


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
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|  <p>UKAS MEDICAL 9091</p> <p>Accredited to ISO 15189:2022</p> | <p>Alder Hey Children's NHS Foundation Trust</p> <p>Issue No: 014 Issue date: 25 November 2025</p> | |
| | <p>Eaton Road Liverpool L12 2AP</p> | <p>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/</p> |
| <p>Testing performed at the above address only</p> | | |

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | Activity |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <p>Address Department of Pathology Alder Hey Children's NHS Foundation Trust Eaton Road Liverpool L12 2AP</p> <p>Local contact Pamela Ashton</p> | <p>Clinical Biochemistry Medical Microbiology Cellular Pathology Mortuary Services</p> |

Site activities performed away from the locations listed above:

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



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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: | 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) | <u>Biochemistry Examination</u> <u>Activities for the Purpose of</u> <u>Clinical Diagnosis (cont'd)</u> | 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) | <u>Biochemistry Examination</u> <u>Activities for the Purpose of</u> <u>Clinical Diagnosis</u> (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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| 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) | 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 |
| Lithium heparin (plasma)/ Plain (serum) | Testosterone | Chemiluminescent Microparticle Immunoassay |



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



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Faeces Serum EDTA or Citrate plasma Serum or Lithium Heparin plasma</p> <p>Blood</p> <p>Blood</p> <p>Blood</p> | <p><u>Immunology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p>Calprotectin Tissue Transglutaminase Total IgE</p> <p>IgA Anti-Tissue Transglutaminase antibodies (TTG)</p> <p>Total IgE</p> <p>Specific IgE:</p> <p>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</p> | <p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA</p> |



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood</p> | <p><u>Immunology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p>Specific IgE (cont):</p> <p>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 Ovomuroid 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</p> | <p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)</p> |



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood</p> | <p><u>Immunology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p>Specific IgE (cont):</p> <p>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 gx4 Mixed Nut Allergens Mixed Nuts fx1 Mixed Nuts fx22 Mixed Pet Feathers ex72 Mixed Tree Pollens</p> | <p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)</p> |



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood</p> | <p><u>Immunology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p>Specific IgE (cont):</p> <p>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</p> | <p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)</p> |



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood</p> | <p><u>Immunology Examination Activities for the Purpose of Clinical Diagnosis</u> (cont'd)</p> <p>Specific IgE (cont):</p> <p>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</p> | <p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>BC SOP-0092 using Phadia ImmunoCap 250 analyser by EliA (cont)</p> |



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| HUMAN BODY FLUIDS (as stated) (cont'd) | <u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)</u> | Documented in-house methods and manufacturer's operating instructions as specified: |
| Blood | <u>Therapeutic Drug Monitoring</u> Quantification of Flecainide | Thermo Ultimate 3000UHPLC BC SOP-0142 using Fluorescence Detection |
| Blood, Urine, CSF | <u>Metabolic</u> 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) | Documented in-house methods and manufacturer's operating instructions as specified: |
| | <u>Metabolic</u> (cont'd) | |
| | 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 | 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 |
| 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 Galactose-1-Phosphate Uridyl Transferase (Gal-1-1PUT) | Enzymatic Shimadzu Spectrophotometer UV Detection BC SOP-0042 |



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood</p> | <p><u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)</u></p> <p>Quantification of:</p> <p>Copper</p> <p>Zinc</p> <p>Selenium</p> <p>Manganese</p> <p>Lead</p> <p><u>Newborn Screening</u></p> | <p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Thermo iCAPQ ICP MS Biochemistry 842</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 requirements</i></p> |



