Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Eaton Road

Liverpool L12 2AP

Accredited to ISO 15189:2012

Alder Hey Children's NHS Foundation Trust

Issue No: 011 Issue date: 16 May 2025

Contact: Laura Kiely Tel: +44 (0) 151 252 5126

Fax: +44 (0) 151 252 5550

E-Mail: Laura.Kiely@alderhey.nhs.uk Website: http://www.alderhey.nhs.uk/

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 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 FridgeTheatre 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)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis	Documented in-house methods and manufacturer's operating instructions as specified:
	Quantification of:	Abbott Alinity Biochemistry 1375 using:
Serum, plasma	ALT	TRIS Buffer without PLP
Serum, plasma	Albumin	BCG Dye Binding
Serum, plasma	ALP	IFCC AMP Buffer
Plasma	Ammonia	GDH
Serum, plasma, urine	Amylase	CNPG3 Substrate
Serum, plasma	AST	TRIS Buffer without PLP
Serum, plasma	Bicarbonate	PEP Carboxylase
Serum, plasma	Total bilirubin	Diazonium
Serum, plasma, urine	Calcium	Arsenazo III Dye Binding
Serum, plasma	Cholesterol	Enzymatic
Serum, plasma, urine	Chloride	Indirect ISE
Serum, plasma	Conjugated bilirubin	Synermed Near Infrared
Serum, plasma	Creatine kinase	N-acetyl-L-cysteine
Serum, plasma, urine	Creatinine	Enzymatic
Serum, plasma	CRP	Immunoturbidimetry
Serum, plasma	Ethanol	Enzymatic
Serum, plasma	GGT	Kinetic IFCC
Serum, plasma, urine CSF	Glucose	Hexokinase G6PD

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HUMAN BODY FLUIDS (as stated) (cont'd)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Quantification of: (cont'd)	Abbott Alinity Biochemistry 1375 using:
Serum, plasma	HDL Cholesterol	Accelerator Selective Detergent
Serum, plasma	Iron	Ferrene Colorimetric
Plasma, CSF	Lactate	Enzymatic
Serum, plasma	LDH	Lactate to Pyruvate
Serum, plasma, urine	Magnesium	Enzymatic
Serum, plasma	Paracetamol	Enzymatic
Serum, plasma, urine	Phosphate	Molybdate UV
Serum, plasma, urine	Potassium	Indirect ISE
Serum, plasma	Salicylate	Enzymatic
Serum, plasma, urine	Sodium	Indirect ISE
Serum, plasma	Total Protein	Biuret
Serum, plasma	Triglycerides	Glycerol Phosphate Oxidase
Serum, plasma, urine	Urea	Urease
Serum, plasma, urine	Uric acid	Endpoint Uricase
Serum, plasma	Anti TPO	Chemiluminescent Immunoassay
Serum, plasma	C3	Immunoturbidimetry
Serum, plasma	C4	Immunoturbidimetry
Serum, plasma	Caeruloplasmin	Immunoturbidimetry
Serum, plasma	IgA	Immunoturbidimetry
Serum, plasma	IgG	Immunoturbidimetry

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HUMAN BODY FLUIDS (as stated) (cont'd)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Quantification of: (cont'd)	Abbott Alinity Biochemistry 1375 using:
Serum, plasma	IgM	Immunoturbidimetry
Serum, plasma	Transferrin	Immunoturbidimetry
Serum, Plasma	Ferritin	Chemiluminescent Immunoassay
Serum, Plasma	Folate	Chemiluminescent Immunoassay
Serum, Plasma	B12	Chemiluminescent Immunoassay
Serum, Plasma	Betahydroxybutyrate	Randox Spectrophotometric Endpoint
Serum, Plasma	Free Fatty Acids	Randox Spectrophotometric Endpoint
Urine	Albumin	Immunoturbidimetry
Urine, CSF	Total Protein	Benzethonium Chloride
Serum, Plasma	Amikacin	PETIA
Serum, Plasma	Gentamicin	PETIA
Serum, Plasma	Methotrexate	Chemiluminescent Immunoassay
Serum, Plasma	Phenobarbitone	PETIA
Serum, Plasma	Phenytoin	PETIA
Serum, Plasma	Theophylline	PETIA
Serum, Plasma	Tobramycin	PETIA
Serum, Plasma	Vancomycin	PETIA
Serum, Plasma	TSH	Chemiluminescent Immunoassay
Serum, Plasma	Free T3	Chemiluminescent Immunoassay

