


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|  |   |  |
|--|---|--|
| <br><b>Accredited to<br/>ISO 15189:2012</b> | <b>Bolton NHS Foundation Trust</b><br><b>Issue No: 005 Issue date: 22 June 2021</b>   |  |
|  | <b>Blood Sciences Department<br/>Laboratory Medicine<br/>Bolton Royal Hospital<br/>Minerva Road<br/>Farnworth<br/>Bolton<br/>BL4 0JR<br/>United Kingdom</b> | <b>Contact: Lewis Hurley<br/>Tel: +44 (0)1204 390 419<br/>E-Mail: Lewis.hurley@boltonft.nhs.uk<br/>Website: www.boltonft.nhs</b> |

**Testing performed at the above address only**

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

| Location details   | Activity                                      |
|--|---|
| Wards and Outpatients' Departments<br>Bolton Royal Hospital              | Phlebotomy                                    |
| Blood Bank Maternity<br>Maternity Unit<br>Bolton Royal Hospital          | Storage and issue of blood and blood products |
| G Block Blood Fridge<br>G Block 2nd Floor<br>Bolton Royal Hospital       | Storage and issue of blood and blood products |
| Blood Bank<br>Pathology Department<br>Bolton Royal Hospital              | Storage and issue of blood and blood products |
| Standby Stock Fridge Transfusion<br>Laboratory<br>Bolton Royal Hospital  | Storage and issue of blood and blood products |
| Stock -40 FFP Freezer<br>Transfusion Laboratory<br>Bolton Royal Hospital | Storage and issue of blood and blood products |



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DETAIL OF ACCREDITATION

| Materials/Products tested     | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used   |
|-------------------------------|--|--|
| HUMAN BODY FLUIDS 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>Cobas Roche 8000 systems<br>Line 1:<br>Cobas 8000 Core AG1631-04<br>Cobas 8000 ISE AQ16J4-03<br>Cobas 8000 c702 AO16L1-08<br>Cobas 8000 e801 AS1742-08<br>Line 2:<br>Cobas 8000 Core AG1638-05<br>Cobas 8000 ISE AQ16J4-05<br>Cobas 8000 c702 AO16L1-10<br>Cobas 8000 e801 AS1736-04 |
| Serum unless stated           | Quantification of:<br><br>Acetaminophen (Paracetamol)<br><br>Alpha-Feto Protein (AFP)<br><br>Albumin<br><br>Alcohol (Ethanol)<br><br>Alkaline Phosphatase<br><br>Alpha-1-antitrypsin<br><br>Alanine Aminotransferase (ALT) | CC-KIT-61<br>CC-ROC-Chem-SOP-2<br><br>CC-KIT-62<br>CC-ROC-Imm-SOP-1<br><br>CC-KIT-53<br>CC-ROC-Chem-SOP-4<br><br>CC-KIT-84<br>CC-ROC-Chem-SOP-20<br>CC-SOP-AUT-048<br>CC-SOP-AUT-051<br><br>CC-KIT-54<br>CCROC-Chem-SOP-5<br><br>CC-KIT-55<br>CC-ROC-Chem-SOP-3<br><br>CC-KIT-55<br>CC-ROC-Chem-SOP-3  |
| Plasma EDTA                   | Ammonia<br><br>Amylase   | CC-KIT-56<br>CC-ROC-Chem-SOP-6<br><br>CC-KIT-57<br>CC-ROC-Chem-SOP-7   |



