


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |  |
|---|---|--|
|  <p><b>UKAS</b><br/>MEDICAL</p> <p><b>8210</b></p> <p>Accredited to<br/>ISO 15189:2022</p> | <p><b>Royal Devon University Healthcare NHS Foundation Trust</b></p> <p>Issue No: 016    Issue date: 04 March 2026</p>        |  |
|   | <p>Department of Blood Sciences<br/>Royal Devon &amp; Exeter Hospital<br/>Area A2<br/>Barrack Road<br/>Exeter<br/>EX2 5DW</p> | <p>Contact: Adrian Cudmore/Mandy Perry<br/>Tel: +44 (0) 1392 402461<br/>Fax: +44 (0) 1392 402905<br/>E-Mail: rduh.bloodsciencesadmin@nhs.net<br/>Website: www.exeterlaboratory.com</p> |
| <p>Testing performed at the above address only</p>  |   |  |

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

| Location details   |  | Activity   |
|--|--|--|
| Department of Blood Sciences<br>Royal Devon & Exeter Hospital<br>Template A<br>Barrack Road<br>Exeter<br>EX2 5DW | <p><b>Contact:</b><br/>Adrian Cudmore<br/>01392 402936</p> | Clinical Chemistry including Fetal Anomaly Screening Programme                 |
|  | <p>Adrian Cudmore<br/>01392 402936</p>                     | General Haematology including Antenatal Sickle cell and thalassaemia screening |
|  | <p>Jennifer Davies<br/>01392 403363</p>                    | Blood transfusion including storage & issue of blood and blood products        |
|  | <p>Adrian Cudmore<br/>01392 402936</p>                     | Special Haematology including Molecular Haematology                            |
|  | <p>Adrian Cudmore<br/>01392 402936</p>                     | Immunology   |



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#### Site activities performed away from the locations listed above:

| Location details  | Activities  |
|---|---|
| Phlebotomy department<br>Royal Devon and Exeter NHS Foundation Trust<br>Barrack Road<br>Exeter<br>EX2 5DW | Venepuncture and collection of blood for diagnostic purposes      |
| Haematology Wards<br>Royal Devon and Exeter NHS Foundation Trust<br>Barrack Road<br>Exeter<br>EX2 5DW     | Fridge for storage & issue of blood and blood products only       |
| Maternity Ward<br>Royal Devon and Exeter NHS Foundation Trust<br>Barrack Road<br>Exeter<br>EX2 5DW        | Fridge for storage & issue of blood and blood products only       |
| Main theatre<br>Royal Devon and Exeter NHS Foundation Trust<br>Barrack Road<br>Exeter<br>EX2 5DW          | 2 Fridges for storage & issue of blood and blood products only    |
| Orthopaedic centre<br>Royal Devon and Exeter NHS Foundation Trust<br>Barrack Road<br>Exeter<br>EX2 5DW    | Fridge for storage & issue of blood and blood products only       |
| Tiverton Hospital<br>Kennedy Way<br>EX16 6NT  | Fridge for storage & issue of blood and blood products only       |
| Sidmouth Hospital<br>Herdons Lane<br>All Saints Road<br>EX10 8EW  | Fridge for storage & issue of blood and blood products only       |
| Nightingale Hospital<br>Moor Lane<br>EX2 7JG  | Blood fridge for storage & issue of blood and blood products only |