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (as stated) (cont'd)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Quantification of: (cont'd)	Abbott Alinity Biochemistry 1375 using:
Serum, Plasma	Free T4	Chemiluminescent Immunoassay
Serum, Plasma	Oestradiol	Chemiluminescent Immunoassay
Serum, Plasma	PTH	Chemiluminescent Immunoassay
Serum, Plasma	Vit D	Chemiluminescent Immunoassay
Lithium heparin (plasma)/ Plain (serum)/EDTA (plasma)	NT-Pro BNP	Chemiluminescent Microparticle Immunoassay
Lithium heparin (plasma)/ Plain (serum)/EDTA (plasma)	Troponin I	Chemiluminescent Microparticle Immunoassay
Lithium Heparin/EDTA Whole Blood	Haemoglobin A1c	Chemiluminescent Microparticle Immunoassay
Lithium heparin (plasma)/ Plain (serum)	Luteinising Hormone (LH)	Chemiluminescent Microparticle Immunoassay
Lithium heparin (plasma)/ Plain (serum)	Follicle Stimulating Hormone (FSH)	Chemiluminescent Microparticle Immunoassay
Lithium heparin (plasma)/ Plain (serum)	Prolactin	Chemiluminescent Microparticle Immunoassay
EDTA Whole Blood	Tacrolimus	Chemiluminescent Microparticle Immunoassay

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HUMAN BODY FLUIDS (as stated) (cont'd)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Calculation of:	Calculated Tests derived from results obtained from Abbott Alinity
	Albumin/ Creatinine Ratio (Urine)	
	Adjusted Calcium (Serum, Plasma)	
	Transferrin Saturation (Serum)	
	LDL Cholersterol (Serum)	
	Acute Kidney Injury (AKI)	
Urine	Measurement of osmolality	Advanced Micro Osmometer Model 3320 BC SOP-0035 Freezing Point Depression
Sweat	Chloride	Chlorochek chloride meter BC SOP-0044
Sweat	Conductivity	Westcor conductivity BC SOP-0044

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		7
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (as stated) (cont'd)	Immunology Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
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
Blood	IgA Anti-Tissue Transglutaminase antibodies (TTG)	
Blood	Total IgE	
Blood	Specific IgE:	
	Almond nut f20 Amoxycilloyl c6 Apple f49 Apricot f237 Aspergillus fumigatus m3 Aubergine f262 Banana f92 Barley f6 Beef f27 Blue Mussel f37 Blueberry f288 Brazil nut f18 Bumble Bee Venom i205 Carrot f31 Cashew nut f202 Cat Epithelium e1 Celery f85 Cheddar Cheese f81 Cheese Allergens Cherry f242 Chicken f83 Chickpea f309 Chlorhexidine c8 Chocolate/Cacao f93 Clinical Interpretation Coconut f36 Cod f3 Common Wasp Venom i3 Coriander f317 Cows Milk f2	

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HUMAN BODY FLUIDS (as stated) (cont'd)	Immunology Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
		BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)
Blood	Crab f23 Cucumber f244 Dog Dander e5 e204 nBos d 6 BSA Cow Egg White f1 Egg Yolk f75 Ethylene Oxide k78 f233 n Gal d 1 Ovomucoid f352 rAra h 8 PR-10 Peanut f417 rApi g 1.01 PR-10 Celery f419 rPru p 1 PR-10 Peach f420 rPru p 3 LTP Peach f421 rPru p 4 Profilin Peach f422 rAra h 1 Peanut f423 rAra h 2 Peanut f424 rAra h 3 Peanut f425 rCor a 8 LTP Hazelnut f427 rAra h 9 LTP Peanut f428 rCor a 1 PR-10 Hazelnut f439 rCor a 9 Hazelnut f440 rCor a 14 Hazelnut f76 nBos d4 a-lactalbumin Milk f77 nBos d5 B-lactalbumin Milk f78 nBos d8 Casein Milk Food Mix Allergens g212 rPhi p12 profilin, Timothy Garlic f47 Gelatin c74 Ginger f270 Gluten f79 Goat Milk f300 Grape f259 Green Bean f315 Green Peppercorn f263 Guinea Pig Epithelium e6 Haddock f42 Hamster Epithelium e84 Hazel nut f17	