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| <p>HUMAN BODY FLUIDS (as stated) (cont'd)</p> <p>Blood Spot</p> <p>Blood Spot</p> | <p><u>Biochemistry Examination Activities for the Purpose of Clinical Diagnosis (cont'd)</u></p> <p><u>Newborn Screening</u></p> <p>Quantification of:</p> <p>Thyroid Stimulating Hormone (TSH)</p> <p>Immune Reactive Trypsin (IRT)</p> <p>Identification of:</p> <p>Haemoglobins A,F, S, C,D and E</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 requirements</i></p> <p>Perkin Elmer Genetics Screening Processor by DELFIA technology using:</p> <p>Newborn Screening 1294</p> <p>Newborn Screening 1296</p> <p>BioRad Variant NBS Screening using HPLC</p> <p>Newborn Screening 1285</p> |



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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 marrrows</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 SOP-0018</p> <p>Tissue Processing using Thermo Shandon Excelsior Tissue Processor HP SOP-0415</p> <p>Tissue Embedding using Leica Embedding Centre HP SOP-0022</p> <p>Microtomy using Thermo Shandon Microtome HP SOP-0015</p> <p>Decalcification HP SOP-0032</p> <p>Preparation of frozen Sections – HP SOP-0018 Equipment: Leica CM1950 cryostat</p> <p>Preparation of Muscle Biopsies HP SOP-0014 Equipment: Leica CM1950 cryostat</p> <p>Cryotomy using Leica CM1950 cryostat HP SOP-0062 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 SOP-0055 |
| 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 HP SOP-0411 |
| | Connective Tissue | Haematoxylin Van Gieson (HVG) HP SOP-0090 |



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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 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 Gycogen, mucins, fungi and basement membranes Ferric Iron Collagen Reticulin fibres | Oil Red O (Lillie & amp; Ashburn's Isopropanol Method) HP SOP-0093 Orcein (Shikata's) HP SOP-0094 Periodic Acid Schiff (PAS) +/- Amylase for muscle biopsies HP SOP- 0413 Periodic Acid Schiff (PAS) +/- Amylase HP SOP-0070 Perl's Prussian Blue HP SOP-0096 Picro-Sirius Red HP SOP-0227 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) | <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-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 |
| | <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 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) | <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 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 | <u>Immunohistochemistry</u> | Dako Autostainer Link 48- Automated IHC Stainer HP SOP201 |
| | For demonstration of: | 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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| <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>Peripheral nerve ganglion</p> <p>Epithelial Cells</p> <p>CD1a protein expression</p> <p>T cells</p> <p>Thymocytes and T helper cells</p> <p>CD5 antigen on T cells and a small number of B cells</p> <p>Cytotoxic/suppressor T cells</p> <p>All germinal centre cells of tonsil</p> <p>Reed-Sternberg cells in Hodgkin's Disease and granulocytes</p> <p>Germinal centre cells, mantle zone lymphocytes, and scattered interfollicular lymphocytes.</p> <p>Mature B cells and follicular lymphocytes</p> <p>B cells in the mantle zone and follicular dendritic reticulum cells in germinal centres</p> <p>Activated B and T cells, plasma cells and Reed-Sternberg cells in Hodgkin's Lymphoma</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>Calret Agilent (Dako)</p> <p>CAM 5.2 BD Bioscience</p> <p>CD1A Agilent (Dako)</p> <p>CD3 Leica</p> <p>CD4 Agilent (Dako)</p> <p>CD5 Leica</p> <p>CD8 Agilent (Dako)</p> <p>CD10 Agilent (Dako)</p> <p>CD15 Agilent (Dako)</p> <p>CD20cy Agilent (Dako)</p> <p>CD21 Agilent (Dako)</p> <p>CD23 Agilent (Dako)</p> <p>CD30 Agilent (Dako)</p> |