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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 AND TISSUES              | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.<br><br>CC/SOP/0284 |
| Serum from venous and capillary collection | Albumin  | Colourimetric, BCG  |
| Serum from venous and capillary collection | Alkaline phosphatase   | Colourimetric, IFCC   |
| Serum from venous and capillary collection | Alanine aminotransferase   | Kinetic, IFCC without PP activation   |
| Serum from venous and capillary collection | Aspartate aminotransferase   | Kinetic, IFCC without PP activation   |
| Serum from venous and capillary collection | Protein (total)  | Colourimetric, Biuret   |
| Serum from venous and capillary collection | Iron   | Colourimetric, Ferrozine  |
| Serum from venous and capillary collection | Magnesium  | Colourimetric, Xylidyl Blue   |
| Serum from venous and capillary collection | Cortisol   | Competitive ECLIA   |
| Serum from venous and capillary collection | Folate   | Competitive ECLIA   |
| Serum from venous and capillary collection | FT3  | Competitive ECLIA   |
| Serum from venous and capillary collection | FT4  | Competitive ECLIA   |
| Serum from venous and capillary collection | Oestradiol   | Competitive ECLIA   |
| Serum from venous and capillary collection | Progesterone   | Competitive ECLIA   |
| Serum from venous and capillary collection | Testosterone   | Competitive ECLIA   |
| Serum from venous and capillary collection | Vitamin D total  | Competitive ECLIA   |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)     | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology |
|  |   | Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies                           |
|  |   | CC/SOP/0284   |
| Serum from venous and capillary collection | HDL-Cholesterol   | Enzymatic Colourimetric, CHER   |
| Serum from venous and capillary collection | Cholesterol (total)   | Enzymatic Colourimetric, ID/MS standardisation  |
| Serum from venous and capillary collection | $\gamma$ -Glutamyl transferase  | Enzymatic Colourimetric, IFCC   |
| Serum from venous and capillary collection | Triglycerides   | Enzymatic Colourimetric, Wahlefeld  |
| Serum from venous and capillary collection | Transferrin   | Immunoturbidimetric   |
| Serum from venous and capillary collection | IgA   | Immunoturbidimetric, Tina-quant   |
| Serum from venous and capillary collection | IgG   | Immunoturbidimetric, Tina-quant   |
| Serum from venous and capillary collection | IgM   | Immunoturbidimetric, Tina-quant   |
| Serum from venous and capillary collection | Chloride  | Indirect ISE  |
| Serum from venous and capillary collection | Urea  | Kinetic, Urease   |
| Serum from venous and capillary collection | hsCRP   | Particle enhanced Immunoturbidimetric assay, Latex Sandwich ECLIA   |
| Serum from venous and capillary collection | Active B12  | Sandwich ECLIA  |
| Serum from venous and capillary collection | CA 125  | Sandwich ECLIA  |
| Serum from venous and capillary collection | Ferritin  | Sandwich ECLIA  |
| Serum from venous and capillary collection | IGF-1   | Sandwich ECLIA  |
| Serum from venous and capillary collection | FSH   | Sandwich ECLIA  |
| Serum from venous and capillary collection | LH  | Sandwich ECLIA  |



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| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection</p> <p>Serum from venous and capillary collection and urine</p> <p>Serum from venous and capillary collection and urine</p> <p>Serum from venous and capillary collection and urine</p> <p>Venous Serum</p> <p>Venous Serum</p> <p>Venous Serum</p> <p>Venous Serum</p> | <p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Prolactin</p> <p>PSA (total)</p> <p>SHBG</p> <p>TSH</p> <p>Creatine kinase</p> <p>Anti-SARS-CoV-2</p> <p>Anti-SARS-CoV-2 S</p> <p>Creatinine</p> <p>Sodium</p> <p>Urate</p> <p>Bilirubin (total)</p> <p>Ethanol</p> <p>Paracetamol</p> <p>Bile acids</p> | <p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.</p> <p>CC/SOP/0284</p> <p>Sandwich ECLIA</p> <p>Sandwich ECLIA</p> <p>Sandwich ECLIA</p> <p>Sandwich ECLIA</p> <p>UV-Test, IFCC</p> <p>Sandwich ECLIA</p> <p>Sandwich ECLIA (double antigen)</p> <p>Enzymatic, Creatininase</p> <p>Indirect ISE</p> <p>Enzymatic Colourimetric, Uricase</p> <p>Colourimetric, Diazo</p> <p>Enzymatic, Alcohol Dehydrogenase</p> <p>Colourimetric, Arylacylamidase</p> <p>Colourimetric, HSD</p> |



