


# 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<br/>8699</p> <p>Accredited to<br/>ISO 15189:2022</p> | <h3>NHS Lothian</h3> <p>Issue No: 020 Issue date: 10 April 2026</p>  |   |
|   | <p><b>Blood Sciences</b><br/>Lothian NHS Board Headquarters<br/>Mainpoint<br/>102 Westport<br/>Edinburgh<br/>EH3 9DN</p> | <p><b>Contact: Bernard Lawless</b><br/>E-Mail: <a href="mailto:Bernard.Lawless@nhs.scot">Bernard.Lawless@nhs.scot</a><br/>Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p> |
| <p><b>Testing performed by the Organisation at the locations specified below</b></p>  |  |   |

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

#### Laboratory locations:

| Location details  | Activity   | Location code |
|---|--|---------------|
| <p><b>Address</b><br/>St John's Hospital<br/>Howden Road West<br/>Livingston<br/>Scotland<br/>EH54 6PP</p> <p><b>Local contact</b><br/>Contact: Fiona Rennie<br/>Tel: +44 (0) 1506 523078<br/>E-mail: <a href="mailto:Fiona.Rennie11@nhs.scot">Fiona.Rennie11@nhs.scot</a><br/>Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>  | <p>Haematology and Blood<br/>Transfusion Clinical<br/>Biochemistry<br/>Electronic Issue – Blood<br/>Fridges</p>  | A             |
| <p><b>Address</b><br/>NHS Lothian<br/>Royal Infirmary of Edinburgh<br/>51 Little France Crescent<br/>Edinburgh<br/>EH16 4SA</p> <p><b>Local contact</b><br/>Contact: Una Jarrold<br/>Tel: 0131 242 6830<br/>E-mail: <a href="mailto:una.jarrold@nhs.scot">una.jarrold@nhs.scot</a></p> <p>Contact: Heather Fife<br/>Tel: 0131 242 6830<br/>E-mail: <a href="mailto:heather.fife@nhs.scot">heather.fife@nhs.scot</a><br/>Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p> | <p>Haematology<br/>Coagulation<br/>Specialist Haematology<br/>Haemostasis<br/>General Chemistry<br/>Endocrine/Tumour<br/>marker/Haematinics/Car-<br/>diac markers<br/>Toxicology<br/>Therapeutic Drug<br/>Monitoring (TDM)<br/>Microbiology Serology</p> | C             |
| <p><b>Address</b><br/>Blood Sciences Department<br/>Western General Hospital<br/>Crewe Road<br/>Edinburgh<br/>EH4 2XU</p> <p><b>Local contact</b><br/>Contact: Sarah Augley<br/>Tel: 0131 537 1896<br/>E-mail: <a href="mailto:sarah.augley@nhs.scot">sarah.augley@nhs.scot</a><br/>Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>   | <p>Clinical Chemistry<br/>Antenatal Screening<br/>Inherited Metabolic<br/>Haematology<br/>Blood Transfusion<br/>Electronic Issue – Blood<br/>Fridges<br/>Gi Proteins</p>   | E             |



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

| Location details  | Activity            | Location code |
|---|---------------------|---------------|
| <p>Theatre<br/>Western General Hospital<br/>Crewe Road<br/>Edinburgh<br/>EH4 2XU</p> <p><b>Local contact</b><br/>Contact: Sarah Augley<br/>Tel: 0131 537 1896<br/>E-mail: sarah.augley@nhslothian.scot.nhs.uk<br/>Website: www.edinburghlabmed.co.uk</p>  | Blood Storage only  | F             |
| <p>Ward 7<br/>Western General Hospital<br/>Crewe Road<br/>Edinburgh<br/>EH4 2XU</p> <p><b>Local contact</b><br/>Contact: Sarah Augley<br/>Tel: 0131 537 1896<br/>E-mail: sarah.augley@nhslothian.scot.nhs.uk<br/>Website: www.edinburghlabmed.co.uk</p>   | Blood Storage only  | G             |
| <p>Clinical Immunology Laboratory<br/>NHS Lothian<br/>Royal Infirmary of Edinburgh<br/>51 Little France Crescent<br/>Edinburgh<br/>EH16 4SA</p> <p><b>Local contact</b><br/>Contact: Una Jarrold<br/>Tel: 0131 242 6830<br/>E-mail: una.jarrold@nhslothian.scot.nhs.uk<br/>Website: www.edinburghlabmed.co.uk</p> | Clinical Immunology | H             |



