation is made after centrifugation and examined under a polarizing microscope CYT 502

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BIOLOGICAL FLUIDS (cont'd)	Cytopathology (Non-Gynae) 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:
Clots	Thrombin plasma clot formation	Cytology Sample Preparation SOP: CYT502 and SOP:CYT505 FNA procedures SOP: CYT504 Immunocytochemistry: Cytology preparation SOP: CYT507
Blood	Haematology examination activities for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
	Detection & speciation (thin films) of malaria parasites: • P. falciparum • P. ovale • P. vivax • P. malariae • P. knowlesi	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy HRO 044
EDTA whole blood	Malaria pLDH and HRP2 antigens	CareUS Malaria Rapydtest (Apacor) using SOP HRO 044 Immunodiagnostic Latex agglutination macroscopic assessment
Blood	Peripheral blood smear analysis Detection of normal and abnormal morphologies and white blood cell differential	Sysmex SP50 May Grunwald Geimsa stain Microscope. HRO 01, HRO 60 Sysmex XN-9000 Reading and reporting using SOP HRO 01 11

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Blood	Haematology examination activities for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
CSF	CSF Film analysis	Cytospin 2 (Shandon) using SOP HRO 09
Blood	Full Blood Count (FBC) analysis of the following parameters: Haemoglobin White cell count Platelets Mean cell volume Mean cell Haemoglobin Mean cell Haemoglobin concentration Red cell count Haematocrit Red cell distribution width Neutrophils Lymphocytes Monocytes Eosinophils Basophils Reticulocytes Nucleated red blood cells	Sysmex XN10/XN9000 Quantitative analysers, flow cytometry, sheaf flow detection and spectrophotometry, electrical impedance, SLS-haemoglobin method, RBC pulse height detection method and calculated red cell parameters SOP HRO 60
Blood	Erythrocyte Sedimentation Rate (ESR)	Diesse Cube 30and SOP HRO 61 Sedimentation

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Blood (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
EDTA Plasma/Serum	Glandular Fever testing (Infectious Mononucleosis)	BioKit Monogen using SOPHRO 042 Latex Agglutination Documented -in-house methods to meet the requirements of the NHS Sickle Cell and Thalassaemia Screening Programme as defined in the 2018 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements
EDTA whole blood	Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A % HbA2 % HbF % HbS%	Variant VII (Bio-Rad) and SOP HEP 215 HPLC
	Sickle Cell Solubility Test	Using Streck Sickledex kit and SOP HEP 202 Solubility/ macroscopic examination

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Citrated plasma	<u>Coagulation examinations for the purpose of clinical diagnosis</u> Prothrombin Time Activated Partial Thromboplastin Time Thrombin Time Clauss Fibrinogen D-Dimers Fibrinogen Degradation Products Inhibitor Screen Factor Assays (FII, FV, FVII, FX, FVIII, FIX, FXa, FXI, FXII) Lupus Anticoagulant screen	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: ACL TOP 550 Using SOP HCO 50 HCO 54, HCO 55,HCO 56 HCO 52 Chromogenic based assays using turbidimetric and absorbance detection

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Citrated plasma (cont'd)	Coagulation examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Citrated plasma	Protein C	ACL TOP 550 Using SOP HCO 50 HCO 54, HCO 55,HCO 56 HCO 52 Chromogenic based assays using turbidimetric and absorbance detection
	Free Protein S	
	Antithrombin III	
Citrated Plasma	Anti Xa inhibitors (DOAC) Rivaroxaban Apixaban Edoxaban	HCO 67
Whole Blood EDTA	Detection of Factor II/V alleles (Factor V Leiden and Prothrombin gene mutation)	Cepheid GeneXpert (PCR) HCO 60 Factor V Leiden and Prothrombin gene mutations
EDTA whole blood	Glucose 6 Phosphate Dehydrogenase Screening	UV-Betrachter (CAMAG) Using SOP HEP 210 and Fluorescence/macroscopic examination
Serum	Serum B12	Dxi (Beckman) and SOP HACCO3 C0731, C0732 and HACCO4
	Serum Folate	
EDTA Whole Blood	Red Cell Folate	
Serum	Ferritin	
	Intrinsic Factor	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Blood Transfusion examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
EDTA whole blood	ABO/RhD grouping by detection of following antigens: Antigen A Antigen B Antigen AB RhD antigens ABO/RhD grouping by detection of following antibodies: Anti-A1 Anti-A2 Anti-B Anti-A,B Anti-D	Automated – Ortho Vision Ortho Biovue Column Agglutination procedures SOP BT 163
Blood	ABO/RhD grouping by detection of following antigens: Antigen A Antigen B Antigen AB RhD antigens ABO/RhD grouping by detection of following antibodies: Anti-A1 Anti-A2 Anti-B Anti-A,B Anti-D	Manual Ortho Biovue workstation Ortho Biovue column agglutination SOP BT029Manual Grouping and Antibody screening
Plasma	Antibody Screening by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, k, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb Lutheran –Lua Lewis – Lea, Leb P–P1	Automated – Ortho Vision Ortho Biovue Column agglutination SOP BT163