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| Materials/Products tested  | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used   |
|--|--|--|
| HUMAN BODY FLUIDS AND TISSUES (cont'd)<br><br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum<br>Venous Serum | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u><br><br>Lactate<br>Calcium (total)<br>Lithium<br>Anti-Thyroglobulin<br>Anti-TPO<br>Cyclosporin<br>Digoxin<br>Tacrolimus<br>Vitamin B12<br>Amylase<br>Ammonia<br>Angiotensin converting enzyme | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.<br><br>CC/SOP/0284<br><br>Colourimetric, LOD<br>Colourimetric, NM-BAPTA<br>Colourimetric, Porphyrin<br>Competitive ECLIA<br>Competitive ECLIA<br>Competitive ECLIA<br>Competitive ECLIA<br>Competitive ECLIA<br>Competitive ECLIA<br>Enzymatic Colourimetric, IFCC<br>Enzymatic, Glutamate dehydrogenase<br>Enzymatic, KK-ACK |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies<br><br>CC/SOP/0284 |
| Venous serum                           | Complement C3   | Immunotubidometric, Tina-quant   |
| Venous serum                           | Complement C4   | Immunotubidometric, Tina-quant   |
| Venous serum                           | Carbamazepine   | KIMS   |
| Venous serum                           | Phenytoin   | KIMS   |
| Venous serum                           | Theophylline  | KIMS   |
| Venous serum                           | Vancomycin  | KIMS   |
| Venous serum                           | Phosphate   | Molybdate UV, Molybdate  |
| Venous serum                           | CRP   | Particle enhanced Immunoturbidimetric assay, Tina-quant  |
| Venous serum                           | AFP   | Sandwich ECLIA   |
| Venous serum                           | AMH   | Sandwich ECLIA   |
| Venous serum                           | Beta-HCG  | Sandwich ECLIA   |
| Venous serum                           | CA 15-3   | Sandwich ECLIA   |
| Venous serum                           | CA 19-9   | Sandwich ECLIA   |
| Venous serum                           | CEA   | Sandwich ECLIA   |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.<br><br>Documented in-house methods to meet the requirements of the Fetal Anomaly Screening Programme as defined in laboratory QA evidence requirements (tests marked *)<br><br>CC/SOP/0284 |
|  | <u>First Trimester Downs Screening:</u>   |   |
| Venous serum                           | Free beta hCG*  | Sandwich ECLIA  |
| Venous Serum                           | hGH   | Sandwich ECLIA  |
| Venous Serum                           | hs Troponin T hs  | Sandwich ECLIA  |
| Venous Serum                           | IgE   | Sandwich ECLIA  |
| Venous Serum                           | PAPP-A*   | Sandwich ECLIA  |
| Venous Serum                           | PIGF  | Sandwich ECLIA  |
| Venous Serum                           | proBNP  | Sandwich ECLIA  |
| Venous Serum                           | PTH   | Sandwich ECLIA  |
| Venous Serum                           | sFlt-1  | Sandwich ECLIA  |
| Venous Serum                           | Anti-CCP  | Sandwich ECLIA (IgG-Capture)  |
| Venous Serum                           | Lactate dehydrogenase   | UV-Test, IFCC   |
| Venous Serum                           | Bicarbonate   | Enzymatic, PEP  |
| Venous Serum                           | Bilirubin (direct)  | Enzymatic, Vanidate Oxidation   |
| Venous Serum                           | Tobramycin  | Enzyme Immunoassay  |
| Venous Serum                           | Gentamycin  | Enzyme Immunoassay, CEDIA   |
| Venous Serum                           | Methotrexate  | Enzyme Immunoassay, EMIT  |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.<br><br>CC/SOP/0284 |
| Venous serum                           | Salicylate  | Enzyme Mediated Colourimetric, Hydroxylase  |
| Venous serum                           | Ceruloplasmin   | Immunoturbidometric   |
| Venous serum                           | Rheumatoid factor   | Immunoturbidometric   |
| Venous serum                           | Free kappa light chains   | Immunoturbidometric, Freelite   |
| Venous serum                           | Free lambda light chains  | Immunoturbidometric, Freelite   |
| Venous serum                           | Alpha-1-antitrypsin   | Immunoturbidometric, Tina-quant   |
| Venous serum                           | Beta-2 microglobulin  | Immunoturbidometric, Tina-quant   |
| Venous Serum and urine                 | Amylase   | Enzymatic Colourimetric, IFCC   |
| Venous Serum and urine                 | Potassium   | Indirect ISE  |
| Venous Serum and plasma                | Insulin   | Sandwich ECLIA  |
| Venous Serum, plasma and urine         | C-peptide   | Sandwich ECLIA  |
| CSF                                    | Lactate   | Colourimetric, LOD  |
| CSF, urine                             | Protein   | Turbidimetric   |
| CSF, urine, venous serum               | Glucose   | UV-Test, Hexokinase   |
| Urine                                  | Calcium   | Colourimetric, NM-BAPTA   |
| Urine                                  | Magnesium   | Colourimetric, Xylidyl Blue   |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.<br><br>CC/SOP/0284 |
| Urine                                  | Microalbumin  | Immunoturbidometric, Tina-quant   |
| Urine                                  | Amphetamines  | KIMS  |
| Urine                                  | Benzodiazepines   | KIMS  |
| Urine                                  | Cannabinoids  | KIMS  |
| Urine                                  | Cocaine   | KIMS  |
| Urine                                  | Methadone   | KIMS  |
| Urine                                  | Opiates   | KIMS  |
| Urine                                  | Urea  | Kinetic, Urease   |
| Urine                                  | Phosphate   | Molybdate UV, Molybdate<br><br>By calculation   |
| Urine                                  | Creatinine Clearance  | CC/SOP/0119   |
| Venous serum                           | Adjusted Calcium  |   |
| Venous serum                           | sFlt-1/PIGF   |   |
| Venous serum                           | Acute Kidney Injury   | Calculated using renal registry national algorithm  |
| Venous serum                           | GFR   | MDRD EPI calculation  |
| Venous serum                           | Urine-C-peptide creatinine ratio  |   |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: |
| Venous serum                           | Non-HDL cholesterol   | By calculation<br>CC/SOP/0119  |
| Urine                                  | Albumin/creatinine ratio  |  |
| Venous serum                           | Free lambda/kappa ratio   |  |
| Venous serum                           | Free kappa/lambda ratio   |  |
| Venous serum                           | Schwartz eGFR   |  |
| Venous serum                           | FIB-4 calculation   |  |
|  |   | Dynex DS2 Automated ELISA system   |
| Venous serum                           | Adalimumab antibody (total)   | CC/SOP/0279  |
| Venous serum                           | Adalimumab drug levels  | CC/SOP/0262  |
| Venous serum                           | GAD antibody  | BS/SOP/0033  |
| Venous serum                           | IA2 antibody  | BS/SOP/0035  |
| Venous serum                           | Infliximab antibody (total)   | CC/SOP/0261  |
| Venous serum                           | Infliximab drug levels  | CC/SOP/0260  |
| Venous serum                           | Ustekinumab drug levels   | CC/SOP/907   |
| Venous serum                           | Vedolizumab antibody (free)   | CC/SOP/903   |
| Venous serum                           | Vedolizumab drug levels   | CC/SOP/0262  |
| Venous serum                           | Zinc Transporter 8 antibody   | BS/SOP/0037  |
|  |   | Mast OC Sensor Pledia  |
| Faeces                                 | Faecal Calprotectin   | CC/SOP/936   |
| Faeces                                 | FIT (faecal immunochemical test)  | CC/SOP/936   |