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DETAIL OF ACCREDITATION

| Materials/Products tested                         | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used  | Location Code |
|---|--|---|---------------|
| HUMAN BODY FLUIDS AND TISSUES<br><br>Venous Blood | <u>Blood Transfusion Testing for the purpose of clinical diagnosis</u>   | Documented In-house methods using:  | A, E          |
|   | Automated Blood Grouping <ul style="list-style-type: none"> <li>• A B O, D ,K</li> <li>• Rhesus: C, c, D, E, e, Cw</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Kpa</li> <li>• Lea, Leb</li> <li>• Lua</li> <li>• M, N, S, s</li> </ul>          | Grifols Eflexis and associated testing protocols – fully automated Grifols cassette technology using SOP: BBANK-71, BBANK-147, BBANK-102      |               |
|   | Manual Blood Grouping <ul style="list-style-type: none"> <li>• A B O, D,K</li> <li>• Rhesus: Cw,C, c, D, E, e,</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Kpa</li> <li>• Lea, Leb</li> <li>• Lua</li> <li>• M, N, S, s</li> </ul>              | Manual procedures by Grifols cassette technology/tube technology using SOP: BBANK-34  |               |
| Serum/Plasma                                      | Automated Antibody Detection and identification <ul style="list-style-type: none"> <li>• Cw, C, c, D, E, e</li> <li>• K, Kpa</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Lea, Leb</li> <li>• P1</li> <li>• M, N, S, s</li> <li>• Lua</li> </ul> | Grifols Eflexis analyser using 3 cell screen, 11 cell panels, NBS panel, Grifols extended 4 cell panel using SOP: BBANK-30 BBANK-71 BBANK-147 | A, E          |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Blood Transfusion Testing for the purpose of clinical diagnosis</u> (cont'd)   | Documented In-house methods using:  |               |
| Serum/plasma                           | Manual Antibody Detection and identification <ul style="list-style-type: none"> <li>• Cw, C, c, D, E, e</li> <li>• K, Kpa</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Lea, Leb</li> <li>• P1</li> <li>• M, N, S, s</li> <li>• Lua</li> </ul> | Manual procedures by tube and Grifolscassette technology-red cell agglutination, macroscopic visual detection and Antibody screen-3 cell panel and 10 /11 cell pane, NBS panel and Grifols extended 4 cell panel using SOP:BBANK-34 | A, E          |
| Plasma                                 | Automated compatibility testing of patients plasma with donor cells   | Fully automated Grifols Eflexis cassette technology using SOP: BBANK-72   | A, E          |
| Plasma                                 | Manual compatibility testing of patients plasma with donor cells  | Manual procedures by Grifols cassette technology and manual procedures by tube technology-red cell agglutination including macroscopic visual detection using SOP: BBANK-34   | A, E          |
| Venous Blood                           | Direct Anti-Human Globulin  | Grifols Eflexis analysers and associated testing protocols – fully automated Grifols cassette technology using SOP: BBANK-121   | A, E          |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Blood Transfusion Testing for the purpose of clinical diagnosis (cont'd)</u>   | Documented In-house methods using:  |               |
| Venous Blood                           | Direct Anti-Human Globulin  | Manual procedures by Grifols cassette technology.<br>Key SOP: BBANK-34  | A, E          |
| Venous Blood                           | Kleihauer- screening of foetal bleed in maternal circulation.   | Acid Elution using CLINtech kit and SOP : BBANK-98  | A             |
| Venous Blood                           | <u>Blood Coagulation Testing for the purpose of clinical diagnosis</u> <ul style="list-style-type: none"> <li>• Prothrombin time (PT) <ul style="list-style-type: none"> <li>○ INR</li> </ul> </li> <li>• Activated Partial Thromboplastin Time (APTT) / Activated Partial Thromboplastin Time Ratio (APTT<sub>r</sub>)</li> <li>• Activated Partial Thromboplastin Time Mix (APTT Mix)</li> <li>• Fibrinogen estimation by Clauss</li> <li>• D-Dimers</li> </ul> | Automated Sysmex CS series clot detection and particle enhanced immunoturbidometric assay using manufacturers instructions and<br><br>SOP: BLSC-118; HAEM 1048; HAEM 1057 | A, C, E       |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology Testing for the purpose of clinical diagnosis</u> | Documented In-house methods using:   |               |
| Whole Blood                            | Erythrocyte Sedimentation Rate (ESR)                             | Westergren Sedimentation Method using the Starrsed RS analyser using SOP HAEM1116  | A, C, E       |
| Venous whole blood                     | Full blood count (FBC)   | Sysmex XN series analysers comprising of XN-10 and XN-20 modules Haematology Analysers using a combination of laser light scatter flow and absorbance, colourimetric, height pulse flow and calculated parameters SOP: HAEM1054; HAEM1055; HAEM1056. | A, C, E       |
|  | White blood count (WBC)  |  |               |
|  | Red blood cell count (RBC)                                       |  |               |
|  | Haemoglobin estimation (Hb)                                      |  |               |
|  | Haematocrit (HCT)  |  |               |
|  | Mean Cell Volume (MCV)   |  |               |
|  | Mean Cell Haemoglobin (MCH)                                      |  |               |
|  | Mean Cell Haemoglobin concentration (MCHC)                       |  |               |
|  | Platelet count (PLT)   |  |               |
|  | Neutrophils  |  |               |
|  | Lymphocytes  |  |               |
|  | Monocytes  |  |               |
|  | Eosinophils  |  |               |
|  | Basophils  |  |               |
|  | Reticulocyte count   |  |               |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology Testing for the purpose of clinical diagnosis</u> (cont'd)  | Documented In-house methods using:   |                        |
| Venous whole blood                     | Film reporting – assessment for cell typing and morphology<br>manual White Blood Cell Differential for enumeration of cell types.  | Blood film preparation using SOP: HAEM-1038<br>and<br>Automated Sysmex SP-50– May Grunwald Giemsa stain – examined by microscopy using SOP: HAEM1053<br><br>Manual staining - Manual staining - May Grunwald Giemsa staining using the RAL back-up stainer: HAEM1072 | A, C, E                |
| Venous whole blood                     | Detection of combined HRP2 and pLDH P falciparum antigen and pan species plasmodial antigen (P. falciparum, P. vivax, P. ovale, P.malariae)<br><br>Malaria Parasite detection <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• P.Vivax</li> <li>• P.Ovale</li> <li>• P.Malariae</li> </ul> Malaria Parasite detection <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• P.Vivax</li> <li>• P.Ovale</li> <li>• P.Malariae</li> <li>• P Knowlesi</li> </ul> | Antigen testing with CareUS Rapydtest kit using SOP: HAEM991<br><br>Thick film – Clintech Field Stain and Thin Film – Giemsa pH7.2 stain examined by microscopy using SOP: HAEM991   | A, C, E<br><br>A, C, E |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology Testing for the purpose of clinical diagnosis (cont'd)</u>   | Documented In-house methods using:  |               |
| Venous whole blood                     | Malaria Parasite detection of Plasmodium Falciparum Parasitaemia  | Thin Film – Giemsa pH7.2 stain, enumeration by microscopy using SOP: HAEM991  | A, C, E       |
| Bone Marrow                            | Bone Marrow Reporting-assessment for cell typing and morphology   | SP-50– May Grunwald Giemsa stain SOP HAEM990 –  | A, C, E       |
| Bone marrow and blood                  |   | Perl's Prussian Blue staining examined by microscopy using SOP: HAEM990   | A, C, E       |
| Urine,                                 | Haemosiderin  | Perl's Prussian Blue staining examined by microscopy using HAEM-W-31; HAEM-W-870 (urinary haemosiderin)                                 | E             |
| Venous whole blood: EDTA               | Haemoglobin S   | Detection of decreased solubility of haemoglobin S with Clin-Tek: Hb S Test Kit using manufacturer's instructions using SOP: HAEM-R-117 | C             |
| Venous Whole Blood, Plasma or Serum    | Infectious Mononucleosis antibody detection.  | Clearview IM II Card agglutination interpreted by visual inspection. SOP HAEM 995   | A, C, E       |
| Plasma, Serum                          | Haematinics:<br><ul style="list-style-type: none"> <li>• Vitamin B12</li> <li>• Folate</li> <li>• Ferritin</li> </ul> | Automated Roche Cobas e801 by electrochemi-luminescence immunoassay (ECLIA)   | A, C, E       |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology Testing for the purpose of clinical diagnosis (cont'd)</u>  | Documented In-house methods using:  |               |
|  | <u>Specialist Haematology</u>  |   |               |
| Whole Blood: EDTA                      | Glucose-6-Phosphate Dehydrogenase (G6PD) Quantification method   | Uvikon Spectrophotometer<br><br>Pointe Scientific Kit using manufacturers instructions and SOP: HAEM-1080 | C             |
|  | <u>Haemoglobinopathy Screening</u>   |   |               |
| Whole Blood: EDTA                      | Quantification<br>Haemoglobin A2 (HbA2)<br>Haemoglobin F (HbF)<br>Haemoglobin S (HbS)  | Capillary Electrophoresis (CE) on Sebia Capillarys 3 Octa<br>SOP HAEM R 365                               | C             |
|  | Determination of variants<br>Hb A2<br>Hb F<br>Hb S<br>Hb E<br>Hb AC<br>Hb D<br>Hb H disease<br>Hb Lepore<br>Hb O <sub>Arab</sub> |   |               |
| Whole Blood: EDTA                      | Variant Hb confirmation  | PerkinElmer Isoelectric focusing Kit using manufacturers instructions and SOP: HAEM-R-323                 | C             |