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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: |
| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
|  | Aspartate Amino Transferase (AST)   | CC-KIT-139<br>CC-ROC-Chem-SOP-8  |
|  | B12   | CC-KIT-67<br>CC-ROC-Imm-SOP-2  |
|  | B Human Chorionic Gonadotrophin (BHCG)  | CC-KIT-93<br>CC-ROC-Imm-SOP-12   |
|  | Bicarbonate   | CC-KIT-77<br>CC-ROC-Chem-SOP-9   |
|  | Bile Acids (TBA)  | CC-KIT-146<br>CC-ROC-Chem-SOP-10   |
|  | Bilirubin Direct  | CC-KIT-142<br>CC-ROC-Chem-SOP-19   |
|  | Bilirubin Total   | CC-KIT-143<br>CC-ROC-Chem-SOP-36   |
| Plasma                                 | Pro-Brain Natriuretic Peptide (BNP)   | CC-KIT-107<br>CC-ROC-Imm-SOP-15  |
|  | C3  | CC-KIT-69<br>CC-ROC-Chem-SOP-14  |
|  | C4  | CC-KIT-70<br>CC-ROC-Chem-SOP-15  |
|  | CA 125  | CC-KIT-71<br>CC-ROC-Imm-SOP-3  |
| Serum and Urine                        | Calcium   | CC-KIT-59<br>CC-ROC-Chem-SOP-11  |
|  | Carbamazepine   | CC-KIT-72<br>CC-ROC-Chem-SOP-12  |



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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: |
| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
|  | Carcinoembryonic Antigen (CEA)  | CC-KIT-73<br>CC-ROC-Imm-SOP-4  |
|  | Chloride (ISE-Na, K, CL)  | CC-KIT-104<br>CC-ROC-Chem-SOP-28   |
|  | Cholesterol   | CC-KIT-74<br>CC-ROC-Chem-SOP-13  |
|  | CMV IgM   | CC-KIT-76<br>CC-ROC-Sero-SOP-5   |
|  | Cortisol  | CC-KIT-78<br>CC-ROC-Imm-SOP-5  |
|  | Creatinine  | CC-KIT-79<br>CC-ROC-Chem-SOP-17  |
| Urine                                  | Creatinine  | CC-KIT-80<br>CC-ROC-Chem-SOP-48  |
|  | Creatine Kinase   | CC-KIT-75<br>CC-ROC-Chem-SOP-16  |
|  | CRP   | CC-KIT-81<br>CC-ROC-Chem-SOP-18  |
|  | Digoxin   | CC-KIT-82<br>CC-ROC-Imm-SOP-6  |
|  | Ferritin  | CC-KIT-85<br>CC-ROC-Imm-SOP-8  |
|  | Folate  | CC-KIT-86<br>CC-ROC-Imm-SOP-9  |
|  | Free Thyroxine (FT4)  | CC-KIT-88<br>CC-ROC-Imm-SOP-11   |



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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: |
| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
|  | Follicle Stimulating Hormone (FSH)  | CC-KIT-87<br>CC-ROC-Imm-SOP-10   |
|  | Gamma Glutamyl Transferase (GGT)  | CC-KIT-90<br>CC-ROC-Chem-SOP-21  |
|  | Gentamicin (Pre, Post and Random)   | CC-KIT-89<br>CC-ROC-Imm-SOP-24   |
| Serum, plasma, CSF                     | Glucose   | CC-KIT-91<br>CC-ROC-Chem-SOP-46  |
|  | HDL   | CC-KIT-94<br>CC-ROC-Chem-SOP-22  |
|  | Hepatitis A IgM antibody  | CC-KIT-63<br>CC-ROC-Sero-SOP-6   |
|  | Hepatitis B Core Antibody   | CC-KIT-64<br>CC-ROC-Sero-SOP-1   |
|  | Hepatitis B Surface Antibody  | CC-KIT-65<br>CC-ROC-Sero-SOP-2   |
|  | Hepatitis BS Antigen Screen   | CC-KIT-92<br>CC-ROC-Sero-SOP-7   |
|  | Hepatitis C Antibody Screen   | CC-KIT-134<br>CC-ROC-Sero-SOP-3  |
|  | HIV AG/AB (HIV 1 + HIV 2) Screen  | CC-KIT-136<br>CC-ROC-Sero-SOP-8  |