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| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Venous serum and urine</p> <p>Sweat</p> | <p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Osmolarity</p> <p>Chloride</p> | <p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Osmo 1 Single Sample Micro-osmometer<br/>CC/SOP/0025</p> <p>Manual method Chloride meter<br/>Coulometry<br/>CC/SOP/0053</p> |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)               | <u>Haematology examination activities for the purpose of clinical diagnosis</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: |
| EDTA whole blood from venous or capillary collection | Full Blood Count including the following parameters:<br><br>Haemoglobin         | Sysmex XN9100<br><br>Electrical impedance, laser light scatter & dye bonding   |
| EDTA whole blood from venous or capillary collection | White Blood Cell count  | HASOPXN9100  |
| EDTA whole blood from venous or capillary collection | Platelet count  |  |
| EDTA whole blood from venous or capillary collection | Red blood cell count  |  |
| EDTA whole blood from venous or capillary collection | Haematocrit   |  |
| EDTA whole blood from venous collection              | MCV   |  |
| EDTA whole blood from venous collection              | MCH   |  |
| EDTA whole blood from venous collection              | MCHC  |  |
| EDTA whole blood from venous collection              | RDW   |  |
| EDTA whole blood from venous collection              | Neutrophil count  |  |
| EDTA whole blood from venous collection              | Lymphocyte count  |  |
| EDTA whole blood from venous collection              | Monocyte count  |  |
| EDTA whole blood from venous collection              | Eosinophil count  |  |
| EDTA whole blood from venous collection              | Basophil count  |  |
| EDTA whole blood from venous collection              | RET-He  |  |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: |
|  | Full Blood Count including the following parameters:                            | Sysmex XN9100  |
| EDTA whole blood                       | Automated cell count – Haematopoietic Progenitor Cell Count (HPC)               | Electrical impedance, laser light scatter & dye bonding  |
|  | Peripheral Blood Cell Morphology  | Sysmex based flow cytometric assay HASOPHPC  |
| EDTA whole blood                       | Blood film for Morphology   | Blood smears stained with May-Grunwald and Giemsa stains<br>HASOPSP-50<br>HASOP RAL Stainer  |
| EDTA whole blood                       | Manual differential   | Automated stainer SP-50<br>HASOPSP-50  |
| EDTA whole blood                       | Digital morphology  | DI-60 Digital Morphology combined with Cellavision Interpretative software<br>HASOPDI-60   |
|  | <u>Bone Marrow Morphology</u>   |  |
| Bone marrow                            | Bone marrow morphology  | Manual MCDh panoptic staining<br>HASOP RAL Stainer   |
| Bone marrow                            | Bone Marrow differential  | Stained using RAL stainer<br>HASOP RAL stainer   |
| Bone marrow                            | Iron stain  | Manual staining using Prussian Blue<br>HASOPS-0008   |



