


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Alder Hey Children's NHS Foundation Trust Issue No: 004 Issue date: 21 October 2021	
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Testing performed at the above address only		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity
Address Department of Pathology Alder Hey Children's NHS Foundation Trust Eaton Road Liverpool L12 2AP Local contact Pamela Ashton	Clinical Biochemistry Haematology & Blood Transfusion Medical Microbiology Cellular Pathology Mortuary Services

Site activities performed away from the locations listed above:

Location details	Activity
Alder Hey Children's NHS Foundation Trust Eaton Road Liverpool L12 2AP	Blood Stock Fridge Blood Issue Fridge Theatre Issue Fridge
Neonatal Unit Liverpool Women's NHS Foundation Trust Crown Street Liverpool L8 7SS	Blood Bank Fridge for Patient Specific Issued Blood Products



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (as stated)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u>	Documented in-house methods and manufacturer's operating instructions as specified:
	Quantification of:	BC SOP-0037ci8200 Abbott Architect using:
Blood, Urine	Sodium	Indirect ion- specific electrodes
Blood, Urine	Potassium	Indirect ion- specific electrodes
Blood, Urine	Chloride	Indirect ion- specific electrodes
Blood	Albumin	BCG dye binding
Urine	Albumin	Turbidimetry
Blood	Alkaline phosphatase	AMP Buffer (IFCC)
Blood	ALT	Tris buffer without PLP
Blood	AST	Tris buffer without PLP
Blood	Ammonia	Glutamate dehydrogenase
Blood, Urine	Amylase	CNPG3 substrate
Blood	Bicarbonate	PEP Carboxylase
Blood	Bilirubin	Diazonium
Blood, Urine	Calcium	Arsenazo III dye binding
Blood	Cholesterol	Enzymatic
Blood	Conjugated bilirubin	Synermed Near Infrared
Blood	Creatine kinase	N-acetyl-L-cysteine
Blood	Creatinine	Enzymatic
Urine	Creatinine	Kinetic Jaffe
Blood	CRP	Immunoturbidimetry
Blood	Ethanol	Enzymatic



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Quantification of: (cont'd)	BC SOP-0037ci8200 Abbott Architect using:
Blood	Folate	Chemiluminescent Microparticle Immunoassay
Blood	Gamma-GT	L-gamma-glutamyl-3-carboxy-4-nitroanilide substrate
Blood, Urine	Glucose	Hexokinase and G6PD
Blood	HDL Cholesterol	Accelerator selective detergent method
Blood	Iron	Ferene colorimetric
Blood	Lactate	Enzymatic
Blood	Lactate dehydrogenase	Lactate to pyruvate
Blood, Urine	Magnesium	Enzymatic
Blood	Paracetamol	Enzymatic
Blood	Phosphate	Phosphomolybdate UV
Blood	Salicylate	Enzymatic
Blood	Total Protein	Biuret
Blood	Triglycerides	Glycerol phosphate oxidase
Blood, Urine	Urea	Urease
Blood, Urine	Uric Acid	Endpoint Uricase
Blood	Vitamin B12	Chemiluminescent Microparticle Immunoassay
CSF	Glucose	Manufacturer's reagents
CSF	Protein	Manufacturer's reagents
CSF	Lactate	Manufacturer's reagents



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Sweat	Quantification of: (cont'd) Chloride Conductivity	BC SOP-0037ci8200 Abbott Architect using: Chlorocheck chloride meter, BC-SOP-0044 Sweat Test SOP Wescor Conductivity Meter, BC-SOP-0044 Sweat Test SOP
Urine	Measurement of osmolality	Advanced Micro Osmometer Model 3320 BC SOP-0035 Freezing Point Depression
Faeces Serum EDTA or Citrate plasma Serum or Lithium Heparin plasma	Calprotectin Tissue Transglutaminase Total IgE	BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA
Whole blood	Determination of blood gases:	SOP Biochemistry 1864 using Radiometer ABL 90 Flex Blood Gas Analyser by
Blood	pH pO2 pCO2 Lactate Carboxyhaemoglobin Methaemoglobin Quantification of Specific Proteins:	Potentiometry Optical Potentiometry Amperometry Spectrophotometry Spectrophotometry
	C3 Complement	Abbott Architect ci8200 BC SOP-0037 using: Manufacturer's reagents
	C4 Complement	Manufacturer's reagents
	Caeruloplasmin	Manufacturer's reagents
	IgA	Manufacturer's reagents
	IgG	Manufacturer's reagents
	IgM	Manufacturer's reagents



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	<u>Blood Gases</u>	
	Transferrin	Manufacturer's reagents
	Ferritin	Chemiluminescent Microparticle Immunoassay
	<u>Intermediary Metabolites</u>	
	Beta- hydroxybutyrate	Randox colorimetric kit
	Free Fatty Acids	Randox colorimetric kit
	<u>Endocrine</u>	
Blood	Quantification of:	Abbott Architect ci8200 BC SOP-0037 using:
	Thyroid Stimulating Hormone (TSH)	Chemiluminescent Microparticle Immunoassay
	Free T4	Chemiluminescent Microparticle Immunoassay
	Total T3	Chemiluminescent Microparticle Immunoassay
	Oestradiol	Chemiluminescent Microparticle Immunoassay
	PTH	Chemiluminescent Microparticle Immunoassay
Blood	Quantification of:	Siemens Immulite XPi Biochemistry 878 by Immunoassay
	ACTH	
	Alphafetoprotein (AFP)	
	Cortisol	
	C-Peptide	