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| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
|  | IgA   | CC-KIT-95<br>CC-ROC-Chem-SOP-23  |
|  | IgG   | CC-KIT-96<br>CC-ROC-Chem-SOP-24  |
|  | IgM   | CC-KIT-97<br>CC-ROC-Chem-SOP-25  |
|  | Parathyroid Hormone (PTH)   | CC-KIT-58<br>CC-ROC-Imm-SOP-25   |
|  | Iron  | CC-KIT-98<br>CC-ROC-Chem-SOP-27  |
|  | Lactate   | CC-KIT-99<br>CC-ROC-Chem-SOP-29  |
|  | Lactate Dehydrogenase (LDH12)   | CC-KIT-100<br>CC-ROC-Chem-SOP-30   |
|  | Luteinising Hormone (LH)  | CC-KIT-101<br>CC-ROC-Imm-SOP-13  |
|  | Lithium   | CC-KIT-102<br>CC-ROC-Imm-SOP-14  |
|  | Magnesium   | CC-KIT-103<br>CC-ROC-Chem-SOP-31   |
| Urine                                  | Magnesium   | CC-KIT-103<br>CC-ROC-Chem-SOP-31   |
| Urine                                  | Microalbumin  | CC-KIT-141<br>CC-ROC-CHEM-SOP-49   |



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| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
|  | Oestradiol  | CC-KIT-83<br>CC-ROC-Imm-SOP-7  |
|  | Phenytoin   | CC-KIT-105<br>CC-ROC-Chem-SOP-32   |
| Serum, Urine                           | Phosphate   | CC-KIT-106<br>CC-ROC-Chem-SOP-26   |
| Serum, Urine                           | Potassium   | CC-KIT-104<br>CC-ROC-Chem-SOP-28   |
|  | Progesterone  | CC-KIT-108<br>CC-ROC-Imm-SOP-16  |
|  | Prolactin   | CC-KIT-60<br>CC-ROC-Imm-SOP-17   |
|  | Rheumatoid Factor   | CC-KIT-109<br>CC-ROC-Chem-SOP-33   |
|  | Rubella IgG Antibody  | CC-KIT-110<br>CC-ROC-Sero-SOP-9  |
|  | Rubella IgM antibody  | CC-KIT-111<br>CC-ROC-Sero-SOP-10   |
|  | Salicylate  | CC-KIT-112<br>CC-ROC-Chem-SOP-34   |
|  | Sex Hormone Binding Globulin (SHBG)   | CC-KIT-113<br>CC-ROC-Imm-SOP-18  |
| Serum, Urine                           | Sodium  | CC-KIT-104<br>CC-ROC-Chem-SOP-28   |



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| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
|  | Syphilis TP   | CC-KIT-115<br>CC-ROC-Sero-SOP-11   |
|  | Testosterone  | CC-KIT-117<br>CC-ROC-Imm-SOP-20  |
|  | Theophylline  | CC-KIT-118<br>CC-ROC-Chem-SOP-37   |
|  | Total Protein   | CC-KIT-121<br>CC-ROC-Chem-SOP-38   |
|  | Total Prostate Specific Antigen (PSA)   | CC-KIT-138<br>CC-ROC-Imm-SOP-21  |
|  | Total T3  | CC-KIT-116<br>CC-ROC-Imm-SOP-19  |
|  | Toxoplasma IgM Antibody   | CC-KIT-120<br>CC-ROC-Sero-SOP-12   |
|  | Triglycerides   | CC-KIT-123<br>CC-ROC-Chem-SOP-40   |
| Plasma (Serum)                         | Troponin T  | CC-KIT-119<br>CC-ROC-Imm-SOP-22  |
|  | Thyroid Stimulating Hormone (TSH)   | CC-KIT-125<br>CC-ROC-Imm-SOP-23  |
|  | UIBC  | CC-KIT-127<br>CC-ROC-Chem-SOP-41   |
| Serum, Urine                           | Urate (Uric Acid)   | CC-KIT-126<br>CC-ROC-Chem-SOP-43   |