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| HUMAN BODY FLUIDS                     | <u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u>  | Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: |               |
| Plasma / Venous blood-citrated plasma | Anti Xa Assay   | Chromogenic Xa assays on Sysmex CS5100 and CS2500 analysers, using manufacturer's instructions and SOP: HAEM1119                       | A,C,E         |
| Plasma / Venous blood-citrated plasma | Therapeutics including Direct Oral Anticoagulant Assays (Therapeutics - Danaparoid, LMWH, Rivaroxaban, Apixaban, Fondaparinux). | Chromogenic Xa assays on Sysmex CS5100 and CS2500 analysers, using manufacturer's instructions and SOP: HAEM1119                       | C             |
| Plasma                                | Assay of the Direct Oral Anticoagulants (DOAC): Fondaparinux (Arixtra), Danaparoid (Orgaran), Apixaban, Rivaroxaban, Edoxaban   | Chromogenic anti-Xa assays on the Sysmex CS 5100 Analysers SOP: HAEM-85  | C             |
|                                       | Dabigatran DTI assay<br>Argatroban DTI assay  | Using SOP: HAEM-R-420  | C             |
|                                       | Anticardiolipin IgG   | Chemiluminescent Werfen Acustar using manufacturers instructions and SOP: HAEM-R-287,291,293   | C             |
|                                       | Anticardiolipin IgM   |  |               |
|                                       | Beta 2 Glycoprotein IgG   |  |               |
|                                       | Beta 2 Glycoprotein IgM   |  |               |
|                                       | vWF:RiCof   | SOP: HAEM-R-287,291 and 292  |               |
|                                       | vWF antigen   |  |               |
|                                       | vWF:Collagen binding  |  |               |
|                                       | Heparin Induced Thrombocytopenia ( HIT)   | SOP HAEM-R-293, 290 and 291  |               |
| Plasma / Venous blood-citrated plasma | ADAMTS13 Activity   | Chemiluminescent Werfen Acustar using manufacturer's instructions and SOP: HAEM-R-291,396  | C             |



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| HUMAN BODY FLUIDS (cont'd)   | <u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)</u>  | Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:   |               |
| Venous blood-citrated plasma | LUPUS Sensitive APTT / Mix<br>DRVV Screen<br>DRVV Confirm  | Assays by Sysmex CS2500 analyser. Clot detection using Manufacturer's instructions and SOP: HAEM-R-419   | C             |
| Venous blood-citrated plasma | Factor assays:<br>Factor II<br>Factor V<br>Factor VII<br>Factor VIII<br>Factor IX<br>Factor X<br>Factor XI<br>Factor XII<br>Factor XIII<br>Chromogenic Factor VIII<br>Chromogenic Bovine Factor VIII<br>Emicizumab Assay | Automated one stage clotting assays and chromogenic assays on the Sysmex CN6500<br>SOPs: HAEM-130, HAEM-R-427, HAEM-R-421, HAEM-R-422, HAEM-R-426  | C             |
| Plasma                       | Anti-thrombin Activity<br>Free Protein S Immune<br>Alpha-2 Antiplasmin<br>Protein C  | Thrombophilia and Fibrinolytic tests using Sysmex CS2500 and CS5100 analysers. Chromogenic and latex immuno analyser using manufacturers instructions and SOP: HAEM-R-413, 414, 415, 417 & 418 | C             |
| Plasma                       | Immune Fibrinogen  | Latex Immunoassay on the CS2500 analyser using manufacturer's instructions and SOP: HAEM-R-416   | C             |
| Plasma                       | Factor VIII Altuvoc for treatment monitoring   | One stage assay and Actin FSL reagents on the Sysmex CN6500<br>SOP: HAEM-130   | C             |
| Plasma                       | <u>Factor VIII inhibitor assay</u><br><u>Factor IX inhibitor assay</u>   | Factor Inhibitor Assay on the Sysmex CN6500<br>SOP: HAEM-135   | C             |



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| HUMAN BODY FLUIDS AND TISSUES                                     | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> | Documented In-house methods using:<br><br>Automated Roche Cobas c702 by Photometry using SOP BIO-1735 |               |
| Serum, Plasma, peritoneal, and pleural fluids                     | Albumin  |   | A, C, E       |
| Serum, Plasma   | Alcohol/ Ethanol   |   | A, C, E       |
| Serum, Plasma   | Alkaline Phosphatase (ALP)   |   | A, C, E       |
| Serum, Plasma   | Alanine aminotransferase (ALT)                                     |   | A, C, E       |
| Plasma  | Ammonia  |   | C, E          |
| Serum, Plasma peritoneal, Pancreatic Cyst Fluid, and drain fluids | Amylase  |   | A, C, E       |
| Serum, Plasma   | Angiotensin Converting Enzyme                                      |   | E             |
| Serum, Plasma   | Aspartate aminotransferase (AST)                                   |   | A C E         |
| Serum, Plasma   | Bile acid  |   | C             |
| Serum, Plasma   | Total Bilirubin  |   | A, C, E       |
| Serum, Plasma   | Caeruloplasmin   |   | C             |
| Serum, Plasma   | Calcium  |   | A, C, E       |
| Serum, Plasma   | Carbamazepine  |   | A, C, E       |
| Serum, Plasma, and pleural fluids                                 | Cholesterol  |   | A, C, E       |
| Serum, Plasma   | Creatine kinase (CK)   |   | A, C, E       |
| Serum, Plasma   | C-Reactive Protein   |   | A, C, E       |
| Serum, Plasma   | D-3 hydroxybutyrate  |   | C             |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)                                     | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:<br><br>Automated Roche Cobas c702 by Photometry using SOP BIO-1735 |               |
| Serum, Plasma  | Direct Bilirubin  |   | A, C          |
| Serum, Plasma  | Enzymatic Creatinine  |   | A, C, E       |
| Serum, Plasma  | Free Fatty Acids  |   | C             |
| Serum, Plasma  | γ-glutamyl transferase (GGT)  |   | A, C, E       |
| Serum, Plasma peritoneal, pleural, Pancreatic Cyst Fluid, and drain fluids | Glucose   |   | A, C, E       |
| Serum, Plasma  | HDL Cholesterol   |   | A, C, E       |
| Serum, Plasma  | Iron  |   | A, C, E       |
| Plasma   | Lactate   |   | A, C, E       |
| Serum, Plasma  | Lithium   |   | A, C, E       |
| Serum, Plasma peritoneal, pleural and drain fluids                         | Lactate Dehydrogenase (LDH)   |   | A, C, E       |
| Serum, Plasma  | Magnesium   |   | A, C, E       |
| Serum, Plasma  | Phosphate   |   | A, C, E       |
| Serum, Plasma  | Theophylline  |   | A, C,         |
| Serum, Plasma  | Total CO <sub>2</sub> (Bicarbonate)   |   | A, C, E       |
| Serum, Plasma peritoneal and pleural fluids                                | Total Protein   |   | A, C, E       |
| Serum, Plasma  | Transferrin   |   | A, C, E       |



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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