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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</p> <p>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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| <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>Pro B cells, Pre-B cells and mature B cells. PAX-5 protein in follicular and non-follicular B cells of tonsil and spleen</p> <p>Neurons and Neuroendocrine cells</p> <p>Trophoblasts of placenta and germ cells in testis</p> <p>Melanocytes, Langerhans cells, histocytes, chondrocytes, adipocytes and Schwann cells</p> <p>Smooth muscle cells</p> <p>Near N-Terminus of SNF2b</p> <p>SV40 T-antigen from virus samples</p> <p>Neurons and Neuroendocrine cells</p> <p>Corticol thymocytes and primitive lymphocytes</p> <p>Transducin-like enhancer protein</p> <p>Brain and adrenal neurons</p> <p>Mesenchymal cells</p> <p>Wilms' Tumour Antigen</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>PAX-5 Leica</p> <p>PGP Agilent (Dako)</p> <p>PLAP Agilent (Dako)</p> <p>S100 Agilent (Dako)</p> <p>SMA Agilent (Dako)</p> <p>SNF/BRG1 Millipore</p> <p>SV40 Thermo</p> <p>Synapto Agilent (Dako)</p> <p>Tdt Cell Marque</p> <p>TLE1 (1F5) Cell Marque</p> <p>Tyrosine hydroxylase Leica</p> <p>Vim Agilent (Dako)</p> <p>WT-1 Leica</p> |



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



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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 UK Standards for Microbiological Investigations (SMIs) and manufacturer's instructions for:</p> <p>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</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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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>CSF</p> <p>Faeces</p> <p>Faeces</p> <p>Blood/ Transfusion Packs</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 and cell count (red and white blood cells)</p> <p>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></p> <p>Detection of <i>Clostridioides difficile</i> glutamate dehydrogenase (DGH) <i>C. difficile</i> toxins A & B</p> <p>Isolation and characterisation of microorganisms of clinical significance</p> | <p>Documented in house methods based on UK Standards for Microbiological Investigations (SMLs) and manufacturer's instructions for:</p> <p>Manual Culture and Microscopical Examination using Kovalside Counting Chamber SOP – MBCSF- Investigation of Cerebrospinal fluid SOP - MBINOCULATION - Inoculation of culture media in bacteriology</p> <p>Manual Culture SOP – MBFAECES - Investigation of faeces samples for bacterial pathogens SOP - MBINOCULATION - Inoculation of culture media in bacteriology</p> <p>Lateral flow test using <i>Clostridioides 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</p> <p>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</p> |



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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 UK 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 – 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</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>Bacterial and fungal isolates</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>Automated identification of microorganisms of clinical significance</p> <p><u>Mycology</u></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 UKStandards 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>Bruker MALDI-TOF SOP MBMALDI Microbiology 2291</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>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 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 UK 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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Alder Hey Children's NHS Foundation Trust

Issue No: 014 Issue date: 25 November 2025

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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 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 albicans 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) | <u>Microbiological examinations to assist in clinical investigations</u> (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 |
| 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 |



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| HUMAN BODY FLUIDS (as stated) (cont'd) | <u>Haematology Examination</u> <u>Activities for the Purpose of</u> <u>Clinical Diagnosis</u> | 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 |
| Blood | Confirmation of Malaria parasites by detection of: <i>P. falciparum</i> (HRPII) | Immunochromogenic method using BinaxNOW SOPHTR 2171 |



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| HUMAN BODY FLUIDS (as stated) (cont'd) | <u>Haematology Examination</u> <u>Activities for the Purpose of</u> <u>Clinical Diagnosis (cont'd)</u> | 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: Clotting Screen including, PT, APTT, APTT Ratio, Fibrinogen Clauss, Thrombin Time, Reptilase Time, PT and APTT mixing tests | Sysmex CS2400 manufacturers' instructions as relevant: for all tests below unless otherwise stated Using clotting assay, chromogenic, immunoassay and aggregation methods Clotting Assay HTC SOP-2004 HTC SOP-1010 Inhibitor Assays |



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| HUMAN BODY FLUIDS (as stated) (cont'd) | <u>Haematology Examination</u> <u>Activities for the Purpose of</u> <u>Clinical Diagnosis (cont'd)</u> | 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) | <u>Haematology Examination</u> <u>Activities for the Purpose of</u> <u>Clinical Diagnosis</u> | 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 | <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)</p> <p>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-026 Use of the 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> <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 |
| | Kleihauer Screen for foetal/maternal bleed estimation | Manual Staining/ Kleihauer Technique HTT SOP-0041 |
| END | | |