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood (cont'd)	<u>Endocrine</u> (cont'd)	
	Quantification of: (cont'd)	Siemens Immulite XPi Biochemistry 878 by Immunoassay
	Follicle Stimulating Hormone	
	Growth Hormone	
	Human Chorionic Gonadotrophin (HCG)	
	IGF1	
	Insulin	
	Luteinising Hormone (LH)	
	Prolactin	
	Testosterone	
	<u>Therapeutic Drug Monitoring</u>	
Blood	Quantification of:	Abbott Architect ci8200 BC SOP-0037 using:
	Amikacin	Particle Enhanced Turbidimetric Immunoassay (PETIA)
	Carbamazepine	Particle Enhanced Turbidimetric Immunoassay (PETIA)
	Digoxin	Particle Enhanced Turbidimetric Immunoassay (PETIA)
	Gentamicin	Particle Enhanced Turbidimetric Immunoassay (PETIA)
	Phenobarbitone	Enzyme immunoassay
	Phenytoin	Enzyme immunoassay
	Theophylline	Enzyme immunoassay



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	<u>Therapeutic Drug Monitoring</u> (cont'd)	
Blood (cont'd)	Quantification of: (cont'd)	Abbott Architect ci8200 BC SOP-0037 using:
	Tobramycin	Particle Enhanced Turbidimetric Immunoassay (PETIA)
Blood	Quantification of Teicoplanin	Abbott Architect Biochemistry 927 using Fluorescence Polarisation Immunoassay
Blood	Quantification of Methotrexate	Abbott Architect ci8200 Biochemistry 425 using Chemiluminescent Magnetic Immunoassay
Blood	Quantification of Flecainide	Thermo Ultimate 3000UHPLC BC SOP-0142 using Fluorescence Detection
	<u>Metabolic</u>	
Blood, Urine, CSF	Quantification of Amino Acids	BC SOP-1107 Biochrom 30 Amino Acid Analyser using ion exchange chromatography
Urine	Quantification of Organic Acids	BC SOP-0151 and Biochemistry 72 Shimadzu GCMS 2010 Plus using Gas Chromatography-Mass Spectrometry



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd) <u>Metabolic</u> (cont'd) Quantification of:	Documented in-house methods and manufacturer's operating instructions as specified:
Blood	Vitamin A and E	Thermo HPLC Ultimate 3000 UPLC: BC SOP-0136
Blood	Phenylalanine and Tyrosine	BC SOP-0134
Blood	Homocysteine	BC SOP-0140
Blood	Catecholamines	BC SOP-0154
Blood	Vanillylmandelic Acid and Homovanillic Acid	BC SOP-0160
Blood Spot	Quantification of phenylalanine	Thermo TSQ Endura MSMS Biochemistry 1223 and Newborn Screening 1291 2 using Tandem Mass Spectrometry
Blood	Quantification of Vitamin D	Thermo TSQ Vantage MSMS using: Biochemistry 33696
Blood	Carnitine	Biochemistry 211
Urine	Quantification of Glycosaminoglycans	UV1800 Spectrophotometer Biochemistry 814 Dimethylene Blue, Shimadzu
Urine	Quantification of: Mucopolysaccharide	Thin Layer Chromatography using: BC SOP-0129
Urine	Oligopolysaccharides	BC SOP-0039
Urine, Faeces	Identification of Reducing Substances	Thin Layer Chromatography Benedict's Test BC SOP-0031
Blood	Quantification of Galactose-1- Phosphate Uridyl Transferase (Gal- 1-1PUT)	Enzymatic Shimadzu Spectrophotometer UV Detection BC SOP-0042



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood	Quantification of: Copper Zinc Selenium Manganese	Thermo iCAPQ ICP MS Biochemistry 842
Urine	Calculation of: Albumin: Creatinine Ratio Adjusted Calcium Transferrin Saturation Low Density Lipoprotein (LDL) cholesterol Acute Kidney Injury (AKI) <u>Newborn Screening</u>	Calculated Tests using Meditech 6
Blood Spot	Quantification of: PKU- Phenylalanine MCADD-Octanoylcarnitine (C8) GA1- Glutaryl carnitine (C5DC) IVA- Isovalerylcarnitine (C5)	Documented in- house methods to meet the requirements of the Newborn Screening programme as defined in the November 2018 version of <i>NHS Newborn Blood Spot Screening Programme: Laboratory QA Evidence requirements</i> Thermo TSQ Endura MSMS Newborn Screening 1291 2Tandem Mass Spectrometry



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<p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood Spot</p>	<p><u>Haematology Examination Activities for the Purpose of Clinical Diagnosis</u></p> <p><u>Newborn Screening</u></p> <p>Quantification of:</p> <p>PKU- Phenylalanine</p> <p>MCADD-Octanoylcarnitine (C8)</p> <p>GA1- Glutaryl carnitine (C5DC)</p> <p>IVA- Isovalerylcarnitine (C5)</p> <p>MSUD- Leucine</p> <p>Homocystinuria- Methionine</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Documented in- house methods to meet the requirements of the Newborn Screening programme as defined in the November 2018 version of <i>NHS Newborn Blood Spot Screening Programme: Laboratory QA Evidence</i> requirements</p> <p>Thermo TSQ Endura MSMS Newborn Screening 1291 2Tandem Mass Spectrometry</p>