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HUMAN BODY FLUIDS (as stated) (cont'd)	Immunology Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
		BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)
Blood	Specific IgE (cont):	
	Honey Bee Venom i1 Horse Dander e3 House Dust Mite d1 i209 rVes v 5 Common Wasp i211 rVes v 1 Common Wasp IGE & Common Resp Allergens IGE & Food IgE (only) k218 rHev b 5 Latex k219 rHev b 6.01 Latex k220 rHev b 6.02 Latex k221 rHev b 8 Profilin, Latex Kiwi Fruit f84 Latex k82 Lentil f235 Lobster f80 Lupin pollen w207 Lupin Seed f335 Macadamia nut f345 Mackerel f206 Maize f8 Mandarin f302 (Tang,sats,clem) Mango f91 Melon f87 Mixed Bean Allergens Mixed Feathers Mixed Fish Allergen fx74 Mixed Food Allergens fx5 Mixed Fowl Feathers ex73 Mixed Fruit fx15 Mixed Fruit fx16 Mixed Grass Pollens Mixed Nut Allergens Mixed Nut Allergens Mixed Pet Feathers ex72 Mixed Pet Feathers ex72 Mixed Tree Pollens	

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HUMAN BODY FLUIDS (as stated) (cont'd)	Immunology Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
		BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)
Blood	Specific IgE (cont):	
	Mixed Tree Pollens tx10 Mould Allergen Mix mx1 Mould Cheese f82 Mugwort w6 Mustard f89 Mutton/Lamb f88 Nutmeg f282 Oat f7 Omega-5 Gliadin f416 Onion f48 Orange f33 Paprika f218 Pea f12 Peach f95 Peanut f13 Pecan nut f201 Penicillin Allergens Pine nuts f253 Pistachio f203 Plum f255 Poppy seed f224 Pork f26 Potato f35 Pumpkin seed f226 Rabbit Epithelium e82 Rape Seed f316 Raspberry f343 Red Kidney Bean f287 Rice f9 Rye f5 Salmon f41 Sesame seed f10 Shrimp/Prawn f24 Silver Birch Pollen t3 Soya Allergen f14 Spice Mix fx72 Strawberry f44 Sunflower seed k84	

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HUMAN BODY FLUIDS (as stated) (cont'd)	Immunology Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
		BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)
Blood	Specific IgE (cont): Sunflower w204 t215 Bev v 1 PR-10 Birch t216 Bev v 2 Profilin Birch Timothy Grass g6 Tomato f25 Tuna f40 Venom Components (Wasp/Bee) Walnut f256 Weed Pollen Mix wx3 Wheat f4 White Bean f15 Ampicilloyl c5 i208 rApi m 1 Honeybee Mixed Poultry Feathers ex71 Mixed Nuts fx76 Penicilloyl V c2 Common Millet f55 Broccoli f260 Herring f205 f440 nCor a 9 Hazelnut f439 rCor a 14 Hazelnut Penicilloyl V c2	

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HUMAN BODY FLUIDS (as stated) (cont'd)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Whole blood		SOP Biochemistry 1864 using Radiometer ABL 90 Flex Blood Gas Analyser by
	pH pO2 pCO2 Lactate Carboxyhaemoglobin Methaemoglobin Endocrine	Potentiometry Opitcal Potentiometry Amperometry Spectrophotometry Spectrophotometry
Blood	Quantification of: Follicle Stimulating Hormone	Siemens Immulite XPi Biochemistry 878 by Immunoassay
	Growth Hormone	
	Human Chorionic Gonadotrophin (HCG)	
	IGF1	
	Insulin	
	Luteinising Hormone (LH)	
	Prolactin	
	Testosterone	
	ACTH	
	Alphafetoprotein (AFP)	
	Cortisol	
	C-Peptide	

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HUMAN BODY FLUIDS (as stated) (cont'd)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Therapeutic Drug Monitoring	
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)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd) Metabolic (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
		The same LIDI O LIW seeks 0000
	Quantification of:	Thermo HPLC Ultimate 3000 UPLC:
Urine	Vitamin A and E	BC SOP-0136
Urine	Phenylalanine and Tyrosine	BC SOP-0134
Urine	Homocysteine	BC SOP-0140
Urine	Catecholamines	BC SOP-0154
Urine	Vanillymandelic 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
	Quantification of	Thermo TSQ Vantage MSMS using:
Blood	Vitamin D (25OH D2 and D3)	Biochemistry 33696
Blood	Carnitine	Biochemistry 211
Urine	Quantification of Glycosaminoglycans	UV1800 Spectrophotometer Biochemistry 814 Dimethylene Blue, Shimadzu
	Quantification of:	Thin Layer Chromatography using:
Urine	Mucopolysaccharide	BC SOP-0129
Urine	Oligosaccharides	BC SOP-0039
Urine, Faeces	Identification of Reducing Substances	Thin Layer Chromatography Benedict's Test BC SOP-0031
Blood	Quantification of Galatactose-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)	Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood	Quantification of:	Thermo iCAPQ ICP MS
	Copper	Biochemistry 842
	Zinc	
	Selenium	
	Manganese	
	Lead	
	Newborn Screening	Documented in- house methods to meet the requirements of the Newborn Screening programme as defined in the November 2018 version of NHS Newborn Blood Spot Screening Programme: Laboratory QA Evidence requirements