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| HUMAN BODY FLUIDS AND TISSUES (cont'd)              | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:                          |               |
| Serum, Plasma, peritoneal, pleural and drain fluids | Triglyceride  | Automated Roche Cobas c702 by Photometry using SOP BIO-1735 | A, C, E       |
| Serum, Plasma                                       | Urate   |   | A, C, E       |
| Serum, Plasma peritoneal, pleural and drain fluids  | Urea  |   | A, C, E       |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)              | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using SOP BIO-1735:<br><br>Automated Roche Cobas c702 by turbidimetry using SOP: BIO-1735<br><br>SOP: BIO-1735<br>SOP: BIO-1735<br>SOP: BIO-1735<br>SOP: BIO-1735<br><br>Automated Roche Cobas c702 by Photometry using SOP: BIO-1735<br><br>SOP: BIO-1735<br>SOP: BIO-1735<br>SOP: BIO-1735<br><br>SOP: BIO-W-145 |               |
| CSF   | Total Protein   |  | A, C, E       |
| CSF   | Lactate   |  | A C E         |
| CSF   | Glucose   |  | A, C, E       |
| CSF   | IgG   |  | A, E          |
| Urine   | Calcium   |  | A, C, E       |
| Urine, Pleural fluid, Peritoneal Fluid, Drain Fluid | Creatinine  |  | A, C, E       |
| Urine   | Magnesium   |  | A, C, E       |
| Urine   | Microalbumin  |  | A, C, E       |
| Serum   | B2-Microglobulin  |  | E             |
| Serum, Plasma                                       | Alpha-1-antitrypsin   |  | E             |
| Serum, Plasma                                       | Haptoglobin   |  | C, E          |
| Serum, Plasma                                       | Immunoglobulins – IgA, IgG, IgM   |  | E             |
| Urine   | Phosphate   |  | A, C, E       |
| Urine   | Total Protein   |  | A, C, E       |
| Urine   | Urate   |  | A, C, E       |
| Urine   | Urea  |  | A, C, E       |
| Urine   | Urine Oxalate   |  | E             |



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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u> | Documented In-house methods using:  |               |
| Serum, Plasma, Urine                   | Chloride  | Automated Roche Cobas c702 by Potentiometry using:<br>SOP: BIO-1735   | A, C, E       |
|  | Potassium   | SOP: BIO-1735   | A, C, E       |
|  | Sodium  | SOP: BIO-1735   | A, C, E       |
|  | <u>Therapeutic drug monitoring</u>  | Automated Roche Cobas c702 by kinetic interaction of microparticles in solution (KIMS) using:                       |               |
| Serum, Plasma                          | Digoxin   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Gentamicin  | SOP: BIO-1735 using CEDIA method  | A, C, E       |
| Serum, Plasma                          | Vancomycin  | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Valproate   | SOP: BIO-1735   | C             |
| Serum, Plasma                          | Phenobarbitone  | SOP: BIO-1735   | C             |
| Serum, Plasma                          | Amikacin  | Automated Roche Cobas c702 by kinetic interaction of microparticles in solution (KIMS) using:<br>SOP: SOP: BIO-1735 | E             |
| Serum, Plasma                          | Tobramycin  | Automated Roche Cobas c702 by kinetic interaction of microparticles in solution (KIMS) using: SOP: BIO-1735         | E             |
| Serum, Plasma                          | Methotrexate  | SOP: BIO-1735   | C, E          |
| Serum, Plasma                          | Phenytoin   | Automated Roche Cobas c702 by kinetic interaction of microparticles in solution (KIMS) using: SOP: BIO-1735         | C             |



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**NHS Lothian**

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u> | Documented In-house methods using:   |               |
|  | <u>Endocrine/Tumour Markers/ Haematinics/Cardiac Markers</u>                | Automated Roche Cobas e801 by electrochemi-luminescence immunoassay (ECLIA) using: |               |
| Serum, Plasma and Peritoneal Fluid     | Alphafetoprotein (AFP)  | SOP: BIO-1735  | C, E          |
| Serum, Plasma                          | CA125   | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Carcinoembryonic antigen (CEA)  | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Cortisol  | SOP: BIO-1735  | A, C, E       |
| Urine                                  | Cortisol  | SOP: BIO-1735  | E             |
| Serum, Plasma                          | C-peptide   | SOP: BIO-1735  | E             |
| Serum, Plasma                          | Free T3   | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Free T4   | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Follicle stimulating hormone (FSH)  | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Human Chorionic Gonadotrophin (HCG)   | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Insulin   | SOP: BIO-1735  | E             |
| Serum, Plasma                          | Luteinising Hormone (LH)  | SOP: BIO-1735  | A, C, E       |
| Serum, Plasma                          | Oestradiol  | SOP: BIO-1735  | A, C, E       |
| Serum                                  | PIFG  | SOP: BIO-1735  | A             |
| Serum                                  | sFIT1   | SOP: BIO-1735  | A             |



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**NHS Lothian**

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:  |               |
|  | <u>Endocrine/Tumour Markers/ Haematinics/Cardiac Markers</u> (cont'd)       | Automated Roche Cobas e801 by electrochemi-luminescence immunoassay (ECLIA) using:                              |               |
| Serum, Plasma                          | 25-OH Vitamin D   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | NTpro-BNP   | SOP: BIO-1735   | C             |
| Serum, Plasma                          | Progesterone  | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Prolactin   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Macroprolactin  | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Prostate specific antigen (PSA)   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | High Sensitivity Troponin T   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Total T3  | SOP: BIO-1735   | C             |
| Serum, Plasma                          | Thyroid stimulating hormone (TSH)   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Sex hormone binding globulin (SHBG)   | SOP: BIO-1735   | A, C, E       |
| Serum, Plasma                          | Dehydroepiandrosterone sulphate (DHEAS)                                     | SOP: BIO-1735   | C             |
| Serum, Plasma                          | Testosterone  | SOP: BIO-1735   | A, C, E       |
| EDTA Plasma                            | Adrenocorticotrophic hormone (ACTH)   | Automated Roche Cobas e801 by electrochemi-luminescence immunoassay (ECLIA) using:<br>SOP: BIO-R-379, BIO-R-492 | C             |
| Serum, Plasma                          | Anti Mullerian Hormone (AMH)  | SOP: BIO-R-539, BIO-R-379   | C             |
| Serum, Plasma                          | Growth Hormone  | SOP: BIO-R-491, BIO-R-379   | C             |
| EDTA Plasma                            | Parathyroid hormone (PTH)   | SOP: BIO-R-457, BIO-R-379   | C             |
| Serum                                  | Thyroid stimulating hormone receptor antibodies (TRAB)                      |   | C             |



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ISO 15189:2022

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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd)  | Documented In-house methods using:  |               |
|  | <u>Endocrine/Tumour Markers/ Haematinics/Cardiac Markers</u> (cont'd)  |   | C             |
| Serum                                  | Thyroglobulin (Tg)<br>Anti-Thyroglobulin (TgAb)  | Roche e801<br>Electro Chemiluminescent<br>SOP: BIO-R-1735   | C             |
| Whole blood                            | Glycated Haemoglobin HbA1c   | TOSOH G11 HPLC<br>SOP: BIO-1707   | A, C, E       |
| Serum/Plasma/Urine                     | Osmolality   | Advanced Instruments Osmometer Pro-Max  | C             |
| Serum/Plasma/Urine                     | Osmolality   | Advanced Instruments Osmo1– Freezing point depression using<br>SOP: BIO-R-63  | A, E          |
| Whole Blood                            | pH   | Radiometer ABL90 Flex plus by Potentiometry, Amperometry, Optical, Spectrophotometry using:<br>SOP: POCT-SOP:3<br>Measured values | A, C, E       |
|  | Lactate<br>Glucose<br>Sodium<br>Potassium<br>Chloride<br>pCO2<br>PO2<br>Total haemoglobin (tHb)<br>Carboxyhaemoglobin (CoHb)<br>Oxyhaemoglobin (O2Hb)<br>Oxygen Saturation (SO2)<br>Met-Haemoglobin (MetHb)<br>Deoxyhaemoglobin (HHb)<br>Hydrogen Ion<br>Ionised Calcium |   |               |
| Pleural and Ascitic                    | Fluid pH   | Measured values   | A,C,E         |
|  | pH   | Calculated Values   |               |