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Haematology Examination Activities for the Purpose of Clinical Diagnosis</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Blood Spot	Quantification of:	Perkin Elmer Genetics Screening Processor by DELFIA technology using:
	Thyroid Stimulating Hormone (TSH)	Newborn Screening 1294
	Immune Reactive Trypsin (IRT)	Newborn Screening 1296
Blood Spot	Identification of:	Sebia Capillarys 2 Neonat Fast Analyser by capillary electrophoresis
	Haemoglobins A, F, S, C, D, E, and O Arab	Newborn Screening 1285
Blood (EDTA)	Full Blood Count (FBC) Analysis for the following parameters: Hb, WBC, RBC, PCV, MCV, MCH, MCHC, RDW, Platelets, MPV, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Reticulocytes, Nucleated RBC	Sysmex XN2000 Automated Haematology Analyser using Fluorescence flow cytometry, electrical impedance, SLS-haemoglobin method, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameter. SOP Haematology 804
Blood	Detection of normal and abnormal blood cell morphologies and white blood cell differential.	Manual blood film and staining with a modified Wrights stain using Hematek staining machine and interpretation. HTR SOP-0095
Blood	Erythrocyte Sedimentation Rate	Manual modified Westgren Method using Aquisel P 4 Micro Dispette HTR SOP 170817
Blood	Glandular Fever Screen for Infectious mononucleosis	Monogen - Latex Agglutination Test HTR SOP 150817
Blood	Sickle Screening Test for Qualitative test to detect the presence of haemoglobin S	TCS Bioscience - Haemoglobin Solubility Test HTR SOP 230817



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Haematology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood	Screening for Malaria Parasites	Thick and thin blood films Preparing, staining and Morphology by Hematek staining machine and manual staining techniques – HTR SOP-2171 and HTR SOP 3000
Blood	Detection of Malarial antigens of: P. falciparum and /or Pan-detection for P. malariae, P. ovale & P. vivax	Humasis Malaria P.f/Pan Antigen Test - Immunochromatographic Assay HTR SOP-2171
Bone Marrow Aspirate (EDTA)	Nucleated Cell count for assessment of Bone Marrow Harvest Cell Concentration	Sysmex XN2000 Automated Haematology Analyser using Fluorescence flow cytometry, electrical impedance, SLS-haemoglobin method, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameters SOP Haematology 804
Bone Marrow	Examination of bone marrow films: in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Manual slide preparation and interpretation. Staining of Bone Marrow Slides using the Hematek® Slide stainer and Manual May Grunwald/Giemsa stain. HTR SOP-0100 HTR SOP 190817 HTR SOP 250817
Blood	Coagulation studies for:	Sysmex CS2400 manufacturers' instructions as relevant: for all tests below unless otherwise stated Using clotting assay, chromogenic, immunoassay and aggregation methods
	Clotting Screen including, PT, APTT, APTT Ratio, Fibrinogen Clauss, Thrombin Time, Reptilase Time, PT and APTT mixing tests	Clotting Assay HTC SOP-2004 HTC SOP-1010



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Haematology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood (cont'd)	Coagulation studies for: (cont'd)	Sysmex CS2400 manufacturers' instructions as relevant: for all tests below unless otherwise stated Using clotting assay, chromogenic, immunoassay and aggregation methods
	D-Dimer	Immunoassay HTC SOP-2003
	Von Willebrand's Screen Von Willebrand's Activity Von Willebrand's Antigen	Immunoassay HTC SOP-2008 HTC SOP-2007
	Clotting factor Assays including Factors; VIII, IX, XI, XII, II, V, VII, X	Clotting Assay HTC SOP-2006 HTC SOP-2005
	Factor XIII	Chromogenic Assay HTC SOP-2009
	Anti XA	Biophen Chromogenic Assay HTC SOP-2002
	Haemophilia Inhibitor Screen	Clotting Assay HTC SOP-2010
	Human Fix Inhibitor Assay	Clotting Assay HTC SOP-2010
Blood	Detection of Rheumatoid Factor	Mastalatex RA 80 -Latex Agglutination HTS SOP-0014



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Blood	Red Cell Folate, Tacrolimus	Architect Immunoassay CMIA Blood Science 1327 SOP Haematology 46314
Blood, Bone Marrow	Leukaemia Immunophenotyping Differential Leukaemia Phenotyping using Navios Flow Cytometer and the following antibodies, CD10,CD19, CD2, CD20, CD34, CD7, CD3, CD4, CD13, CD33, CD64, CD117,TDT, HLA-DR,DQ,DP	Navios Flow Cytometer Blood Sciences 1390
Blood, Bone Marrow	T and B Lymphocyte Subsets: CD45, CD3, CD4, CD8, CD19, CD56/16	Navios Flow Cytometer HTS SOP-140
Blood	CD34 Count	Navios Flow Cytometer HTS SOP-0006
Blood	Haemoglobinopathy investigations including; Hb Electrophoresis, Hb A2 Estimation, Hb A Assay, Hb S Assay, Hb F and identifications of abnormal Haemoglobins	TOSOH G8 HPLC HTS SOP-1000
CSF, Body Fluids	Presence of cellular material	Shandon Cytospin, Manual Microscopy and staining with a modified Wrights stain using Hematek staining machine and interpretation. HTR SOP-0100
Blood	Spherocytosis Screen	5-EMA by Flow cytometry SOP Haematology 46317
Blood	G6PD Screen	Binax NOW G6PD Dye Reduction Slide Test SOP Haematology 442