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

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HUMAN TISSUES AND FLUIDS	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis	Documented in-house methods and manufacturer's operating instructions as specified:
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen Dissection HP SOP-0018
		Tissue Processing using Thermo Shandon Excelsior Tissue Processor HP SOP-0415
Formalin- fixed and processed tissues (to paraffin wax)		Tissue Embedding using Leica Embedding Centre HP SOP-0022
Formalin- fixed and processed tissues (to paraffin wax)		Microtomy using Thermo Shandon Microtome HP SOP-0015
Bone tissue and bone marrrows		Decalcification HP SOP-0032
Surgical tissue		Preparation of frozen Sections – HP SOP-0018 Equipment: Leica CM1950 cryostat
Muscle tissue		Preparation of Muscle Biopsies HP SOP-0014 Equipment: Leica CM1950 cryostat
Kidney/ skin biopsies	Detection of the following autoantibodies: C3 Clq Fibrinogen	Cryotomy using Leica CM1950 cryostat HP SOP-0062 Direct Immunofluorescence HP SOP-0111

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HUMAN TISSUES AND FLUIDS (cont'd)	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis (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 SOP-0055
Formalin- fixed paraffin embedded	Special Stains	Manual Staining Techniques
tissue sections on microscope slides unless otherwise stated	For demonstration of:	
	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
	Haemopoeitic cells and parasites	Giemsa Method HP SOP-0078
	Helicobacter pylori	Giemsa Method HP SOP-0079
	Gram +/- organisms	Gram Stain HP SOP-0087
Formalin fixed tissue and BAL	Fungi and Pneumocystis sp.	Grocott's Hexamine Method HP SOP-0095
	Collagen, mitochondrial aggregations, ragged red fibres,	Gromori's Trichrome
	nemaline rods, connective tissue	HP SOP-0411
	Connective Tissue	Haematoxylin Van Gieson (HVG) HP SOP-0090

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HUMAN TISSUES AND FLUIDS (cont'd)	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides	Special Stains (cont'd)	Manual Staining Techniques
unless otherwise stated (cont'd)	For demonstration of: (cont'd)	
	Myelin	Luxol Fast Blue Method (LFB) HP SOP-0177
	Connective Tissue	Martius Scarlet Blue (MSB) HP SOP-0085
	Melanin	Masson Fontana Method HP SOP-0083
	Connective Tissue	Masson's Trichrome HP SOP-0084
	Basement Membrane	Methenamine Silver Method HP SOP-0089
Frozen tissue or BAL preparations	Lipids (in frozen tissue and BAL)	Oil Red O (Lillie & amp; Ashburn's Isopropanol Method) HP SOP-0093
	Hepatitis B, copper-associated protein	Orcein (Shikata's) HP SOP-0094
	Distribution of glycogen in muscle biopsies	Periodic Acid Schiff (PAS) +/- Amylase for muscle biopsies HP SOP- 0413
	Gycogen, mucins, fungi and basement membranes	Periodic Acid Schiff (PAS) +/- Amylase HP SOP-0070
	Ferric Iron	Perl's Prussian Blue HP SOP-0096
	Collagen	Picro-Sirius Red HP SOP-0227
	Reticulin fibres	Reticulin (Gordon & amp: Sweet's Method) HP SOP-0100
Frozen tissue	Lipids (frozen muscle biopsy)	Sudan Black HP SOP-0412

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HUMAN TISSUES AND FLUIDS (cont'd)	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides	Special Stains (cont'd)	Manual Staining Techniques
tissue sections on microscope silves	For demonstration of: (cont'd)	
	Mast Cells	Toluidine Blue HP SOP-0105
	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
	Enzymatic Special Stains	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
		HP SOP-0404
Frozen tissue - muscle biopsies	Presence/absence of oxidative enzymes (COX, SDH)	Combined Cytochrome Oxidase (COX) and Succinate Dehydrogenase (SDH)
		HP SOP-0410
Frozen tissue - muscle biopsies	Cytochrome oxidase activity	Cytochrome Oxidase (COX)
		HP SOP-0409

