


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8429 Accredited to ISO 15189:2012	Milton Keynes University Hospital NHS Foundation Trust	
	Issue No: 009	Issue date: 01 September 2021
	Department of Pathology Milton Keynes University Hospital NHS Foundation Trust Standing Way Eaglestone Milton Keynes MK6 5LD	Contact: Jessica Dixon Tel: +44 (0)1908 995812 E-Mail: jessica.dixon@mkuh.nhs.uk Website: www.mkhospital.nhs.uk
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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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BIOLOGICAL FLUIDS	<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 samples	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	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 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



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	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: tissue architecture and nuclear detail (Identification of basophilic and eosinophilic structures)	Haematoxylin and Eosin staining including frozen sections Leica ST 5020 AutoStainer – automated H&E stainer Leica Tissue Stainer ST5020: Staining and Maintenance. SOP: HIS042
FFPE sections on glass slides	Special stains for the detection of:	Interpretive/diagnostic microscopy using Olympus BX53 Microscopes HIS513
	Acid Mucins	Documented in-house procedures for manual special stains using SOP: HIS050
	Acid and neutral mucins	Alcian Blue
	Amyloid	Alcian Blue PAS
	Helicobacter/Microorganisms	Congo Red
	gram positive and gram negative bacteria	Giemsa
	Fungus	Gram
	connective tissue	Grocott
	melanin	HVG
	Collagen and muscle	Masson Fontana
	elastic fibres	Masson Trichrome
	fibrin	Miller's Elastic Stain
		MSB



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections on glass slides	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains using SOP: HIS050 and SOP: HIS220
	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



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	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 trophoblasts	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



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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 dendritic cells, CALLA	CD10
	Granulocytes, Reed-Sternberg cells	CD15
	B cells	CD20
	Mature B cells, Follicular dendritic cells	CD21
	Lymphoid/lymphoma cell types	CD23
	Granulocytes, plasma cells, RS Cells and other lymphomas.	CD30
	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



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	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 haematopoietic 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
	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5/6
	Normal and neoplastic epithelial cells with restricted expression compared to CK20	Cytokeratin 7
	Epithelial basal cells and SCC	Cytokeratin 14
	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



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Human tissues and Biological fluids (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	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
	Glial Fibrillary Acidic Protein expressed in glial cells, astrocytomas and ependymomas	GFAP
	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



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	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)	Immunohistochemistry: Leica Bond III Leica Bond using SOP: HIS202 UK NEQAS – immunocytochemistry Procedures using SOP: HIS200 SOP: HIS172 SOP HDIMM003
	Nuclei of cells containing a high level of oestrogen	Oestrogen
	Mesothelioma	P16
	P53 protein for growth arrest and apoptosis	P53
	Prostate basal cells, proliferative cells	P63
	Combination of cytokeratins for epithelial derived tumours	Pan CK
	Germ cell tumours	PLAP
	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
	Renal proximal tubular brush borders and Renal Cell Carcinoma.	RCCM
	Normal and neoplastic neural tissues and melanoma.	S100
	Smooth muscle cells, myoepithelial cells	SMA



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	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



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<p>HUMAN BIOLOGICAL FLUIDS</p> <p>Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples</p> <p>Serous body fluids CSF specimens FNA specimens Cyst fluid specimens Bronchiolar Lavage specimens Brushings from bronchus, oesophagus, bronchus, bile duct Sputum samples</p> <p>Endobronchial ultrasound lymph node FNA</p> <p>FNA specimens including Breast Cyst fluid specimens</p> <p>Synovial fluid</p>	<p><u>Cytopathology (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 micro organisms</p> <p>Demonstration of : Cells (nuclei and cytoplasm) and micro organisms</p> <p>Demonstration of : Cells (nuclei and cytoplasm) and micro organisms</p> <p>Crystal identification Sodium urate Calcium pyrophosphate</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 CYT 502 Cytology Sample preparation to include Cytospin prep Centrifuge prep Direct prep</p> <p>Interpretive/diagnostic microscopy: Olympus microscopes SOP HIS513 - Consultant microscopic reporting of histology and cytology SOP HIS500 - Frozen section reporting in with reporting of pathology specimens</p> <p>Papanicolau (PAP) and Rapid Romanowsky stain using Leica Jung autostainer XL HIS 172</p> <p>Direct smears, Romanowsky and PAP stain using using Leica Jung autostainer XL, Leica Dialux microscope and procedures for EBUS Clinic specimens SOP: CYT 508</p> <p>Papanicalou and Rapid Romanowsky stain using Leica Jung autostainer XL HIS 172</p> <p>Wet preparation is made after centrifugation and examined under a polarizing microscope CYT 502</p>