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Plasma	Antibody Screening by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, k, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb Lutheran –Lua Lewis – Lea, Leb P–P1	Manual Ortho Biovue Column agglutination SOP BT029 Manual Grouping and Antibody screening
Plasma	Antibody Identification Rh –C,D,E,c,e, Cw Kell –K, k, Kpa Lutheran –Lua Lewis – Lea, Leb P–P1	Automated – Ortho Vision Ortho Biovue Column Agglutination Indirect antiglobulin and enzyme techniques SOP BT053 Antibody Investigation BT070 Antenatal Serology Guidelines SOP BT017 Investigation of a suspected transfusion reaction
Plasma	Antibody Identification Rh –C,D,E,c,e, Cw Kell –K, k, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb Lutheran –Lua Lewis – Lea, Leb P–P1	Manual - Ortho Biovue Column Agglutination Indirect antiglobulin and enzyme techniques SOP BT053 Antibody Investigation BT070 Antenatal Serology Guidelines SOP BT017 Investigation of a suspected transfusion reaction
Blood Plasma	Antibody titre for the following antibodies: C,E,e,K,Fya,Fyb,Jka,Jkb,M,N,S,s	Ortho Biovue Column agglutination SOP BT053 Antibody Investigation BT070 Antenatal Serology Guidelines

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood	Direct Antiglobulin Test (DAT)	Automated Ortho Vision Ortho Biovue Column Agglutination using SOP BT163 and SOP BT021Manual Ortho Biovue Column Agglutination using SOP BT021 Direct antiglobulin test and SOP BT030 Infant and cord blood
Blood	Compatibility testing	Ortho Biovue Column agglutination SOP BT015 Crossmatching guidelines SOP BT0016 Emergency blood issue procedures and BT100 procedure for crossmatch and issue of red cells
Blood	Foetal Maternal Haemorrhage	Acid elution/microscopic enumeration using SOP BT025 Kleihauer technique and BT074 management of Anti D Prophylaxis
EDTA Whole blood	Confirmation of RhD negative results	Automated Ortho Vision Ortho Biovue Column Agglutination using SOP BT 163 and BT029 Confirmation of RhD Negative tests
	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> Quantitative determination of:	Documented in house methods and manufacturers instructions for
Serum Urine	Osmolality	Advanced Osmometer OSMO1 following manufacturer's instructions utilising osmometry. SOP C0406

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u> Quantitative determination of: (cont'd) <u>Endocrinology</u>	Documented in house methods and manufacturers instructions for
Serum Plasma	TSH	Beckman Coulter DXI analysers using manufacturers recommended procedures and reagents. Utilising Immunoassay and SOP C0727
	FT4	SOP C0728
	FT3	SOP C0704
	Thyroid Peroxidase antibody	SOP C0741
	FSH	SOP C0723
	LH	SOP C0722
	Progesterone	SOP C0724
	Prolactin	SOP C0725
	Oestradiol	SOP C0726
Serum	Sex Hormone Binding Globulin (SHBG)	SOP C0736
	Testosterone	SOP C0750
	Growth Hormone	SOP C0747
	Cortisol	SOP C0742
	PTH	SOP C0752
Serum Plasma	Vitamin D	SOP C0754

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
	Endocrinology	
	Quantitative determination of: (cont'd)	Beckman Coulter DXI analysers using manufacturers recommended procedures and reagents.
	Tumour Markers	Utilising Immunoassay
Serum	PSA	SOP C0730
	AFP	SOP C0743
	CEA	SOP C0745
	CA125	SOP C0746
	CA153	SOP C0753
	CA199	SOP C0749
Serum, plasma	HCG	SOP C0735
	Cardiac Markers	
Serum, plasma	Troponin I	Beckman Coulter DXI analysers using manufacturers recommended procedures and reagents. Utilising Immunoassay and SOP C0734
EDTA Plasma	BNP	SOP C0751
	Protein Analysis	
Serum	IGG	Beckman Coulter AU5800 Spectrophotometer SOP C0336
	IGA	
	IGM	
Faeces	Calprotectin	Beckman Coulter AU5800 Turbimetric immunoassay SOP C0369