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| Serum unless stated (cont'd)           | Quantification of: (cont'd)   | Cobas Roche 8000 systems (cont'd)  |
| Serum, Urine                           | Urea  | CC-KIT-128<br>CC-ROC-Chem-SOP-42   |
| Urine, CSF                             | Protein   | CC-KIT-122<br>CC-ROC-Chem-SOP-39   |
|  | Valproate   | CC-KIT-129<br>CC-ROC-Chem-SOP-44   |
|  | Vancomycin  | CC-KIT-130<br>CC-ROC-Chem-SOP-45   |
| Urine                                  | Myoglobin   | Manual testing - spectrophotometry<br>CC-SOP-MNS-004<br>CC-SOP-H&S-082   |
| Serum, Urine                           | Osmolality  | Vitech 3320 – Osmometer<br>CC-SOP-AUT-012<br>CC-ESD-70   |



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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: |
| Serum unless stated (cont'd)           | Protein Electrophoresis:<br>Albumin<br>Alpha – 1 glycoprotein<br>Alpha – 2 glycoprotein<br>Beta Globulin<br>Gamma Globulin                                       | Sebia Hydrasys Gel electrophoresis analyser<br>Backup screen<br>CC-SOP-EPH-005   |
| Urine                                  | Bence Jones Protein  | CC-SOP-EPH-005   |
|  | CK – Isoenzymes:<br>CK-MM<br>CK-MB<br>CK-BB<br>Macro CK  | CC-SOP-EPH-008<br>LM-BIO-SOPS-152<br>LM-BIO-SOPS-463   |
| Serum                                  | Heavy chains:<br>• IgG, IgA, IgM, IgD, IgE<br>Light chains:<br>• kappa, lambda, free kappa and free lambda   | Immunofixation<br>LM-BIO-SOPS-150  |
| Urine                                  | Paraproteins:<br>Heavy chains: IgG, IgA, IgM<br>Light chains: kappa, lambda  | Immunofixation<br>LM-BIO-SPS-150   |
|  | Alkaline Phosphatase Isoenzymes:<br>• Liver isoenzyme<br>• Bone isoenzyme<br>• Placental isoenzyme<br>• Intestinal isoenzyme                                     | CC-SOP-EPH-007<br>LM-BIO-SOPS-153<br>LM-BIO-SOPS-463   |
|  | Protein Electrophoresis screen:<br>Albumin<br>• Alpha – 1 glycoprotein<br>• Alpha – 2 glycoprotein<br>• Beta 1-Globulin<br>• Beta 2-globulin<br>• Gamma Globulin | Sebia Minicap Capillary zone electrophoresis separation method<br>LM-BIO-SOPS-528  |



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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:   |
| Serum                                  | Serum paraproteins including: <ul style="list-style-type: none"> <li>• Heavy chains: IgG, IgA, IgM</li> <li>• Light chains: kappa and lambda</li> </ul> | Sebia Minicap Capillary zone electrophoresis immuno-typing LM-BIO-SOPS-528<br><br>Diasorin Liaison XL using Chemiluminescence methodology CC-DIA-SW-9, CC-DIA-SW-8, CC-DIA-SW-10, CC-DIA-SW-11, CC-DIA-SW-12 |
| Serum                                  | Varicella-Zoster IgG  | Direct competitive chemiluminescence LM-BS-BIO-74 LM-BIO-SOPS-385  |
| Serum                                  | Measles IgG Antibody  | Direct competitive chemiluminescence CC-DIA-SW-17  |
| Serum                                  | TPO Ab  | Sandwich chemiluminescence immunoassay. LM-BS-BIO-70   |
| Serum                                  | Vitamin D   | Direct competitive chemiluminescence LM-BS-BIO-74  |