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HUMAN TISSUES AND FLUIDS (cont'd)	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Enzymatic Special Stains (cont'd)	Manual Staining Techniques
	For demonstration of: (cont'd)	
Frozen tissue - muscle biopsies	Myophosphorylase activity	Myophosphorylase
		HP SOP 0406
Frozen tissue - muscle biopsies	Muscle fibre type patterns	NADH Tetrazolium Reductase
		HP SOP-0407
Frozen tissue - muscle biopsies	Succinate Dehydrogenase activity	Succinate Dehydrogenase (SDH)
		HP SOP-0408
Formalin- fixed paraffin embedded tissue sections on microscope slides	Immunohistochemistry For demonstration of:	Dako Autostainer Link 48- Automated IHC Stainer HP SOP201 Localisation and visualisation of antigens as an aid to diagnosis using the following antibodies:
	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
	C5-b9 complex	C5. b9 Abcam

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

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

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HUMAN TISSUES AND FLUIDS (cont'd)	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	Immunohistochemistry (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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HUMAN TISSUES AND FLUIDS (cont'd)	Histological/ Cytological Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
	Diagnostic Cytology	
Bronchioalveolar Lavage Fluid and CSF Samples		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
	Microbiological examinations to assist in clinical investigations	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
	<u>Bacteriology</u>	
Wound: Pus, Fluids, Swabs, Tissue	Isolation and characterisation of microorganisms of clinical significance	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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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd) Bacteriology (cont'd)	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
Respiratory Fluids: Sputum, Respiratory Aspirates, Bronchial Lavages Respiratory Swabs	Isolation of microorganisms of clinical significance Isolation and presumptive identification of non-tubercle Acid-alcohol fast bacilli	Manual Culture SOP – MBSPUTA - 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
Swabs - Various	Isolation of MRSA	Manual Culture SOP - MBSCREEN - Screening specimens for MRSA, MSSA, Candida species and Neisseria meningitidis SOP - MBINOCULATION - Inoculation of culture media in bacteriology
Urine	Isolation and characterisation of microorganisms of clinical significance and Quantification of white and red blood cells, bacteria, casts and epithelial cells	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
Swabs- Various	Isolation and characterisation of microorganisms of clinical significance (Surveillance Bacteriology)	Manual Culture SOP – MBSURVEILLANCE - Surveillance for potentially significant and resistant organisms in critically ill patients SOP - MBINOCULATION - Inoculation of culture media in bacteriology

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd)	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
	Bacteriology (cont'd)	
CSF	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 Campylobacter spp. E.coli O157 Salmonella sp. Shigella spp. Yersinia enterocolitica	Manual Culture SOP – MBFAECES - Investigation of faeces samples for bacterial pathogens SOP - MBINOCULATION - Inoculation of culture media in bacteriology
Faeces	Detection of Clostridiodes difficile glutamate dehydrogenase (DGH) C. difficile toxins A & B	Lateral flow test using Clostridioides difficile QUIK CHEK Complete Rapid Cassette (Alere) SOP – MBQUIKCHEK - Detection of C.difficile 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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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd) Bacteriology (cont'd)	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
ENT Swabs	Isolation and characterisation of microorganisms of clinical significance	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 Bordetella pertussis and Bordetella parapertussis SOP – MBBINAXNOWTREPA - BinaxNOW Strep A Test Kit
Bacterial Suspensions/ Cultures isolated in-house from all samples listed above	Antibiotic Susceptibility Testing of clinically significant bacteria	Using a combination of manual and automated techniques using EUCAST as appropriate SOP – MBAST - Antibiotic Sensitivity Testing Procedures SOP - MBVITEK2 - Bacterial Identification and Antimicrobial Susceptibility Testing using the BioMerieux Vitek2 Compact SOP – MBRESISITANCE - 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