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for
Serum Urine	Detection of free monoclonal light chains (Kappa and Lambda) or intact paraproteins IgG, IgA or IgM	Sebia Hydrasys 2 and electrophoresis SOP C0681, C0862
	Identification of serum protein major fractions: 1. Albumin 2. Alpha-one globulins (major protein alpha-one antitrypsin) 3. Alpha- two globulins (mailly alpha-two macroglobulin and haptoglobin 4. Beta-globulins (major protein transferrin) 5. Gamma globulins	
	Identification and quantification of paraproteins • IgG • IgA • IgM • Lambda and kappa light chain type free lambda and kappa light chains	Immunofixation using Sebia Hydrasys 2 and SOP C0683 Paraprotein quantification C0684
	Monoclonal band densitometry Identification of IgG, IgA and IgM bands	Sebia Hydrasys 2 and densitometric scanning C0684
Serum	Detection, paraprotein quantitation and selected Immunotyping	Sebia Capillarys Flex II capillary electrophoresis SOP C0685 and SOP C0686
EDTA (Whole Blood)	Glycated Haemoglobin (HbA1C)	TOSOH G11 and HPLC SOP C0667
Faeces	Faecal Immunochemical Testing (FIT) for symptomatic testing	Mast OC Sensor latex Agglutination and SOP C0655

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
Urine		Siemens Multistix SOP C0408
	Bilirubin	SOP C0407
	Urobilinogen	
Urine Faeces Body fluids	p.H	SOP C0412
		Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Beckman Coulter AU5800 Indirect ISE electrode
Serum Plasma Urine Sweat	Sodium Potassium Chloride	SOP C0324 C0358 C0321 C0305
		Beckman Coulter AU5800 spectrophotometry
Serum Plasma	Bicarbonate	SOP C0306

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
	General Chemistry	
	Quantitative determination of:	Beckman Coulter AU5800 Spectrophotometry
Serum	Angiotensin Converting Enzyme (ACE)	C0314
Serum	B2 Microglobulin	Latex agglutination SOP C0370
Serum Plasma Urine	Creatinine	C0307
	Phosphate	C0327
	Urea	C0334
	Calcium	C0303
Serum Plasma Urine CSF	Glucose	C0309
Serum Plasma	CK	C0313
	LDH	C0323
	AST	C0311
	ALT	C0301
	GGT	C0339
	ALP	C0310
	Total Bilirubin	C0329
	Conjugated Bilirubin	C0317
	Albumin	C0300
	Total Protein	C0333
	Urate	C0328

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Beckman Coulter AU5800 Spectrophotometry
Serum Plasma	Amylase	C0302
	Magnesium	C0337
	C reactive protein	C0315
	Ammonia	C0341
	Cholesterol	C0304
Serum	Transferrin	C0440
	Triglycerides	C0330
	HDL Cholesterol	C0320
	Iron	C0308
Serum	IgE	C0748
Plasma Serum CSF	Lactate	C0322
Serum Plasma	Paracetamol	C0338
	Salicylate	C0342
Serum Plasma Urine	Ethanol	C0356
Urine	Microalbumin	C0360
Urine CSF	Micro Total Protein	C0340
Serum Plasma	Bile acids	C0365 (Sentinel Kit)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Beckman AU5800 Spectrophotometry
Serum Plasma	Lithium	C0367
	Therapeutic drug monitoring	
		Beckman AU5800 Spectrophotometry
Serum Plasma	Gentamicin	C0319
	Vancomycin	C0343
	Phenytoin	C0326
	Phenobarbitone	C0325
	Carbamazepine	C0312
	Valproic Acid	C0335
	Theophylline	C0331
	Digoxin	C0318
Serum	Methotrexate	C0364
CSF	Xanthochromia	Uvikon Spectrophotometer using SOP C0416
Serum Plasma	Estimated glomerular filtration rate AKI	Beckman Coulter AU5800 and LIMS Calculation

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis	In-house documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant
Blood	Isolation of microorganisms of clinical significance	Liquid media culture BD BACTEC FX System SOP MIC-S01
Bronchoalveolar lavage, Bronchial aspirate, brushings & washings, Cellular and fluid material contained on swabs, Endotracheal tube specimens, Nasopharyngeal aspirate, Pleural fluid, Sputum	Isolation of microorganisms of clinical significance	Manual inoculation and media culture SOP MIC-S20 SOP MIC-S24
Swabs of high vaginal, low vaginal, vaginal, vulval, cervical, urethral, penile and placental, IUCD, Semen	General isolation and characterisation of micro-organisms of clinical significance and presumptive identification	Manual inoculation of selected culture media SOP MIC-S21
Eyes, wounds, nose, throat, ears	General isolation and characterisation of micro-organisms of clinical significance and presumptive identification	Manual inoculation of selected culture media SOP MIC-S20
Nose, throat, axilla, groin, umbilical, wound swab, Sputum Urine	Screening for Methicillin-Resistant Staphylococcus aureus	Manual inoculation and chromogenic media culture SOP MIC-S22
Rectal swab, faeces	Screening for Carbapenemase-producing Enterobacteriaceae (CPE)	Manual inoculation and chromogenic media culture SOP MIC-S22
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture SOP MIC-S10
CSF, ascitic and peritoneal fluids	Detection, identification and quantification (inc. differential) of: White blood cells, Red blood cells, Bacterial cells	Microscopy & staining (Gram and differential) SOP MIC-S11
Female genital tract swab	Microscopic diagnosis of bacterial vaginosis	Gram-stained microscopic examination against Hay's criteria SOP MIC-S21