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**NHS Lothian**  
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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd)                             | Documented In-house methods using:<br><br>Radiometer Abflex90 by Potentiometry, Amperometry, Optical, Spectrophotometry using: SOP: POCT-SOP:3 |               |
|  | Bicarbonate <ul style="list-style-type: none"> <li>Standard Bicarbonate</li> <li>Base Excess</li> </ul> | Calculated Values  | A, C, E       |
| CSF                                    | Xanthochromia (Hb Pigments)   | BIO-UV Spectrophotometer using SOP BIO-1823  | C, E          |
|  | <u>Calculated tests</u>   | Automated using Apex VALR 1012 v 1.1   |               |
| Serum, Plasma                          | Total cholesterol:HDL cholesterol ratio   |  | A, C, E       |
|  | Free Androgen Index   |  | C,            |
|  | Calculated free testosterone  |  |               |
|  | Free testosterone albumin   |  |               |
|  | Estimated glomerular filtration rate (eGFR)   |  | A, C, E       |
|  | LDL Cholesterol   |  | A, C, E       |
|  | Transferrin saturation  |  | A, C, E       |
|  | BCCA Adjusted calcium   |  | A, C, E       |
|  | Acute Kidney Injury (AKI)   |  | A, C, E       |
|  | Adjusted Phenytoin  |  | A, C, E       |
|  | FIB-4   |  | A, C, E       |



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ISO 15189:2022

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:                 |               |
|  | <u>Calculated tests</u> (cont'd)  | Automated using Apex using SOP: VALR-1012 v 1.1    | A, C, E       |
| Serum, Plasma, Urine                   | Creatinine clearance<br>Renal phosphate reabsorption                        |  |               |
| Serum                                  | PIFG:sFIT1 ratio  |  | A             |
| Urine                                  | Albumin:Creatinine ratio  |  |               |
|  | Protein:Creatinine ratio  |  | A, C, E       |
|  | Oxalate:creatinine ratio  |  | E             |
|  | Total Porphyrin:Creatinine ratio  |  | E             |
|  | PBG:creatinine ratio  |  | E             |
|  | Amylase output  |  | A, C, E       |
|  | Calcium output  |  |               |
|  | Chloride output   |  |               |
|  | Creatinine output   |  |               |
|  | Potassium output  |  |               |
|  | Magnesium output  |  |               |
|  | Sodium output   |  |               |
|  | Protein output  |  |               |
|  | Urate output  |  |               |
|  | Phosphate output  |  |               |
|  | Urea output   |  | A, C, E       |
|  | Cortisol output   |  | E             |
|  | Oxalate output  |  |               |
|  | Metadrenaline output  |  |               |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:  |                                 |
| Urine (cont'd)                         | <u>Calculated tests</u> (cont'd)<br>Normetadrenaline output<br>5HIAA output | Automated using Apex using SOP: VALR-1012 v 1.1   | A, C, E                         |
| Serum / Plasma                         | <u>Toxicology</u><br>Paracetamol<br>Salicylate<br>Ethanol<br>Testosterone   | Automated Roche cobas c702 by Photometry SOP: BIO-R-10<br>SOP: BIO-1735<br>SOP: BIO-1735<br>SOP: BIO-1735<br>Waters UPLC Xevo Tandem Quadropole Spectrometer using SOP: BIO-R-387 | A, C, E<br>A, C<br>A, C, E<br>C |
| Whole Blood                            | Ciclosporin<br>Sirolimus<br>Tacrolimus                                      | Waters UPLC Xevo Tandem Quadropole Spectrometer using SOP: BIO-R-386  | C<br>C<br>C                     |
| Urine                                  | Tetrahydrocannabinol (THC)  | Analysis of Cannabinoids in Urine by Roche COBAS c702 using SOP BIO-R-611   | C                               |



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**NHS Lothian**  
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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:  |               |
| Urine and Oral fluid                   | Drugs of Abuse  | Flexible Scope on the Waters LC Tandem Mass Spectrometer– Triple quadrupole spectrometry using Xevo- SOP: BIO-R-501 for Oral fluid and Acquity -BIO-R-418 for Urine and BIO-R-568 for Flexible Scope. Listed in spreadsheet on User info on website. BIO-R-567  | C             |
| Urine                                  | 5HIAA   | Status available on Laboratory Medicine website:<br><a href="https://edinburghlabmed.co.uk/Specialities/BloodScience/Biochemistry/Toxicologyflexscope/pages">https://edinburghlabmed.co.uk/Specialities/BloodScience/Biochemistry/Toxicologyflexscope/pages</a><br>Detected by Chromsystems HPLC system using SOP: BIO-W-518, BIO-W-487 | E             |
|  | Metadrenaline   |   | E             |
|  | Normetadrenaline  |   | E             |
| Urine                                  | 3-methoxytyramine   | Detected by Chromsystems HPLC system using SOP: BIO-W-487   | E             |



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| HUMAN BODY FLUIDS AND TISSUE (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>                                    | In house methods using manufacturer's instructions  |               |
|                                       | <u>Protein Electrophoresis</u>   |   |               |
| Serum                                 | Paraprotein bands  | Sebia Capillarys 3 Octa by Detection of paraprotein bands using SOP BIO-1780, BIO-1781                        | E             |
|                                       |  | Sebia Hydrasys by electrophoretic separation and isoelectrofocusing techniques using SOP:                     | E             |
| Serum                                 | Alpha-1 Antitrypsin Phenotyping  | SOP: BIO-W-95   | E             |
| Serum                                 | Alkaline Phosphatase iso-enzymes   | SOP: BIO-W-35   | E             |
| Serum / CSF                           | Oligoclonal bands  | SOP: BIO-W-98   | E             |
| CSF                                   | CSF Beta-2 Transferrin   | SOP: BIO-W-96   | E             |
| Serum/ Urine                          | Urine Bence Jones Protein  | SOP: BIO-W-32   | E             |
| Serum/ Urine                          | Immunofixation   | SOP: BIO-W-31 & BIO-W-33  | E             |
|                                       | <u>Special Chemistry</u>   |   |               |
| Serum                                 | Antenatal screening assays <ul style="list-style-type: none"> <li>• Free Beta HCG</li> <li>• PAPP-A</li> </ul> | Revity AutoDelfia by dissociation fluoroimmunoassay using SOP: BIO-W-311, BIO-W-497                           | E             |
| Serum                                 | <u>Coeliac Screening:</u><br>Tissue Transglutaminase IgG<br>Tissue Transglutaminase IgA                        | Dynex DS2 (ELISA) using SOP: BIO-W-1 (IgA), BIO-W-287(IgG),   | E             |
| Faeces                                | Calprotectin<br>Elastase   | Dynex DS2 (ELISA) using SOP: BIO-W-84, BIO-W-88   |               |
| Serum/Plasma                          | <ul style="list-style-type: none"> <li>• Aldosterone</li> <li>• Renin</li> </ul>                               | Diasorin Liaison- Specialist Immunoassays (competitive chemiluminescent assays) using SOP: GENRL-82, BIO-1903 | A             |