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Microbiological examinations to assist in clinical investigations (cont'd)	Documented in house methods based on UKStandards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
Bacteriology (cont'd)	
Identification of microorganisms of clinical significance	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
Automated identification of microorganisms of clinical significance	Bruker MALDI-TOF SOP MBMALDI Microbiology 2291
Mycology	
Antifungal Susceptibility Testing of yeast of clinical significance	Sensititre Plates (Thermo Scientific) MBCANDIDA ID & SENS MBANTIFUNGAL_AST
Parasitology	
Detection of parasites (ova, cysts, trophozoites and worms) of clinical significance	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
	Microbiological examinations to assist in clinical investigations (cont'd) Bacteriology (cont'd) Identification of microorganisms of clinical significance Automated identification of microorganisms of clinical significance Mycology Antifungal Susceptibility Testing of yeast of clinical significance Parasitology Detection of parasites (ova, cysts, trophozoites and worms) of clinical

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd) Serology	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
Serum (Blood)	Identification of Streptococcal Antibodies -Antistreptolysin-O (ASO) and antiDNAase b	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.
	<u>Virology</u>	
Nasopharyngeal Aspirates	Detection of Respiratory syncytial virus (RSV)	Rapid RSV lateral flow Test using BinaxNOW (Alere) SOP – MBBINAXNOWRSV - Binax NOW RSV test

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd) Molecular Diagnostics	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
Respiratory Aspirates, Combined Nose and Throat Swabs	Detection/ Identification of Respiratory viruses and bacteria 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	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

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd)	Documented in house methods based on UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:
Positive Blood Culture Broth	Identification of microorganisms of clinical significance 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 glabrata Candida krusei Candida parapsilosis Candida tropicalis	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

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations to assist in clinical investigations (cont'd)	Documented in house methods based on UK 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
		SOP MBCEPHEID using Cepheid GeneXpert by PCR and
Rectal Swab/ Faeces	Carbapenemase resistance gene detection	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

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HUMAN BODY FLUIDS (as stated) (cont'd)	Haematology Examination Activities for the Purpose of Clinical Diagnosis	Documented in-house methods and manufacturer's operating instructions as specified:
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 240717
Blood	Erythrocyte Sedimentation Rate	Manual modified Westegren Method using Aquisel P 4 Micro Dispette HTR SOP 170817
Blood	Glandular Fever Screen for Infectious Mononucleosis	Clearview IM II Glandular Fever Screening Kit- a rapid chromatographic immunoassay SOP Haematology 2356
Blood	Sickle Screening Test for Qualitative test to detect the presence of haemoglobin S	TCS Bioscience - Haemoglobin Solubility Test HTR SOP 230817
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

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HUMAN BODY FLUIDS (as stated) (cont'd)	Haematology Examination Activities for the Purpose of Clinical Diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
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 Inhibitor Assays

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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Alder Hey Children's NHS Foundation Trust

Issue No: 011 Issue date: 16 May 2025

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (as stated) (cont'd)	Haematology Examination Activities for the Purpose of Clinical Diagnosis (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 A Inhibitor Screen F VIII	Clotting Assay HTC SOP-2010
	Human FIX Inhibitor Assay (Haemophilia B)	Clotting Assay HTC SOP-2010
Blood	Detection of Rheumatoid Factor	Mastalatex RA 80 -Latex Agglutination HTS SOP-0014

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HUMAN BODY FLUIDS (as stated) (cont'd)	Haematology Examination Activities for the Purpose of Clinical Diagnosis	Documented in-house methods and manufacturer's operating instructions as specified:
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 Blood Sciences 1335
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 Transfusion Examinations to assist in clinical investigations	Documented in-house methods and manufacturer's operating instructions as specified:
Blood		Grifols Erytra Automated Immunohaematology Analyser and Manual Grifols Techniques using Gel Cards:
	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)	HBT-026 Use of the Eryhtra for ABO, Rh(D), Grouping and Antibody Screening
	Neonatal Blood Group and Direct Antiglobulin Test (patients <4m old) ABO and RhD systems: A RhD positive B RhD positive AB RhD positive O RhD Positive A RhD negative B RhD negative AB RhD negative AB RhD negative AB RhD negative AB RhD Negative	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
	Group and Antibody Screen ABO and RhD systems: - A RhD positive - B RhD positive - AB RhD positive - O RhD Positive - A RhD negative - B RhD negative - AB RhD negative - AB RhD negative - O RhD Negative	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
	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)	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

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HUMAN BODY FLUIDS (as stated) (cont'd)	Blood Transfusion Examinations to assist in clinical investigations (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified:
Blood		Grifols Erytra Automated Immunohaematology Analyser and Manual Grifols Techniques using Gel Cards:
	Direct Antiglobulin Test (C3d, IgG,)	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
	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
	END	

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