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HUMAN BIOLOGICAL FLUIDS (cont'd)	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)</u>	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	<u>Haematology examination activities 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:
	Detection & speciation (thin films) of malaria parasites:	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy HRO 044
	<ul style="list-style-type: none"> • P. falciparum • P. ovale • P. vivax • P. malariae • P. knowlesi 	
EDTA whole blood	Malaria pLDH and HRP2 antigens	Care Start Malaria Rapydtest (Apacor) using SOP HRO 044 Immunodiagnostic Latex agglutination macroscopic assessment
Bone Marrow	Bone marrow film analysis in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Sysmex SP10 May Grunwald Geimsa stain Microscope. HRO 01 Reading and reporting using SOP HRO 01 11
Blood	Peripheral blood smear analysis Detection of normal and abnormal morphologies and white blood cell differential	Sysmex SP10 May Grunwald Geimsa stain Microscope. HRO 01, HRO 60 Reading and reporting using SOP HRO 01 11



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Blood	<u>Haematology examination activities 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:
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



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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:
Bone marrow	Iron deposits	Manual staining equipment (TCS Biosciences Ltd kit) using SOP HCYT 403 Cytochemistry Perls staining
Blood	Erythrocyte Sedimentation Rate (ESR)	Starrsed Auto Compact Using SOP HRO 61 Sedimentation
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



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EDTA whole blood	Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A % HbA2 % HbF % HbS%	Variant VII (Bio-Rad) and SOP HEP 215 HPLC
Citrated plasma	Sickle Cell Solubility Test <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, FXI, FXII) Lupus Anticoagulant screen	Using SOP HEP 202 and Solubility/ macroscopic examination Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: ACL TOP 500 Using SOP HCO 50 HCO 54, HCO 55, HCO 56 HCO 52 Chromogenic based assays using turbidimetric and absorbance detection



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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:
Citrated plasma (cont'd)	<u>Coagulation examinations 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:
Citrated plasma	Protein C	ACL TOP 500 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	
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	



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<p>HUMAN BODY FLUIDS</p> <p>EDTA whole blood</p> <p>Blood</p> <p>Plasma</p>	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>ABO/RhD grouping by detection of following antigens: Antigen A Antigen B Antigen AB RhD antigens</p> <p>ABO/RhD grouping by detection of following antibodies: Anti-A1 Anti-A2 Anti-B Anti-A,B Anti-D</p> <p>ABO/RhD grouping by detection of following antigens: Antigen A Antigen B Antigen AB RhD antigens</p> <p>ABO/RhD grouping by detection of following antibodies: Anti-A1 Anti-A2 Anti-B Anti-A,B Anti-D</p> <p>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</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Automated – Ortho Vision Ortho Biovue Column Agglutination procedures SOP BT 163</p> <p>Manual Ortho Biovue workstation Ortho Biovue column agglutination SOP BT029Manual Grouping and Antibody screening</p> <p>Automated – Ortho Vision Ortho Biovue Column agglutination SOP BT163</p>



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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:
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



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Whole Blood	Direct Antiglobulin Test (DAT)	Automated Ortho Vision Ortho Biovue Column Agglutination using SOP BT163 and SOP BT021 Manual 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
EDTA Whole blood	Confirmation of RhD negative results	Ortho Biovue Column Agglutination using BT029 Confirmation of RhD Negative tests



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

Milton Keynes University Hospital NHS Foundation Trust

Issue No: 009 Issue date: 01 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Serum Plasma Urine Whole blood	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> Quantitative determination of: Osmolality	Documented in house methods and manufacturers instructions for Advanced Osmometer following manufacturer's instructions utilising osmometry. SOP C0406
	pH PCOC2 PO2 Oxygen saturation Lactate Derived results: Bicarbonate Base excess Sodium Glucose Chloride Carboxyhaemoglobin	Cobas b 123 analyser using manufacturer's recommended procedure and reagents. Blood gas Co-oximetry and SOP C0403.
Whole blood	Haemoglobin Methaemoglobin	Calculated parameters utilising the measurement of pH, PCOC2 and PO2 on Cobas b 123 electrode analysis SOP C0403



