


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>Bolton NHS Foundation Trust</b>  <b>Issue No: 010 Issue date: 26 March 2025</b>	
	<b>Blood Sciences Department Laboratory Medicine Bolton Royal Hospital Minerva Road Farnworth Bolton BL4 0JR United Kingdom</b>	<b>Contact: Lewis Hurley Tel: +44 (0)1204 390 419 E-Mail: Lewis.hurley@boltonft.nhs.uk Website: www.boltonft.nhs</b>
<b>Testing performed at the above address only</b>		

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

<b>Location details</b>	<b>Activity</b>
Wards and Outpatients' Departments Bolton Royal Hospital	Phlebotomy
Blood Bank Maternity Maternity Unit Bolton Royal Hospital	Storage and issue of blood and blood products
G Block Blood Fridge G Block 2nd Floor Bolton Royal Hospital	Storage and issue of blood and blood products
Blood Bank Pathology Department Bolton Royal Hospital	Storage and issue of blood and blood products
Standby Stock Fridge Transfusion Laboratory Bolton Royal Hospital	Storage and issue of blood and blood products
Stock -40 FFP Freezer Transfusion Laboratory 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:  Cobas Roche 8000 systems Line 1: Cobas 8000 Core AG1631-04 Cobas 8000 ISE AQ16J4-03 Cobas 8000 c702 AO16L1-08 Cobas 8000 e801 AS1742-08 Line 2: Cobas 8000 Core AG1638-05 Cobas 8000 ISE AQ16J4-05 Cobas 8000 c702 AO16L1-10 Cobas 8000 e801 AS1736-04
Serum	Quantification of:  Acetaminophen (Paracetamol)	CC-KIT-61 CC-ROC-Chem-SOP-2
Serum	Acute Kidney Injury (AKI)	CC-KIT-79 LM-BIO-SOPS-230 (calculated) CC-ROC-CHEM-SOP-17
Serum	Alpha-Feto Protein (AFP)	CC-KIT-62 CC-ROC-Imm-SOP-1
Serum	Albumin	CC-KIT-53 CC-ROC-Chem-SOP-4
Urine	Albumin:Creatinine ratio	CC-KIT-141 CC-ROC-CHEM—SOP-49 (calculated) CC-ROC-CHEM-SOP-17 (calculated) CC-KIT-79
Serum	Alcohol (Ethanol)	CC-KIT-84 CC-ROC-Chem-SOP-20 CC-SOP-AUT-048 CC-SOP-AUT-051
Serum	Alkaline Phosphatase	CC-KIT-54 CCROC-Chem-SOP-5



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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: (Cont'd)
	Quantification of (cont'd):	Cobas Roche 8000 systems (cont'd):
Serum	Alpha-1-antitrypsin	CC-KIT-55 CC-ROC-Chem-SOP-3
Serum	Alanine Aminotransferase (ALT)	CC-KIT-55 CC-ROC-Chem-SOP-3
Plasma EDTA	Ammonia	CC-KIT-56 CC-ROC-Chem-SOP-6
Serum	Amylase	CC-KIT-57 CC-ROC-Chem-SOP-7
	Anti-cyclic citrullinated peptide	CC-KIT-175 CC-ROC-Imm-SOP-26
	Aspartate Amino Transferase (AST)	CC-KIT-139 CC-ROC-Chem-SOP-8
	B12	CC-KIT-67 CC-ROC-Imm-SOP-2
	B Human Chorionic Gonadotrophin (BHCG)	CC-KIT-93 CC-ROC-Imm-SOP-12
	Bicarbonate	CC-KIT-77 CC-ROC-Chem-SOP-9
	Bile Acids (TBA)	CC-KIT-146 CC-ROC-Chem-SOP-10
	Bilirubin Direct	CC-KIT-142 CC-ROC-Chem-SOP-19
	Bilirubin Total	CC-KIT-143 CC-ROC-Chem-SOP-36



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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)
Plasma	Pro-Brain Natriuretic Peptide (BNP)	CC-KIT-107 CC-ROC-Imm-SOP-15
Serum	C3	CC-KIT-69 CC-ROC-Chem-SOP-14
Serum	C4	CC-KIT-70 CC-ROC-Chem-SOP-15
Serum	CA 125	CC-KIT-71 CC-ROC-Imm-SOP-3
Serum, Urine	Calcium	CC-KIT-59 CC-ROC-Chem-SOP-11
Urine	Calcium:Creatinine ratio	CC-KIT-79 CC-ROC-CHEM-SOP-17 (Calculated) CC-KIT-59 CC-ROC-CHEM-SOP-11 (Calculated)
Serum	Carbamazepine	CC-KIT-72 CC-ROC-Chem-SOP-12
Serum	Carcinoembryonic Antigen (CEA)	CC-KIT-73 CC-ROC-Imm-SOP-4
Serum	Chloride (ISE-Na, K, CL)	CC-KIT-104 CC-ROC-Chem-SOP-28
Serum	Cholesterol	CC-KIT-74 CC-ROC-Chem-SOP-13
Serum	CMV IgM	CC-KIT-76 CC-ROC-Sero-SOP-5
Serum	Corrected calcium	CC-KIT-59 CC-ROC-CHEM-SOP-11 calculated)