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HUMAN BODY FLUIDS (as stated) (cont'd) Blood	<p><u>Blood Transfusion Examinations to assist in clinical investigations</u></p> <p>Antibody ID Panel C, c, C(w), D, E, e, K, k, Kp(a), Js(a), Fy(a), Fy(b), Jk(a), Jk(b), S, s, M, N, P1, Le(a), Le(b), Lu(a), Co(b), Xg(a)</p> <p>Neonatal Blood Group and Direct Antiglobulin Test (patients <4m old) ABO and RhD systems:</p> <ul style="list-style-type: none"> - A RhD positive - B RhD positive - AB RhD positive - O RhD Positive - A RhD negative - B RhD negative - AB RhD negative - O RhD Negative <p>Group and Antibody Screen ABO and RhD systems:</p> <ul style="list-style-type: none"> - A RhD positive - B RhD positive - AB RhD positive - O RhD Positive - A RhD negative - B RhD negative - AB RhD negative - O RhD Negative <p>Antibody Screen C, c, C(w), D, E, e, K, k, Kp(a), Js(a), Fy(a), Fy(b), Jk(a), Jk(b), S, s, M, N, P1, Le(a), Le(b), Lu(a), Co(b), Xg(a)</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Grifols Erytra Automated Immunohaematology Analyser and Manual Grifols Techniques using Gel Cards:</p> <p>HBT-009- - Automated process using Grifols Erytra and Manual Technique</p> <p>HBT-007 Manual grouping, DAT and antibody screening using the Grifols system AND HBT-026- Use of the Automated Erytra for ABO, Rh(D) grouping and antibody screening</p> <p>HBT-007 Manual grouping, DAT and antibody screening using the Grifols system AND HBT-026-Use of the Automated Erytra for ABO, Rh(D) grouping and antibody screening</p> <p>HBT-007 Manual grouping, DAT and antibody screening using the Grifols system AND HBT-026-Use of the Automated Erytra for ABO, Rh(D) grouping and antibody screening</p>



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HUMAN BODY FLUIDS (as stated) (cont'd)	<u>Blood Transfusion Examinations to assist in clinical investigations</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood	Direct Antiglobulin Test (C3d, IgG,)	Grifols Erytra Automated Immunohaematology Analyser and Manual Grifols Techniques using Gel Cards: HBT-007 Manual grouping, DAT and antibody screening using the Grifols system AND HBT-026-Use of the Automated Erytra for ABO, Rh(D) grouping and antibody screening
Blood	Cross Match	HBT-004 Use of the Erytra for cross matching and issue of blood AND HBT-006 Manual cross matching and issue of blood
Blood	Kleihauer Screen for foetal/maternal bleed estimation	Manual Staining/ Kleihauer Technique HTT SOP-0041
Blood	Feto-Maternal Haemorrhage Enumeration of Foetal Red Blood Cells in maternal circulation	Navios Flow Cytometer Blood Science 68728



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<p>HUMAN TISSUES AND FLUIDS</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens</p> <p>Formalin- fixed and processed tissues (to paraffin wax)</p> <p>Formalin- fixed and processed tissues (to paraffin wax)</p> <p>Bone tissue and bone marrows</p> <p>Surgical tissue</p> <p>Muscle tissue</p> <p>Kidney/ skin biopsies</p>	<p><u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Detection of the following autoantibodies: C3 Clq Fibrinogen</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Specimen Dissection HP SOP0018</p> <p>Tissue Processing Histopathology 37527 Using Thermo Shandon Excelsior Tissue Processor</p> <p>Tissue Embedding HP SOP0022 Using Leica Embedding Centre</p> <p>Microtomy HP SOP0015 Using Thermo Shandon Microtome</p> <p>Decalcification HP SOP-0032</p> <p>Preparation of frozen Sections – HP SOP0018 Equipment: Leica CM1900 cryostat</p> <p>Preparation of Muscle Biopsies HP SOP0014 Equipment: Leica CM1900 cryostat</p> <p>Cryotomy using Leica CM1900 cryostat Direct Immunofluorescence HP SOP-0111</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides, fresh frozen sections or CSF	For demonstration of general tissue architecture	Automated Haematoxylin and Eosin Staining using Leica Stainer and Coverslipper HP SOP0055
Formalin- fixed paraffin embedded tissue sections on microscope slides unless otherwise stated	<u>Special Stains</u> For demonstration of:	Manual Staining Techniques
	Acid Mucins	Alcian Blue HP SOP-0034
	Amyloid	Congo Red (Highman's Modification) HP SOP-0071
	Elastic fibres	Elastic Van Gieson (Miller's) HP SOP-0074
	Bile Pigments	Fouchet Method HP SOP-0077
	Haemopoietic cells and parasites	Giemsa Method HP SOP-0078
	<i>Helicobacter pylori</i>	Giemsa Method HP SOP-0079
	Gram +/- organisms	Gram Stain HP SOP-0087
Formalin fixed tissue and BAL	Fungi and <i>Pneumocystis sp.</i>	Grocott's Hexamine Method HP SOP-0095
	Collagen, mitochondrial aggregations, ragged red fibres, nemaline rods, connective tissue	Gromori's Trichrome Histopathology 816
	Connective Tissue	Haematoxylin Van Gieson (HVG) HP SOP-0090



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Alder Hey Children's NHS Foundation Trust