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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:  |
| Whole Blood                            | Full blood count including: <ul style="list-style-type: none"> <li>• White cell count</li> <li>• Haemoglobin</li> <li>• Platelets</li> <li>• Red cell count</li> <li>• Haematocrit</li> <li>• Mean cell volume</li> <li>• Mean cell haemoglobin</li> <li>• Red cell distribution width</li> <li>• Neutrophils absolute</li> <li>• Lymphocytes absolute</li> <li>• Monocyte absolute</li> <li>• Eosinophils absolute</li> <li>• Basophils absolute</li> <li>• Nucleated red blood cells</li> <li>• Reticulocytes %</li> <li>• Reticulocyte count</li> </ul> | Sysmex XN – Coulter principle, impedance, fluorescent flow cytometry and spectrophotometry<br><br>HM-GENH-SOP-6   |
| Whole Blood (EDTA or citrate)          | Erythrocyte sedimentation rate   | Automated - Starssed Inversa Westergren methodology<br><br>HM-GENH-SOP-5  |
| Whole Blood                            | Detection of normal and abnormal morphologies and manual differential white cell count   | Blood film assessment via microscopy following manual blood film preparation and Romanowsky staining using Siemens Hematek 2000 stainer<br><br>HM-SOP-GENH-006  |
| Whole Blood                            | Detection and Identification of Plasmodium species: <ul style="list-style-type: none"> <li>• <i>P.falciparum</i></li> <li>• <i>P.vivax</i></li> <li>• <i>P.ovale</i></li> <li>• <i>P.malariae</i></li> <li>• <i>P.knowlesi</i></li> </ul>  | Blood film assessment (thick and thin films) . Microscopy following manual blood film preparation and Romanowsky staining using Siemens Hematek 2000 stainer and manual giemsa stain<br><br>HM-SOP-GENH-025 |



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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:            |
| Serum                                  | Infectious mononucleosis heterophile antibody  | Launch accusay mono – solid phase qualitative IM heterophile antibody test<br><br>LM-HM-SOP-30  |
| Whole Blood                            | Glucose 6 phosphate dehydrogenase (G6PD)   | Alere Binax NOW enzyme chromatographic test for qualitative detection of G6PD enzyme activity<br><br>LM-HM-SOP-88                                       |
| Citrated Plasma                        | Coagulation studies: <ul style="list-style-type: none"> <li>• Activated partial thromboplastin time</li> <li>• Prothrombin time</li> <li>• Fibrinogen assay (Claus)</li> <li>• Inhibitor screen (APTT &amp; PT)</li> </ul> Factor assays: <ul style="list-style-type: none"> <li>• Factor II</li> <li>• Factor IX</li> <li>• Factor V</li> <li>• Factor VII</li> <li>• Factor VIII C</li> <li>• Factor X</li> <li>• Factor XI</li> <li>• Factor XII</li> </ul> | Werfen ACL TOP 500 turbidimetric clot detection<br><br>HM-SOP-COA-032<br>LM-HM-SOP-41<br>HM-SOP-COA-008<br><br>Werfen ACL TOP 500<br><br>HM-SOP-COA-034 |
| Citrated Plasma                        | D-dimer  | Werfen ACL TOP<br>HM-SOP-COA-037  |
| Plasma                                 | Thrombophilia tests:<br>Free protein S <ul style="list-style-type: none"> <li>• Functional antithrombin</li> <li>• Functional protein C</li> <li>• Lupus inhibitor</li> </ul>  | Werfen ACL TOP<br>S LM-HM-SOP-17<br>HM-SOP-COA-039<br>LM-HM-SOPS-4<br>HM-SOP-COA-036  |