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|--|--|---|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:  |
| Urine                                  | Manual Haematology<br>Urinary Haemosiderin   | Manual staining using Prussian Blue<br>HASOPS-0014  |
| CSF                                    | Morphology   | Shandon Cytospin<br>Manual MCDh panoptic staining<br>Microscopy<br>HASOPM-0001  |
| EDTA whole blood                       | Erythrocyte Sedimentation Rate (ESR)   | Manual method using Becton Dickinson Seditainer Tubes<br>HASOPM-0004  |
| EDTA Plasma and serum                  | Glandular Fever screen   | Monogen test using latex agglutination<br>HASOPM-0007   |
| EDTA whole blood                       | Haemoglobinopathy<br>Haemoglobinopathy screen quantification of:<br>HbA2<br>HbF<br>HbS   | Documented in-house methods to meet the requirements of the NHS Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements'<br>HASOPTHAL using Sebia Capillarys 3 Tera |
| EDTA whole blood                       | Sickle Cell Solubility   | Sickledex test kit using a turbidimetric assay<br>HASOPM-0020   |
| EDTA whole blood                       | Detection of HRP2 and pLDH antigens for the identification of Malaria parasites          | CareUS test using an immunoassay by laminar flow<br>HASOPM-0032   |
| EDTA whole blood                       | Malaria Blood films  | Blood Film review using Giemsa (thin film) and Field's (thick film) stains<br>HASOPS-0009   |