Issue No: 004 Issue date: 21 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides unless otherwise stated (cont'd)	<u>Special Stains</u> (cont'd) For demonstration of: (cont'd) Myelin Connective Tissue Melanin Connective Tissue Basement Membrane	Manual Staining Techniques Luxol Fast Blue Method (LFB) HP SOP-0177 Martius Scarlet Blue (MSB) HP SOP-0085 Masson Fontana Method HP SOP-0083 Masson's Trichrome HP SOP-0084 Methenamine Silver Method HP SOP-0089
Frozen tissue or BAL preparations	Lipids (in frozen tissue and BAL) Hepatitis B, copper-associated protein Distribution of glycogen in muscle biopsies Ferric Iron Collagen Reticulin fibres	Oil Red O (Lillie & Ashburn's Isopropanol Method) HP SOP-0093 Orcein (Shikata's) HP SOP-0094 Periodic Acid Schiff (PAS) +/- Amylase for muscle biopsies Histopathology 909 Perl's Prussian Blue HP SOP-0096 Picro-Sirius Red HP SOP-0227 Reticulin (Gordon & Sweet's Method) HP SOP-0100
Frozen tissue	Lipids (frozen muscle biopsy)	Sudan Black Histopathology 817



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides	<u>Special Stains</u> (cont'd) For demonstration of: (cont'd)	Manual Staining Techniques
	Mast Cells	Toluidine Blue HP SOP-105
	Calcium	Von Kossa HP SOP-0106
	Mycobacterium	Wade-Fite HP SOP- 0108
	Spirochaetes	Warthin & Starry HP SOP-0107
	Acid- Fast Bacilli	Ziehl-Neelsen (ZN) (Kinyoun's Cold Method HP SOP-0109
	<u>Enzymatic Special Stains</u>	Manual Staining Techniques
	For demonstration of:	
Frozen tissue – rectal biopsies	Esterase activity	Acetyl Cholinesterase Method HP SOP-0112
Frozen tissue - muscle biopsies	Acid phosphatase activity	Acid Phosphatase Histopathology 830
Frozen tissue - muscle biopsies	Presence/absence of oxidative enzymes (COX, SDH)	Combined Cytochrome Oxidase (COX) and Succinate Dehydrogenase (SDH) Histopathology 832
Frozen tissue - muscle biopsies	Cytochrome oxidase activity	Cytochrome Oxidase (COX) Histopathology 829
Frozen tissue - muscle biopsies	ATPase activity	Myosin ATPases (ATPases) Histopathology 831



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	<u>Enzymatic Special Stains</u> (cont'd)	Manual Staining Techniques
	For demonstration of: (cont'd)	
Frozen tissue - muscle biopsies	Myophosphorylase activity	Myophosphorylase Histopathology 833
Frozen tissue - muscle biopsies	Muscle fibre type patterns	NADH Tetrazolium Reductase Histopathology 835
Frozen tissue - muscle biopsies	Succinate Dehydrogenase activity	Succinate Dehydrogenase (SDH) Histopathology 836
Formalin- fixed paraffin embedded tissue sections on microscope slides	<u>Immunohistochemistry</u>	Dako Autostainer Link 48- Automated IHC Stainer HP SOP201 Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:
	For demonstration of:	
	Epithelial Cells	AE/AE3 Thermo
	Foetal Liver Cells	αFP Agilent (Dako)
	ALK protein and NPM-ALK chimeric protein	ALK Leica
	Neurons and astrocytes in brain, CSF, all foetal tissue	APP Merck
	Cytoplasmic staining in tumours	β-Catenin Agilent (Dako)
	Most normal tissue cell nuclei	BAF-47 (INI-1) BD Bioscience
	Mantle zone B-cells and all effector T-cells.	BCL2 Agilent (Dako)
	Cells expressing BCL6 protein	BCL6 Agilent (Dako)
	Complement split product C4d	C4D Oxford
	C5-b9 complex	C5. b9 Abcam



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	<u>Immunohistochemistry</u> (cont'd) For demonstration of: (cont'd)	Dako Autostainer Link 48- Automated IHC Stainer HP SOP201 Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:
	Peripheral nerve ganglion	Calret Agilent (Dako)
	Epithelial Cells	CAM 5.2 BD Bioscience
	CD1a protein expression	CD1A Agilent (Dako)
	T cells	CD3 Leica
	Thymocytes and T helper cells	CD4 Agilent (Dako)
	CD5 antigen on T cells and a small number of B cells	CD5 Leica
	Cytotoxic/suppressor T cells	CD8 Agilent (Dako)
	All germinal centre cells of tonsil	CD10 Agilent (Dako)
	Reed-Sternberg cells in Hodgkin's Disease and granulocytes	CD15 Agilent (Dako)
	Germinal centre cells, mantle zone lymphocytes, and scattered interfollicular lymphocytes.	CD20cy Agilent (Dako)
	Mature B cells and follicular lymphocytes	CD21 Agilent (Dako)
	B cells in the mantle zone and follicular dendritic reticulum cells in germinal centres	CD23 Agilent (Dako)
	Activated B and T cells, plasma cells and Reed-Sternberg cells in Hodgkin's Lymphoma	CD30 Agilent (Dako)