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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 Plasma	Quantitative determination of: (cont'd)	
	<u>Endocrinology</u>	
	TSH	Beckman 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
SerumPlasma	Vitamin D	SOP C0754
	<u>IgE</u>	Beckman AU5800 Spectrophotometry and SOP C0748



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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
	<u>Endocrinology</u>	
	Quantitative determination of: (cont'd)	Beckman DXI analysers using manufacturers recommended procedures and reagents.
	<u>Tumour Markers</u>	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
	<u>Cardiac Markers</u>	
Serum, plasma	Troponin I	Beckman DXI analysers using manufacturers recommended procedures and reagents. Utilising Immunoassay and SOP C0734
EDTA Plasma	BNP	SOP C0751
	<u>Protein Analysis</u>	
Serum	IGG	Beckman AU5800 Spectrophotometer SOP C0336
	IGA	
	IGM	
Faeces	Calprotectin	Beckman AU5800 Turbimetric immunoassay SOP C0369



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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 Identification of serum protein major fractions: 1. Albumin 2. Alpha-one globulins (major protein alpha-one antitrypsin) 3. Alpha- two globulins (mainly 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	Sebia Hydrasys 2 and electrophoresis SOP C0681, C0862 Immunofixation using Sebia Hydrasys 2 and SOP C0683 Paraprotein quantification C0684
Serum	Monoclonal band densitometry Identification of IgG, IgA and IgM bands Detection, paraprotein quantitation and selected Immunotyping	Sebia Hydrasys 2 and densitometric scanning C0684 Sebia Capillarys Flex II capillary electrophoresis SOP C0685 and SOP C0686
EDTA Plasma	Glycated Haemoglobin	Menarini 8180 and HPLC SOP C0667
Faeces	Detection of faecal haemoglobin Faecal Immunochemical testing (FIT)	Mast OC Sensor latex Agglutination and SOP C0655



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for
Urine	Myoglobin	Manual qualitative assay SOP C0714
Urine		Siemens Multistix SOP C0408
	Bilirubin	SOP C0407
	Urobilinogen	
Urine Faeces Body fluids	p.H	SOP C0412
Urine	Specific gravity	
	Quantitative determination of:	Documented in house methods and manufacturers instructions for
Serum Plasma Urine Sweat	Sodium Potassium Chloride	Beckman AU5800 Indirect ISE electrode SOP C0324 C0358 C0321 C0305
Serum Plasma	Bicarbonate	Beckman AU5800 spectrophotometry SOP C0306



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u> General Chemistry	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Documented in house methods and manufacturers instructions for
Serum	Angiotensin Converting Enzyme (ACE)	Beckman AU5800 Spectrophotometry 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



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HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Documented in house methods and manufacturers instructions for
Serum	Amylase	Beckman AU5800 Spectrophotometry
Plasma		C0302
	Magnesium	C0337
	C reactive protein	C0315
	Ammonia	C0341
	Cholesterol	C0304
Serum	Transferrin	C0440
	Triglycerides	C0330
	HDL Cholesterol	C0320
	Iron	C0308
Plasma	Lactate	C0322
Serum		
Plasma	Paracetamol	C0338
	Salicylate	C0342
Serum	Ethanol	C0356
Plasma		
Urine	Microalbumin	C0360
Urine	Micro Total Protein	C0340
CSF		
Serum	Bile acids	C0365
Plasma		



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HUMAN TISSUES AND BIOLOGICAL 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 Plasma	Quantitative determination of: Lithium	Beckman AU5800 Spectrophotometry C0367
Serum Plasma	<u>Therapeutic drug monitoring</u> Gentamicin	Beckman AU5800 Spectrophotometry C0319
	Vancomycin	C0343
	Phenytoin	C0326
	Phenobarbitone	C0325
	Carbamazepine	C0312
	Valproic Acid	C0335
	Theophylline	C0331
	Digoxin	C0318
Serum	Methotrexate	C0364
Serum Plasma	Sodium Potassium	Nova Prime Direct ISE using SOP C0404
CSF	Xanthochromia	Uvikon Spectrophotometer using SOP C0416
Serum Plasma	Estimated glomerular filtration rate AKI	Beckman AU5800 and LIMS Calculation
END		