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| HUMAN BODY FLUIDS AND TISSUE (cont'd) | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | In house methods using manufacturer's instructions                           |               |
|                                       | <u>Special Chemistry</u> (cont'd)   |  |               |
| Urine                                 | <ul style="list-style-type: none"> <li>Porphobilinogen</li> </ul>           | RECIPE ClinEasy Complete Kit on BIO-UV for Porphobilinogen in Urine BIO-W-26 | E             |
| Urine                                 | <ul style="list-style-type: none"> <li>Total Porphyrins</li> </ul>          | Direct Spectrophotometry using SOP: BIO-W-281                                | E             |
| Serum/Plasma                          | Serum Cryoglobulin  | Manual- visual inspection- protein precipitation using SOP: BIO-W-100        | E             |
| Plasma, Urine                         | Inherited Metabolic   | Biochrome 30+ Ion exchange HPLC Amino Acid Analyser                          | E             |
| Plasma, Urine                         | Amino Acid profile  | SOP: BIO-E-100 Amino acids   |               |
| Plasma, Urine                         | Alanine   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Arginine  | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Aspartate   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Citrulline  | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Cystine   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Glutamate   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Glutamine   | SOP: BIO-E-100   |               |
| Plasma, Urine, CSF                    | Glycine   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Histidine   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Isoleucine  | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Leucine   | SOP: BIO-E-100   |               |
| Plasma, Urine                         | Lysine  | SOP: BIO-E-100   |               |



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| HUMAN BODY FLUIDS AND TISSUE (cont'd)<br><br>Plasma, Urine<br>Plasma, Urine<br>Plasma, Urine<br>Plasma, Urine<br>Plasma, Urine<br>Plasma, Urine<br>Plasma, Urine<br>Plasma, Urine | <u>Clinical Biochemistry for the purpose of clinical diagnosis</u> (cont'd) | In house methods using manufacturer's instructions  | E             |
|   | Inherited Metabolic (cont'd)  | Biochrome 30+ Ion exchange HPLC Amino Acid Analyser   |               |
|   | Methionine  | SOP: BIO-E-100  |               |
|   | Proline   | SOP: BIO-E-100  |               |
|   | Phenylalanine   | SOP: BIO-E-100  |               |
|   | Serine  | SOP: BIO-E-100  |               |
|   | Taurine   | SOP: BIO-E-100  |               |
|   | Threonine   | SOP: BIO-E-100  |               |
|   | Tyrosine  | SOP: BIO-E-100  |               |
|   | Valine  | SOP: BIO-E-100  |               |
| Plasma  | Tyrosine  | Agilent HPLC using isocratic HPLC with fluorescence detection using<br>SOP: BIO-E-99                        | E             |
|   | Phenylalanine   | SOP: BIO-E-99   |               |
|   | Homocysteine  | SOP: BIO-E-62   |               |
| Urine   | Organic Acid Profile<br>Orotic Acid<br>Methylmalonic acid                   | Agilent GCMS using Gas chromatography with mass spectra.<br>SOP: BIO-E-71<br>SOP: BIO-E-73<br>SOP: BIO-E-68 | E             |
|   |   | Shimadzu UV1900i Spectrophotometer detected by Photometry   |               |
| Plasma  | Biotinidase   | SOP : BIO-E-53  | E             |



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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

Testing performed by the Organisation at the locations specified below

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|--|---|--|---------------|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry testing for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:   |               |
|  | Inherited Metabolic (cont'd)  |  |               |
| Leukocytes                             | Protein   | Lowry method, photometry using SOP: BIO-E-65   | E             |
| Leukocytes, Fibroblasts                | Arylsulphatase A  | SOP: BIO-E-157, BIO-E-66   | E             |
| Urine                                  | Mucopolysaccharide quantitative   | SOP: BIO-E-70  | E             |
| Urine                                  | Mucopolysaccharide electrophoresis  | Electrophoresis: one dimensional electrophoresis - manual method using SOP: BIO-E-69 | E             |
| Biopsy (Duodenal,Jejunal)              | <u>Disaccharidase Enzyme analysis</u>   | Shimadzu RF6000 Fluorimeter detected by Fluorimetry and SOP: BIO-E-54                | E             |
|  | Lactase   | SOP: BIO-E-54  | E             |
|  | Maltase   | SOP: BIO-E-54  | E             |
|  | Sucrase   | SOP: BIO-E-54  | E             |
| Sweat                                  | Sweat Chloride  | Detected by Photometry using Shimadzu UV1900i Spectrophotometer SOP: BIO-E-35        | E             |
|  | Sweat conductivity  | Wescor WE-3120 Sweat conductivity meter detected by Conductivity using SOP: BIO-E-1  | E             |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Clinical Biochemistry testing for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:  |               |
|  |   | Shimadzu RF6000 Fluorimeter detected by Fluorimetry using   | E             |
| Leukocytes, Fibroblast                 | Leucocyte screen Lysosomal enzyme screen (panel of enzymes)                         | SOP: BIO-E-157, BIO-E-66  | E             |
| Leukocytes/Fibroblasts                 | Acid esterase<br>B-galactosidase<br>a-mannosidase<br>a-fucosidase<br>B-mannosidase  | SOP: BIO-E-157, BIO-E-66  |               |
| Leukocytes, Fibroblasts, Plasma        | hexosaminidase total  | SOP: BIO-E-157, BIO-E-66<br>BIO-E-67  |               |
| Leukocytes, Fibroblasts,               | hexosaminidase A<br>B-glucosidase<br>Sphingomyelinase<br>Galactocerebrosidase       | SOP: BIO-E-157, BIO-E-66  |               |
|  | <u>Individual lysosomal enzymes</u>   |   |               |
| Leukocytes                             | a-galactosidase   | SOP: BIO-E-44   |               |
| Leukocytes, Fibroblasts                | a-Glucosidase   | SOP: BIO-E-46   |               |
|  | a-iduronidase   | SOP: BIO-E-47   |               |
| Plasma                                 | B-glucuronidase   | SOP: BIO-E-67   |               |
| Whole Blood                            | Galactose-1- Phosphate uridylyltransferase - qualitative                            | Manual method using Water bath, UV lamp, and detected using UV light fluorescence using SOP: BIO-E-61 |               |