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)</p>	<p><u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p><u>Immunohistochemistry</u> (cont'd)</p> <p>For demonstration of: (cont'd)</p> <p>Endothelial cells</p> <p>All lymphoid cells</p> <p>CD56 antigen on the membrane of NK cells, a subset of activated T lymphocytes and neuroectodermal cells</p> <p>Macrophages</p> <p>B cells</p> <p>MIC2 gene products</p> <p>Mast Cells</p> <p>CEA-positive glycolyx surface of gastrointestinal cells.</p> <p>Secretory granules in cells of most neuroendocrine organs</p> <p>Several types of normal and neoplastic epithelia</p> <p>Adenocarcinoma arising from epithelia</p> <p>Cytomegalovirus-infected cells</p> <p>Mantle Cell Lymphomas</p> <p>Lymphatic endothelium, ganglion cells and nerve</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Dako Autostainer Link 48-Automated IHC Stainer HP SOP201</p> <p>Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:</p> <p>CD34 Agilent (Dako)</p> <p>CD45 Agilent (Dako)</p> <p>CD56 Leica</p> <p>CD68K Agilent (Dako)</p> <p>CD79α Agilent (Dako)</p> <p>CD99 (mic2) Agilent (Dako)</p> <p>CD117 (CKit) Agilent (Dako)</p> <p>CEA Agilent (Dako)</p> <p>ChromA Agilent (Dako)</p> <p>CK7 Agilent (Dako)</p> <p>CK20 Agilent (Dako)</p> <p>CMV Agilent (Dako)</p> <p>CYCLIN D1 Agilent (Dako)</p> <p>D2-40 Agilent (Dako)</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	<u>Immunohistochemistry</u> (cont'd) For demonstration of: (cont'd)	Dako Autostainer Link 48- Automated IHC Stainer HP SOP201 Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:
	Smooth and striated muscle cells	DESMIN (D33) Agilent (Dako)
	Epstein-Barr virus-infected cells expressing the latent membrane protein (LMP)	EBV Agilent (Dako)
	Epithelial cells in a wide variety of tissues	EMA Agilent (Dako)
	Endothelial cells	ERG Agilent (Dako)
	A-subunit of coagulation Factor X111	Factor XIIIa Thermo
	Astrocytes in CNS	GFAP Agilent (Dako)
	Erythrocyte membrane	Glut-1 Affinity Fisher
	N-terminus Histone H3 with K27M mutation	H3-K27M Millipore
	hCG-containing cells	HCG Agilent (Dako)
	HLA class 1 antigens, widely distributed on most human nucleated cells	HLA-ABC Agilent (Dako)
	Melanocytes	HMB-45 Leica
	Heat-stable antigens of the H. pylori organism	H. Pylori Agilent (Dako)
	HSV I infected cells	HSV I Agilent (Dako)
	HSV II infected cells	HSV II Thermo



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)</p>	<p><u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p><u>Immunohistochemistry</u> (cont'd)</p> <p>For demonstration of: (cont'd)</p> <p>Proliferating cells</p> <p>Poly (C9) component in the C5b-9 complex</p> <p>Mast Cells</p> <p>Epithelial Tissues</p> <p>Epithelial Antigen present on most epithelia</p> <p>MyoD1 positive cells</p> <p>Myoblasts in developing muscle tissue</p> <p>Uncharacterised molecule of 57kD found in most normal human tissues, including most epithelial and endothelial cells</p> <p>Neurons of the central and peripheral nervous system</p> <p>Nkx2.2 protein</p> <p>Neurons of neuroendocrine cells</p> <p>P57 protein</p> <p>Parvovirus B19 infected cells</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Dako Autostainer Link 48-Automated IHC Stainer HP SOP201 Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:</p> <p>Ki-67 Agilent (Dako)</p> <p>Mac-2 (C5b-9) Agilent (Dako)</p> <p>MCT Agilent (Dako)</p> <p>MNF116 Agilent (Dako)</p> <p>MOC31 Agilent (Dako)</p> <p>MyoD1 Agilent (Dako)</p> <p>Myogenin Biogenex</p> <p>NB84A Leica</p> <p>NFP Agilent (Dako)</p> <p>NKX 2.2 BD Bioscience</p> <p>NSE Agilent (Dako)</p> <p>P57 Leica</p> <p>Parvovirus Abcam</p>



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Issue No: 004 Issue date: 21 October 2021

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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	<u>Immunohistochemistry</u> (cont'd) For demonstration of: (cont'd)	Dako Autostainer Link 48-Automated IHC Stainer HP SOP201 Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:
	Pro B cells, Pre-B cells and mature B cells. PAX-5 protein in follicular and non-follicular B cells of tonsil and spleen	PAX-5 Leica
	Neurons and Neuroendocrine cells	PGP Agilent (Dako)
	Trophoblasts of placenta and germ cells in testis	PLAP Agilent (Dako)
	Melanocytes, Langerhans cells, histocytes, chondrocytes, adipocytes and Schwann cells	S100 Agilent (Dako)
	Smooth muscle cells	SMA Agilent (Dako)
	Near N-Terminus of SNF2b	SNF/BRG1 Millipore
	SV40 T-antigen from virus samples	SV40 Thermo
	Neurons and Neuroendocrine cells	Synapto Agilent (Dako)
	Corticol thymocytes and primitive lymphocytes	Tdt Cell Marque
	Transducin-like enhancer protein	TLE1 (1F5) Cell Marque
	Brain and adrenal neurons	Tyrosine hydroxylase Leica
	Mesenchymal cells	Vim Agilent (Dako)
	Wilms' Tumour Antigen	WT-1 Leica



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Issue No: 004 Issue date: 21 October 2021

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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Bronchioalveolar Lavage Fluid and CSF Samples	<u>Diagnostic Cytology</u>	Preparation of a monolayer of cells using Class I Safety Cabinet MBCLASS1 Thermo Shandon Cytospin BAL and CSF Preparation HP SOP0401
Cytological preparations on microscope slides	Multichromatic stain to differentiate cells in cytological preparations	Papanicolaou stain using Rapid Chrome Staining Kit HP SOP 0402
Wound: Pus, Fluids, Swabs, Tissue	<u>Microbiological examinations to assist in clinical investigations</u>	Documented in house methods based on PHE Standards for Microbiological Investigations (SMLs) and manufacturer's instructions for:
	<u>Bacteriology</u>	Manual Culture SOP - MBWOUND - Processing Wound Swabs and Associated Specimens SOP - MBINOCULATION - Inoculation of culture media in bacteriology
Catheter Drain and Line Tips	Isolation and characterisation of microorganisms of clinical significance	Manual Culture SOP – MBCANNULA - Processing cannulae and associated specimens SOP - MBINOCULATION - Inoculation of culture media in bacteriology