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|---|--|---|
| EDTA whole blood  | Molecular malaria assay<br>Detection of <i>Plasmodium</i><br>mitochondrial DNA | Loop-mediated amplification using<br>the ILLumiGene assay<br>HASOPO-0012                          |
| EDTA whole blood from venous<br>or capillary collection | HbA1c testing<br><br>HbA1c (Glycated Haemoglobin)                              | Sebia Capillarys Tera<br>Capillary electrophoresis<br><br>HASOPGHB                                |
|   | Routine Coagulation  | IL Werfen ACL TOP 550 analyser<br>using Coagulometric (turbidimetric)<br>and Immuno-turbidimetric |
| Citrated whole blood                                    | coagulation screen   | HASOPC-0024   |
| Citrated whole blood                                    | Prothrombin time   | HASOPC-0024   |
| Citrated whole blood                                    | INR  | HASOPC-0024   |
| Citrated whole blood                                    | APTR   | HASOPC-0024   |
| Citrated whole blood                                    | D-dimer  | HASOPC-0024   |
| Citrated whole blood                                    | Clauss Fibrinogen  | HASOPC-0024   |
| Citrated whole blood                                    | Thrombin Time  | HASOP-0018HASOPC-0018   |
|   | Special Coagulation  | IL Werfen ACL TOP analyser 550  |
| Citrated whole blood                                    | Liquid Heparin   | One stage chromogenic assay<br>HASOPC-0040  |
| Citrated whole blood                                    | Coagulation Factors 2, 5, 7,8, 9,<br>10,11 and 12                              | One stage factor assay<br>HASOPC-0035   |
| Citrated whole blood                                    | Coagulation Factor Inhibitor Assay   | Bethesda Assay<br>HASOPC-0017   |
| Citrated whole blood                                    | Von Willebrand Factor Antigen  | Immunoturbidometric assay for vWF<br>Antigen<br>HASOPC-0026                                       |
| Citrated whole blood                                    | Von Willebrand Factor Activity   | Immunoturbidometric assay for vWF<br>Activity<br>HASOPC-0027                                      |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)<br><br>Citrated whole blood<br><br>Citrated whole blood<br><br>Citrated whole blood<br><br>Citrated whole blood<br><br>Citrated whole blood | <u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u><br><br>Thrombophilia screen<br><br>Lupus Anticoagulant<br><br>Antithrombin<br><br>Free Protein S<br><br>Protein C<br><br>Direct oral anticoagulants: <ul style="list-style-type: none"> <li>• Apixaban</li> <li>• Rivaroxaban</li> </ul> | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:<br><br>IL Werfen ACL TOP 550 analyser analyser<br><br>Direct Russells Viper Venom time HASOPC-0014<br><br>Chromogenic assay HASOPC-0011<br><br>Latex Agglutination HASOPC-0013<br><br>Chromogenic assay HASOPC-0025<br><br>DOAC assay HASOPC-0048 |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>  | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:            |
| EDTA whole Blood                       | Blood grouping (ABO and RhD) and antibody screening  | BioRad IH500 analyser using column agglutination technology<br>TRLP0103   |
| EDTA whole Blood                       | Antibody identification: Detection of antibodies to the following antigen: D, C, c, E, e, Cw, V, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua, Lub, Xga | Manual technique using BioRad column agglutination technique<br>TRLP0020<br><br>BioRad IH500 analyser using column agglutination technology<br>TRLP0056 |
| EDTA whole Blood                       | Blood grouping (ABO and RhD)   | Manual direct agglutination tube technique<br>TRLP0009  |
| EDTA whole Blood                       | Manual ABO/D for Newborns  | Manual techniques using BioRad column agglutination technology<br>TRLP0010  |
| EDTA whole Blood                       | Direct Antiglobulin Test: detection of IgG, IgA, IgM, C3d, C3c on the surface of red cells   | Manual technique using BioRad column agglutination technology<br><br>Automated method using BioRad IH500 column agglutination<br>TRLP0017               |
| EDTA whole Blood                       | Red cell antigen phenotyping: detection of antigen types: C, c, E, e, K  | Automated method using BioRad IH500 column agglutination<br>TRLP0084  |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:   |
| EDTA whole Blood                       | Detection of A subgroup  | A1 test: manual using tube technology<br>TRLP0080  |
| EDTA whole Blood                       | Feto-maternal haemorrhage  | Manual test using Guest Medical acid elution technique<br>TRLP0019   |
| EDTA whole Blood                       | Weak/Partial D testing   | Manual technique using BioRad column agglutination technology<br>TRLP0031  |
| EDTA whole Blood Plasma                | Crossmatch- Compatibility testing of patient plasma with donor cells                           | Manual serological crossmatch using BioRad column agglutinin IAT<br>TRLP0029<br><br>Electronic Crossmatch<br>TRLP0098<br><br>Manual Neonatal serological Crossmatching using BioRad column agglutination<br>TRLP0041 |