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Testing performed at main address only

| Materials/Products tested              | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used  |
|--|---|---|
| HUMAN BODY FLUIDS 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:      |
| Whole Blood                            | Haemoglobin screen: <ul style="list-style-type: none"> <li>• Haemoglobin A2</li> <li>• Haemoglobin F</li> </ul>   | Tosoh G8 high performance liquid chromatography analyser<br><br>LM-HM-SOPS-23<br>LM-HM-SOPS-20  |
| Whole Blood                            | Haemoglobin S   | Sickledex Kit Solubility Test<br><br>LM-HM-SOP-23   |
| Whole Blood                            | Haemoglobin A1c   | Tosoh G8 high performance liquid chromatography<br><br>LM-HM-SOPS-24  |
| Whole Blood                            | Molecular haematology:<br><br>BCR-ABL fusion gene   | Cepheid GeneXpert quantification of BCR-ABL transcript as a ratio of BCR-ABL/ABL by real-time PCR and PCR assays<br>LM-MOL-SW-15                  |
|  | <u>Blood Transfusion activities for the purpose of clinical treatment</u>   | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:      |
| Blood (red cells)                      | Blood Grouping by antigen detection: <ul style="list-style-type: none"> <li>• A, B and O groups</li> <li>• Rhesus C, c, D, E, e</li> <li>• Kell antigen status</li> </ul> | Automated testing on Ortho Clinical Diagnostics (OCD) Vision Analyser and Manual Biovue Column Agglutination Technique Indirect Antiglobulin Test |



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**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Blood Transfusion activities for the purpose of clinical treatment (cont'd)</u>  | In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: |
| Blood (plasma)                         | Antibody Screening and identification: <ul style="list-style-type: none"> <li>• Rhesus</li> <li>• Kell</li> <li>• Duffy</li> <li>• Kid</li> <li>• Lewis</li> <li>• P</li> <li>• MNS</li> <li>• Lutheran</li> <li>• Lewis</li> </ul> | BT-SOP-1<br>HM-SOP-BT-061  |
| Blood (red cells)                      | Direct Antiglobulin Test  |  |
| Blood                                  | Compatibility testing of patient's plasma with donor cells  | Compatibility testing of patient's plasma with donor cells<br>IAT and Saline spin crossmatch<br>HM-SOP-BT-060<br>HM-SOP-BT-029               |
| Blood (red cells)                      | Phenotype testing: <ul style="list-style-type: none"> <li>• Rhesus</li> <li>• Kell</li> </ul>   | HM-SOP-BT-061  |
| Blood (red cells)                      | Feto-maternal haemorrhage (FMH)   | Kleihauer Acid Elution Technique<br>Clin-Tech Shepards Stain<br>HM-SOP-BT-014  |



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| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum</p> <p>Serum</p> <p>Serum</p> <p>Serum</p> | <p><u>Antenatal Screening activities for the purpose of clinical diagnosis</u></p> <p>Down's, Edwards' and Patau's syndromes</p> <p>Papp-A<br/>Free beta HCG</p> <p>Down's syndrome:<br/>AFP<br/>Free beta HCG<br/>UE3<br/>Inhibin A</p> <p>Down's, Edwards' and Patau's syndromes<br/>Papp-A<br/>Free beta HCG</p> <p>HIV 1&amp;2 antibody and HIV 1 p24 antigen<br/>Syphilis total antibody<br/>Hepatitis B surface antigen</p> | <p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Documented in-house methods to meet the requirements of the Foetal Anomaly Screening Programme as defined in the July 2018 PHE Foetal Anomaly screening (FASP): laboratory QA evidence requirements</p> <p>First trimester screening antenatal screening</p> <p>Perkin Elmer AutoDELFIA (fluorometric immunoassay)<br/>SOP LM-BIO-SOPS-466</p> <p>Second trimester screening<br/>Perkin Elmer AutoDELFIA (fluorometric immunoassay)<br/>SOP LM-BIO-SOPS-466</p> <p>Fast track first trimester screening -<br/>Perkin Elmer Delfia Xpress (fluorometric immunoassay)<br/>SOP ANS-SW-6</p> <p>Documented in-house methods to meet the requirements of the Infectious diseases in pregnancy screening program as defined in the July 2018 PHE Infectious diseases in pregnancy screening (IDPS): laboratory QA evidence requirements</p> <p>Cobas C8000 analyser<br/>SOPs CC-ROC-Sero-SOP-1; 2; 8; 11.</p> |
| END   |   |  |