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Respiratory Fluids: Sputum, Respiratory Aspirates, Bronchial Lavages Respiratory Swabs</p> <p>Swabs - Various</p> <p>Urine</p> <p>Swabs- Various</p>	<p><u>Microbiological examinations to assist in clinical investigations</u> (cont'd)</p> <p><u>Bacteriology</u> (cont'd)</p> <p>Isolation of microorganisms of clinical significance Isolation and presumptive identification of non-tubercle Acid-alcohol fast bacilli</p> <p>Isolation of MRSA</p> <p>Isolation and characterisation of microorganisms of clinical significance and Quantification of white and red blood cells, bacteria, casts and epithelial cells</p> <p>Isolation and characterisation of microorganisms of clinical significance (Surveillance Bacteriology)</p>	<p>Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>Manual Culture SOP – MBRESPIRATORY - Processing respiratory specimens in bacteriology SOP – MBCF - Investigation of Sputum and associated specimens from Cystic fibrosis (CF) patients SOP - MBCL3 - Working in the CL3 Laboratory SOP – MBCLASSI - Working in the Class I safety cabinet SOP - MBINOCULATION - Inoculation of culture media in bacteriology</p> <p>Manual Culture SOP - MBSCREEN - Screening specimens for MRSA, MSSA, Candida species and Neisseria meningitidis SOP - MBINOCULATION - Inoculation of culture media in bacteriology</p> <p>Manual Culture and Microscopic Examination using KovaSlide Counting Chambers SOP – MBURINE - Processing Urine samples at Alder Hey SOP - MBINOCULATION - Inoculation of culture media in bacteriology</p> <p>Manual Culture SOP – MBSURVEILLANCE - Surveillance for potentially significant and resistant organisms in critically ill patients SOP - MBINOCULATION - Inoculation of culture media in bacteriology</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations to assist in clinical investigations</u> (cont'd)	Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
CSF	<u>Bacteriology</u> (cont'd) Isolation and characterisation of microorganisms of clinical significance and cell count (red and white blood cells)	Manual Culture and Microscopical Examination using KovaSlide Counting Chamber SOP – MBCSF- Investigation of Cerebrospinal fluid SOP - MBINOCULATION - Inoculation of culture media in bacteriology
Faeces	Isolation of bacterial pathogens of clinical significance <i>Campylobacter</i> spp. <i>E.coli</i> O157 <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Yersinia enterocolitica</i>	Manual Culture SOP – MBFAECES - Investigation of faeces samples for bacterial pathogens SOP - MBINOCULATION - Inoculation of culture media in bacteriology
Faeces	Detection of <i>Clostridium difficile</i> glutamate dehydrogenase (DGH) <i>C. difficile</i> toxins A & B	Lateral flow test using <i>Clostridium difficile</i> QUIK CHEK Complete Rapid Cassette (Alere) SOP – MBQUIKCHEK - Detection of <i>C.difficile</i> antigen and toxin in stool samples using the QuikChek complete kit
Blood/ Transfusion Packs	Isolation and characterisation of microorganisms of clinical significance	Blood Culture using BacT/Alert 3D Monitoring System (bioMerieux) SOP – MBBC - Processing Blood Cultures samples at Alder Hey SOP – MBTRANSFUSION - Sampling blood for the investigation of Transfusion Reactions