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|--|--|--|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u>   | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: |
| Blood                                  | Cryoglobulins  | Manual methodology<br>HASOPP-0005  |
| Serum                                  | Protein analysis and monoclonal band quantification:<br>gamma globulins,<br>beta-2 globulins,<br>beta-1 globulins,<br>alpha-2 globulins,<br>alpha-1 globulins<br>albumin | Sebia Capillarys 3 using capillary zone electrophoresis<br>HASOPP-0008   |
| Urine                                  | Bence-Jones protein  | Sebia Hydrasys 2 using agarose gel electrophoresis<br>HASOPP-0007<br>HASOPP-0009   |
| Blood, urine                           | Paraprotein typing:<br>IgG, IgM, IgA, IgD, IgE, kappa, lambda  | Sebia Hydrasys 2 using agarose gel electrophoresis immunofixation<br>HASOPP-0007   |
| Serum                                  | Anti-nuclear antibodies screen   | IL Quantalyser 2 using immunofluorescence<br><br>Hep2 method<br>IMSOP121, IMSOP127, IMSOP168, IMSOP169                                       |
| Serum                                  | Smooth muscle antibodies<br>Mitochondrial antibodies<br>Liver and kidney microsomal antibodies   | LKS method   |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>   | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: |
| Serum                                  | IgG antibodies against the GBM (glomerular basement membrane) antigen   | Phadia 250 ELISA<br>IMSOP179, IMSOP170   |
| Serum                                  | IgG antibodies against MPO (myeloperoxidase) antigen  | IMSOP179, IMSOP170   |
| Serum                                  | IgG class autoantibodies directed against PR3 (proteinase 3) antigen  | IMSOP179, IMSOP170   |
| Serum                                  | Autoimmune test – Beta 2 glycoprotein 1 (B2GP-1); components for IgM and IgG  | IMSOP179, IMSOP170   |
| Serum                                  | ENA screen and ENA profile  | IMSOP179   |
| Serum                                  | Tissue Transglutaminase   | IMSOP142   |
| Serum                                  | Cardiolipins; components for IgG and IgM  | IMSOP179, IMSOP170   |
| Serum                                  | IgG antibodies directed Double stranded DNA (dsDNA)   | IMSOP179, IMSOP170   |
| Serum                                  | TSH Receptor Antibodies   | IMSOP176   |
| Serum                                  | Intrinsic Factor Antibodies   | IMSOP179   |
| Serum                                  | IgG antibodies directed to M2   | IMSOP170, IMSOP179   |
| Serum                                  | Specific IgE to:<br><br>Almond<br>Aspergillus fumigatus<br>Banana<br>Blue Mussel<br>Brazil nut<br>Cashew nut<br>Cat epithelium and dander | IMSOP166, IMSOP170   |



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|--|---|---|
| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Specific IgE to:</p> <p>Cheddar cheese<br/>Coconut<br/>Common wasp<br/>Dog dander<br/>Egg white<br/>Egg yolk</p> <p>Feather mix:</p> <ul style="list-style-type: none"> <li>• Goose</li> <li>• Chicken</li> <li>• Duck</li> <li>• Turkey</li> </ul> <p>Fish<br/>Gluten</p> <p>Grass pollen mix:</p> <ul style="list-style-type: none"> <li>• Cocksfoot</li> <li>• Meadow fescue</li> <li>• Rye</li> <li>• Timothy</li> <li>• Meadow</li> </ul> <p>Hazel nut<br/>Honey bee<br/>Horse dander<br/>House dust mite<br/>Kiwi<br/>Latex<br/>Macadamia nut<br/>Milk</p> <p>Mould mix:</p> <ul style="list-style-type: none"> <li>• Penicillium chrysogenum</li> <li>• Cladosporium herbarium</li> <li>• Aspergillus fumigatus</li> <li>• Alternaria alternata</li> </ul> | <p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Phadia 250 ELISA</p> <p>IMSOP166, IMSOP170</p> |



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|---|---|---|
| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Specific IgE to: (cont'd)</p> <p>Peanut<br/>Pecan nut<br/>Pine nut pignols<br/>Pistachio nut<br/>Rabbit epithelium<br/>Sesame seed<br/>Shrimp<br/>Soya bean<br/>Strawberry</p> <p>Specific IgE to:</p> <p>Tomato</p> <p>Tree pollen mix:</p> <ul style="list-style-type: none"> <li>• Box elder</li> <li>• Silver birch</li> <li>• Oak</li> <li>• Elm</li> <li>• Walnut</li> </ul> <p>Walnut</p> <p>Weed pollen mix:</p> <ul style="list-style-type: none"> <li>• Ambrosia artemisiifolia</li> <li>• Artemisia vulgaris</li> <li>• Plantago lanceolata</li> <li>• Chenopodium album</li> </ul> <p>Wheat</p> | <p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Phadia 250 ELISA</p> <p>IMSOP166, IMSOP170</p> |
| <p><b>END</b></p>   |   |   |