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**NHS Lothian**

**Issue No: 020 Issue date: 10 April 2026**

**Testing performed by the Organisation at the locations specified below**

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| HUMAN BODY FLUIDS (cont'd) | <u>Microbiology Serology for the purpose of clinical diagnosis</u> | In house methods using manufacturer's instructions |               |
| Serum, Plasma              | Hepatitis B Surface Antigen (HBsAg) Qualitative                    | Roche 801; SOP VIRS-223                            | C             |
| Serum, Plasma              | Cytomegalovirus IgG assay (CMV IgG)                                | Roche 801; SOP VIRS-203                            | C             |
| Serum, Plasma              | Hepatitis B Core antibodies II (Anti-HBc)                          | Roche 801; SOP VIRS-223                            | C             |
| Serum, Plasma              | Human T-lymphotropic virus I/II (HTLV-I/II)                        | Roche 801; SOP VIRS-203                            | C             |
| Serum, Plasma              | HIV combi (AK+AG)  | Roche 801; SOP VIRS-225                            | C             |
| Serum, Plasma              | Anti-HBc IgM   | Roche 801; SOP VIRS-223                            | C             |
| Serum, Plasma              | Hepatitis B e antibodies (Anti-HBe)                                | Roche 801; SOP VIRS-223                            | C             |
| Serum, Plasma              | Hepatitis B e antigen (HBeAg)                                      | Roche 801; SOP VIRS-223                            | C             |
| Serum, Plasma              | Hepatitis B surface antibody (Anti-HBs)                            | Roche 801; SOP VIRS-223                            | C             |
| Serum, Plasma              | Hepatitis A IgM antibody (HAVAb-IgM)                               | Roche 801; SOP VIRS-222                            | C             |
| Serum, Plasma              | Hepatitis C antibodies (Anti-HCV)                                  | Roche 801; SOP VIRS-224                            | C             |
| Serum, Plasma              | Rubella IgG  | Roche 801; SOP VIRS-203                            | C             |
| Serum, Plasma              | Treponema pallidum (Syphilis)                                      | Roche 801 ; SOP VIRS-228                           | C             |
| Serum, Plasma              | Toxoplasma IgG   | Roche 801; SOP VIRS-203                            | C             |
| Serum, Plasma              | Ebstein-Barr virus viral capsid antigen IgG (EBV VCA IgG)          | Roche 801 VIRS-226                                 | C             |
| Dried blood spots          | Human Immunodeficiency virus (HIV Ag/Ab)                           | Roche 801; SOP VIRS-151                            | C             |
|                            | Hepatitis B Surface Antigen (HBsAg) Qualitative                    | Roche 801; SOP VIRS-151                            | C             |



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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

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|-----------------------------------|---|---|---------------|
| HUMAN BODY FLUIDS (cont'd)        | <u>Microbiology Serology for the purpose of clinical diagnosis</u> (cont'd) | In house methods using manufacturer's instructions.   |               |
| Dried blood spots                 | Hepatitis B Core antibodies II (Anti-HBc)                                   | Roche 801; SOP VIRS-151   | C             |
| Dried blood spots                 | Hepatitis C antibodies (Anti-HCV)   | Roche 801; SOP VIRS-151   | C             |
| Serum, Plasma                     | Epstein-Barr virus capsid antigens IgM (EBV VCA IgM)                        | Diasorin Liaison XL by Qualitative, Quantitative determination of Ag/Ab status by Indirect chemiluminescence immunoassay (CLIA) using SOP: VIRS-157 | C             |
| Serum, Plasma                     | Epstein-Barr virus capsid antigens IgG (EBV VCA IgG)                        | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Epstein-Barr virus Nuclear Antigen IgG (EBV EBNA)                           | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Parvovirus B19 IgG  | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Parvovirus B19 IgM  | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Hepatitis B surface antigen (HBsAg)   | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Varicella Zoster virus IgG (VZV IgG)  | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Measles IgG   | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum                             | Mumps IgG   | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Serum, Plasma                     | Cytomegalovirus IgM (CMV IgM)   | Roche 801; SOP VIRS-203   | C             |
| Serum, Plasma                     | CMV IgG avidity   | Diasorin Liaison XL SOP: VIRS-157   | C             |
| Whole blood (Test specific tubes) | Interferon gamma (Quantiferon)  | Chemiluminescence Immunoassays DiaSorin Liaison XL  | A             |



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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

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| HUMAN BODY FLUIDS (cont'd) | <u>Microbiology Serology for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:<br><br>QuantiFERON –TB GOLD (QFT) measuring responses to TB peptide antigens using SOP: VIRS-275   |               |
| Serum/Plasma               | Hepatitis delta antibody (HDV)  | HDV total antibody by Diasorin Liaison XL using SOP: VIRS-157   | C             |
| Serum, Plasma              | Hepatitis B core IgG/IgM (HBc IgG/IgM)                                      | Biomerieux VIDAS 3 by Qualitative, Quantitative determination of Ag/Ab status by immunoassay sandwich method with a final fluorescent detection, Enzyme Linked Fluorescent Assay (ELFA) using SOP: SER-22 | C             |
| Serum, Plasma              | Human Immunodeficiency virus I/II (HIV I/II Ag/Ab)                          | Biomerieux VIDAS 3 using HIV DUO Ag/Ab Assay : SOP SER-22   | C             |
| Serum, Plasma              | Hepatitis B surface antigen (HBs Ag)  | Biomerieux VIDAS 3; SOP SER-22  | C             |
| Serum, Plasma              | Hepatitis C antibody (Anti-HCV)   | Biomerieux VIDAS 3; SOP SER-22  | C             |
| Serum, Plasma              | Rubella IgM   | Roche 801; SOP VIRS-203   | C             |
| Serum/Plasma               | HAV IgM   | Biomerieux VIDAS 3; SOP SER-22  | C             |
| Serum/Plasma               | HEV IgG   | Biomerieux VIDAS 3; SOP SER-22  | C             |
| Serum/Plasma               | HEV IgM   | Biomerieux VIDAS 3; SOP SER-22  | C             |



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**Issue No: 020 Issue date: 10 April 2026**

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| HUMAN BODY FLUIDS (cont'd)             | <u>Microbiology Serology for the purpose of clinical diagnosis</u> (cont'd) | Documented In-house methods using:   |               |
| Serum, Plasma (Citrate, EDTA, Heparin) | Human immunodeficiency virus I or II (HIV I or II)                          | Bio-Rad Geenius HIV Confirmatory Assay by immunochromatographic test for the confirmation and differentiation of antibodies to HIV-1 and HIV-2 using SOP: VIRS-181 | C             |
| Serum, Plasma, CSF                     | Treponema pallidum (Syphilis) Rapid plasma reagin (RPR)                     | Slide Agglutination Assay using SOP: VIRS-128, SOP VIRS-127  | C             |
| Serum, Plasma                          | Treponema Pallidum Hemagglutination Assay (TPHA)                            | Agglutination Assay using SOP: SER-11  | C             |
| Serum, Plasma                          | HSV Type I IgG  | Roche 801; SOP VIRS-309  | C             |
| Serum, Plasma                          | HSV Type II IgG   | Roche 801; SOP VIRS-309  | C             |
| Serum, Plasma                          | Total Hepatitis A Antibody  | Roche 801; SOP VIRS-222  | C             |