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>ENT Swabs</p> <p>Bacterial Suspensions/ Cultures isolated in-house from all samples listed above</p>	<p><u>Microbiological examinations to assist in clinical investigations</u> (cont'd)</p> <p><u>Bacteriology</u> (cont'd)</p> <p>Isolation and characterisation of microorganisms of clinical significance</p> <p>Antibiotic Susceptibility Testing of clinically significant bacteria</p>	<p>Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>Manual Culture SOP – MBEAR - Investigation of Ear Infections SOP – MBEYE - Investigation of Bacterial Eye Infection SOP – MBTHROAT - Investigation of Throat swabs SOP – MBNASAL - Investigation of nose swabs and associated nasal samples SOP – MBPERTUSSIS - Culture of specimens for <i>Bordetella pertussis</i> and <i>Bordetella parapertussis</i> SOP – MBBINAXNOWTREPA - BinaxNOW Strep A Test Kit</p> <p>Using a combination of manual and automated techniques using EUCAST as appropriate</p> <p>SOP – MBAST - Antibiotic Sensitivity Testing Procedures SOP - MBVITEK2 - Bacterial Identification and Antimicrobial Susceptibility Testing using the BioMerieux Vitek2 Compact SOP – MBRESITANCE - Resistance mechanism testing methods SOP - MBGRADIENTSTRIP_AST - Performing Antimicrobial Susceptibility Testing by MIC Gradient Strip Tests SOP - MBDISC DISPENSER - Use of a cartridge disc dispenser for antimicrobial susceptibility testing</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Cultures isolated in-house from all samples listed above</p> <p>Skin, Nails, Hair</p> <p>Yeast Suspensions</p> <p>Faeces, Sellotape Slides, Urine</p>	<p><u>Microbiological examinations to assist in clinical investigations</u> (cont'd)</p> <p><u>Bacteriology</u> (cont'd)</p> <p>Identification of microorganisms of clinical significance</p> <p><u>Mycology</u></p> <p>Isolation and identification of clinically significant dermatophyte fungi including direct examination of material.</p> <p>Antifungal Susceptibility Testing of yeast of clinical significance</p> <p><u>Parasitology</u></p> <p>Detection of parasites (ova, cysts, trophozoites and worms) of clinical significance</p>	<p>Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>Using identification strips, conventional tests and the Vitek 2 Compact (bioMerieux) SOP – MBORGID - Organism identification procedures SOP - MBORGID-TESTS - Diagnostic tests used for Bacterial Identification SOP - MBVITEK2 - Bacterial Identification and Antimicrobial Susceptibility Testing using the BioMerieux Vitek2 Compact</p> <p>Manual culture and microscopic examination. SOP – MBMYCOLOGY - Processing Mycology Samples</p> <p>Sensititre Plates (Thermo Scientific) MBCANDIDA ID & SENS MBANTIFUNGAL_AST</p> <p>Microscopy using Faecal Parasite Concentrator SOP – MBOCP - Examination of specimens other than blood for Ova, cysts and Parasites (OCP) SOP – MBEYECAL - Calibration of an eye piece micrometre</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum (Blood)</p> <p>Faeces</p> <p>Nasopharyngeal Aspirates</p>	<p><u>Microbiological examinations to assist in clinical investigations</u> (cont'd)</p> <p><u>Serology</u></p> <p>Identification of Streptococcal Antibodies -Antistreptolysin-O (ASO) and antiDNAase b</p> <p><u>Virology</u></p> <p>Detection of Rotavirus and Adenovirus</p> <p>Detection of Respiratory syncytial virus (RSV)</p>	<p>Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>Latex agglutination and ELISA test SOP – MBASO - Rapid determination of the antistreptolysin-O titre (ASOT) in serum using the BioKit rheumajet ASO kit SOP – MBASD - Semi-quantitative determination of streptococcal antideoxyribonuclease B (anti DNAase b) using the bioMerieux ASD-Kit.</p> <p>ELISA Tests SOP – MBPROSPECTROTA - Processing of stool samples for the detection of Rotavirus Group A using the Remel ProSpec™ Rotavirus Kit SOP - MBPROSPECTADENO - Processing of stool samples for the detection of Adenovirus using the Remel ProSpec™ Adenovirus Kit</p> <p>Rapid RSV lateral flow Test using BinaxNOW (Alere) SOP – MBBINAXNOWRSV - Binax NOW RSV test</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Respiratory Aspirates, Combined Nose and Throat Swabs</p>	<p><u>Microbiological examinations to assist in clinical investigations</u> (cont'd)</p> <p><u>Molecular Diagnostics</u></p> <p>Detection/ Identification of Respiratory viruses and bacteria</p> <p>Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A, including subtypes H1, H1-2009, and H3 Influenza B Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus Bordetella parapertussis (IS1001) Bordetella pertussis (ptxP) Chlamydia pneumoniae Mycoplasma pneumoniae</p>	<p>Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>Nested PCR using FilmArray (bioMerieux) SOP – MBFILMARRAY - BioMerieux FilmArray PCR Platform procedures SOP - MBCL3 - Working in the CL3 Laboratory SOP - MBCLASS1 - Working in the Class I safety cabinet</p>



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Issue No: 004 Issue date: 21 October 2021

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Positive Blood Culture Broth</p>	<p><u>Microbiological examinations to assist in clinical investigations</u> (cont'd)</p> <p>Identification of microorganisms of clinical significance</p> <p>Staphylococcus Staphylococcus aureus Enterococcus Streptococcus Streptococcus agalactiae Streptococcus pneumoniae Streptococcus pyogenes Haemophilus influenzae Neisseria meningitidis Listeria monocytogenes Enterobacteriaceae Acinetobacter baumannii Enterobacter cloacae complex Escherichia coli Klebsiella oxytoca Klebsiella pneumoniae Proteus Pseudomonas aeruginosa Serratia marcescens mecA – methicillin resistance vanA/B – vancomycin resistance KPC – carbapenem resistance Candida albicans Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis</p>	<p>Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>Nested PCR using FilmArray (bioMerieux) SOP – MBFILMARRAY - BioMerieux FilmArray PCR Platform procedures SOP - MBCL3 - Working in the CL3 Laboratory SOP - MBCLASS1 - Working in the Class I safety cabinet</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations to assist in clinical investigations</u> (cont'd)	Documented in house methods based on PHE Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
CSF	Detection/ Identification of viruses and bacteria that may cause meningitis or encephalitis Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cytomegalovirus Enterovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Human parechovirus Varicella zoster virus Cryptococcus neoformans/gattii	Nested PCR using FilmArray (bioMerieux) SOP – MBFILMARRAY - BioMerieux FilmArray PCR Platform procedures SOP - MBCL3 - Working in the CL3 Laboratory SOP - MBCLASS1 - Working in the Class I safety cabinet
Rectal Swab/ Faeces	Carbapenemase resistance gene detection	SOP MBCEPHEID using Cepheid GeneXpert by PCR and Cepheid Xpert Carba-R Kit
Faeces	Detection of Norovirus	Cepheid Xpert Norovirus Kit
Nose/ throat swabs, ET aspirates/NPA	Detection of SARS CoV-2 RNA (E and N2 targets) (COVID)	Cepheid Xpert SARS-Cov-2 Kit
END		