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant
Urine	Detection, identification and quantification of: white blood cells, red blood cells, bacterial cells, Casts	Automated urinalysis, image capture and recognition Iris IQ200 Sprint Urine Analyser SOP MIC-S02
Urine	Isolation of microorganisms of clinical significance	Manual inoculation and chromogenic media culture SOP MIC-S02
Urine	Detection of: Legionella pneumophilia serotype 1 antigen,	Rapid immunochromatographic assay Abbott BinaxNOW Urinary Antigen Testing and Use of the Alere Reader BinaxNOW Legionella urinary antigen card SOP MIC-S17
Urine	Detection of: Streptococcus pneumonia soluble antigen	Rapid immunochromatographic assay – Abbott BinaxNOW Urinary Antigen Testing and Use of the Alere Reader BinaxNOW Streptococcus pneumonia urinary antigen card SOP MIC-S17
Bronchoalveolar lavage, Bronchial aspirate, brushings & washings, Aspirates, Fluids, Sputum, Tissue	Presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Auramine phenol staining (screening) and incident-light fluorescence microscopy ZN stain for confirmation of AFB SOP MIC-S09
Faeces	Isolation of microorganisms of clinical significance	Manual inoculation and media culture SOP MIC-S09
Faeces	Detection of Clostridium difficile GDH antigen and toxins A & B	Enzyme-Linked Immunosorbent Assay (ELISA) TechLab C. diff Quik Chek Complete SOP MIC-S45

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant
Faeces	Detection of Helicobacter pylori	Immunochromatographic test – Prolab Proflow H. pylori SOP MIC-S45
Bacterial cultures isolated inhouse from all samples listed above	Identification of microorganisms of clinical significance	Manual biochemical identification methods - Streptococcal Grouping Method (PathoDxtra) Oxidase, Optochin, Bacitracin and Metronidazole, Prolex Staph Latex, Biotech NG-Test CARBA 5 ESBL & AmpC Testing Use of API Identification Strips. SOP MIC-S28 SOP MIC-S38 SOP MIC-S39 SOP MIC-S56 SOP MIC-S60
Bacterial cultures isolated inhouse from all samples listed above	Identification of microorganisms of clinical significance	BD Matrix-assisted laser desorption/ionisation (MALDI-TOF) SOP MIC-S31
Bacterial cultures isolated inhouse from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Automated antimicrobial susceptibility testing using EUCAST SOP MIC-S27 methodology Vitek 2 Compact SOP MIC-S26
Bacterial cultures isolated inhouse from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual antimicrobial susceptibility testing using EUCAST methodology - Disc diffusion & gradient minimum inhibitory concentration determination SOP MIC-S27

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Virology examination activities for the purposes of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant SOP MIC-S48 Examination Phase only. Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the NHS Infectious diseases in pregnancy screening: laboratory quality assurance evidence requirements. *An asterix shall be used to identify the tests which form part of the ANNB programme*
Serum, Plasma	Detection of: Hepatitis B surface antigen (HBs Ag)* HIV Ab/Ag* IgG antibodies to hepatitis C virus (anti-HCV)* Varicella-Zoster IgG	Enzyme-Linked Fluorescent Assay (ELFA) - VIDAS SOP MIC-S48

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	Molecular examination activities for the purposes of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant
Faeces	Identification and differentiation of norovirus genogroup I and genogroup II RNA	Cepheid GeneXpert - Norovirus assay SOP MIC-S55
Sputum	Detection of Mycobacterium tuberculosis (MTB) complex DNA	Cepheid GeneXpert – MTB/RIF assay SOP MIC-S55
Nasopharyngeal anterior nasal swab	Detection and differentiation of RNA from SARS-CoV-2, influenza A, influenza B, and/or respiratory syncytial virus (RSV)	Cepheid GeneXpert -CoV-2/Flu/RSV assay SOP MIC-S55
Nasopharyngeal anterior nasal swab	Detection of viral and bacterial pathogens associated with respiratory tract infections	Meningitis/Encephalitis & Respiratory 2.1 plus Panel Biofire FilmArray Systems SOP MIC-S51
CSF	Detection of bacterial, viral, and yeast pathogens associated with meningitis and encephalitis	Meningitis/Encephalitis & Respiratory 2.1 plus Panel Biofire Film Array Systems SOP MIC-S51
END		