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**NHS Lothian**  
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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u>  | Documented In-house methods using   |               |
| Serum                      | Immunofluorescence – antibodies to:<br><br>Anti nuclear antibody (ANA)-<br>Gastric parietal cell antibody (GPC)<br>Anti mitochondrial antibody (AMA)<br>Smooth muscle antibody (SMA)<br>Liver Kidney Microsomal antibody (LKM)<br>Anti Neutrophil cytoplasmic antibody (ANCA) | <u>Autoimmune Immunofluorescence</u><br><br>Quantalyser 2 slide processor using indirect immunofluorescence<br>BS-IMM-S29 Operation and maintenance of the Quanta-lyser 2 Slide Processor<br><br>BS-IMM-S26 Measurement of anti-nuclear antibody using NOVA Lite Hep2 DAPI ANA kit and the Quantlayer 2<br><br>BS-IMM-S27 Measurement of gastric parietal cell, anti-mitochondrial and smooth muscle antibody and liver kidney microsomal using NOVA Lite rat liver, kidney, stomach kit and the Quantalyser 2<br><br>BS-IMM-S28 Measurement of anti-neutrophil cytoplasmic antibody using the NOVA Lite DAPI ANCA Kit and the Quantalyser 2<br><br>BS-IMM-S10 Operation of Olympus CX41 Microscope | H             |
| Serum                      | Complement C3 and C4  | Using Roche Cobas c702<br>SOP: BS-IMM-S55   | C             |



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**NHS Lothian**  
**Issue No: 020 Issue date: 10 April 2026**

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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u> | Documented In-house methods using   |               |
| Serum (cont'd)             | Autoimmune FEA  | Phadia 250 using fluorescence enzyme immunoassay (FEIA)                                       | H             |
|                            | Autoantibodies to (cont'd):   | BS-IMM-S24 Operation and Maintenance of the Phadia 250  | H             |
|                            | Cyclic citrullinated peptide (CCP)  | BS-IMM-S34 Measurement of anti-CCP by FEIA using the Phadia 250                               | H             |
|                            | Glomerular basement membrane (GMB)  | BS-IMM-S13 Measurement of anti-GBM antibodies by FEIA using Phadia 250                        | H             |
|                            | dsDNA antibody  | BS-IMM-S37 Measurement of dsDNA by FEIA using the Phadia 250                                  | H             |
| Serum                      | Rheumatoid Factor   | BS-IMM-S57 Measurement of RHF antibodies by Fluoroenzyme Immunoassay using the Phadia 250     | H             |
| Serum                      | Anti M2   | BS-IMM-S58 Measurement of anti-M2 antibodies by fluoroenzyme immunoassay using the Phadia 250 | H             |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>                               | Documented In-house methods using   |               |
| Serum (cont'd)             | Extractable nuclear antigen(ENA) profile (consisting of Ro (SS-A), La (SS-B), SmDP, U1RNP, Scl-70S, Jo-1), centromere | BS-IMM-S18 Measurement of ENA screen and Ro, La, SmDP, U1RNP, Scl-70S & Jo-1 by FEIA using Phadia 250 | H             |
|                            | Myeloperoxidase (MPO) Proteinase 3 (PR3)  | BS-IMM-S36 Measurement of MPO & PR3 antibodies by FEIA using Phadia 250                               | H             |
|                            | <u>Allergy</u>  | Phadia 250 using sandwich immunoassay<br>BS-IMM-S24 Operation and maintenance of the Phadia 250       |               |
|                            | Total IgE   | BS-IMM-S22 Measurement of Total IgE using the Phadia 250  | H             |
|                            | Tryptase  | BS-IMM-S23 Measurement of Tryptase using the Phadia 250   | H             |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)  | Documented In-house methods using:  |               |
| Serum (cont'd)             | <u>Allergy</u> (cont'd)  | Phadia 250 using sandwich immunoassay   |               |
|                            | <u>Food Allergens</u><br>Egg white f1<br>Milk f2<br>Cod f3<br>Wheat f4<br>Sesame f10<br>Peanut f13<br>Soya f14<br>Hazelnut f17<br>Brazil nut f18<br>Almond f20<br>Crab f23<br>Shrimp f24<br>Pork f26<br>Coconut f36<br>Blue mussel f37<br>Tuna f40<br>Salmon f41<br>Gluten f79<br>Kiwi f84<br>Melon f87<br>Banana f92<br>Pecan nut f201<br>Cashew nut f202<br>Pistachio f203<br>Pine nut f253<br>Walnut f256<br>Tomato<br>Lentil<br>Chicken meat<br>Citrus mix (FX29)<br>Apple<br>White Bean<br>Omega-5 gliadin f416 | BS-IMM-S24 Operation and maintenance of the Phadia 250<br>BS-IMM-S35 Measurement of Specific IgE using Phadia 250 | H             |
|                            | <u>Food mixes</u><br>Mixed nuts fx1<br>Mixed fish fx2<br>Mixed nuts (2) fx22   |   | H             |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)   | Documented In-house methods using:   | H             |
| Serum (cont'd)             | <u>Allergy</u> (cont'd)   | Phadia 250 using sandwich immunoassay  | H             |
|                            | <u>Animal/ birds</u><br>Cat dander e1<br>Horse dander e3<br>Dog dander e5<br>Mouse epithelium e71<br>Mouse urine e72<br>Rat epithelium e73<br>Rat urine e74 | BS-IMM-S24 Operation and maintenance of the Phadia 250<br>BS-IMM-S35 Measurement of Specific IgE using Phadia 250  | H             |
|                            | <u>Animal/ bird mixes</u><br>Mixed animal ex1<br>Mixed rodent ex70<br>Mixed feathers ex71<br>Mixed cagebird ex72  | Phadia 250 using sandwich immunoassay<br>BS-IMM-S24 Operation and maintenance of the Phadia 250<br>BS-IMM-S35 Measurement of Specific IgE using Phadia 250 | H             |
|                            | <u>Drugs</u><br>Pennicilloyl G c1<br>Pennicilloyl V c2<br>Ampicilloyl c5<br>Amoxicilloyl c6<br>Suxamethonium c202   |  |               |
|                            | <u>Venoms</u><br>Honey bee venom i1<br>Wasp venom i3  |  |               |
|                            | <u>Pollen/ mould mixes</u><br>Mixed grass gx3<br>Mixed tree tx1<br>Mixed moulds mx1   |  |               |
|                            | <u>Miscellaneous</u><br>Latex k82<br>House dust mite d1   |  |               |
|                            | <u>Pollens/ Moulds</u><br>Aspergillus m3<br>Rape pollen w203  |  |               |



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| HUMAN BODY FLUIDS (cont'd)<br><br>Serum | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)<br><br><u>Allergy</u> (cont'd)<br><br><u>Avian and Aspergillus precipitins</u><br>Aspergillus precipitins Gm3<br>Budgie antigen Ge90<br>Pigeon antigen Ge91<br>Parrot antigen Ge92 | Documented In-house methods using:<br><br>Phadia 250 using sandwich immunoassay<br><br>BS-IMM-S25 Measurement of Avian and Fungal related antibodies using Phadia 250 | H             |
| END                                     |  |   |               |