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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	Cortisol	CC-KIT-78 CC-ROC-Imm-SOP-5
Serum	Creatinine	CC-KIT-79 CC-ROC-Chem-SOP-17
Urine	Creatinine	CC-KIT-80 CC-ROC-Chem-SOP-48
Serum	Creatine Kinase	CC-KIT-75 CC-ROC-Chem-SOP-16
Serum	CRP	CC-KIT-81 CC-ROC-Chem-SOP-18
Serum	Digoxin	CC-KIT-82 CC-ROC-Imm-SOP-6
Serum	Estimated GFR	CC-KIT-79 CC-ROC-CHEM-SOP-17 (calculated)
Serum	Ferritin	CC-KIT-85 CC-ROC-Imm-SOP-8
Serum	Folate	CC-KIT-86 CC-ROC-Imm-SOP-9
Serum	Free Thyroxine (FT4)	CC-KIT-88 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:
	Quantification of: (cont'd)	Cobas Roche 8000 systems (cont'd)
Serum	Follicle Stimulating Hormone (FSH)	CC-KIT-87 CC-ROC-Imm-SOP-10
Serum	Gamma Glutamyl Transferase (GGT)	CC-KIT-90 CC-ROC-Chem-SOP-21
Serum	Gentamicin (Pre, Post and Random)	CC-KIT-89 CC-ROC-Imm-SOP-24
Serum, plasma, CSF	Glucose	CC-KIT-91 CC-ROC-Chem-SOP-46
Serum	HDL	CC-KIT-94 CC-ROC-Chem-SOP-22
Serum	Hepatitis A IgM antibody	CC-KIT-63 CC-ROC-Sero-SOP-6
Serum	Hepatitis B Core Antibody	CC-KIT-64 CC-ROC-Sero-SOP-1
Serum	Hepatitis B Surface Antibody	CC-KIT-65 CC-ROC-Sero-SOP-2
Serum	Hepatitis B Surface Antigen Screen	CC-KIT-92 CC-ROC-Sero-SOP-7
Serum	Hepatitis C Antibody Screen	CC-KIT-134 CC-ROC-Sero-SOP-3
Serum	HIV AG/AB (HIV 1 + HIV 2) Screen	CC-KIT-136 CC-ROC-Sero-SOP-8



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



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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:
	Quantification of: (cont'd)	Cobas Roche 8000 systems (cont'd)
Serum	Oestradiol	CC-KIT-83 CC-ROC-Imm-SOP-7
Serum	Phenytoin	CC-KIT-105 CC-ROC-Chem-SOP-32
Serum	Phosphate	CC-KIT-106 CC-ROC-Chem-SOP-26
Serum, Urine	Potassium	CC-KIT-104 CC-ROC-Chem-SOP-28
Serum	Progesterone	CC-KIT-108 CC-ROC-Imm-SOP-16
Serum	Procalcitonin	CC-KIT-223 CC-ROC-Imm-SOP-27
Serum	Prolactin	CC-KIT-60 CC-ROC-Imm-SOP-17
Urine	Protein:Creatinine ratio	CC-KIT-122 CC-ROC-CHEM-SOP-39 (calculated) CC-ROC-CHEM-SOP-17 (calculated) CC-KIT-79
Serum	Rheumatoid Factor	CC-KIT-109 CC-ROC-Chem-SOP-33





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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:
	Quantification of: (cont'd)	Cobas Roche 8000 systems (cont'd)
Serum	Rubella IgG Antibody	CC-KIT-110 CC-ROC-Sero-SOP-9
Serum	Rubella IgM antibody	CC-KIT-111 CC-ROC-Sero-SOP-10
Serum	Salicylate	CC-KIT-112 CC-ROC-Chem-SOP-34
Serum	Sex Hormone Binding Globulin (SHBG)	CC-KIT-113 CC-ROC-Imm-SOP-18
Serum, Urine	Sodium	CC-KIT-104 CC-ROC-Chem-SOP-28
Serum	sFlt-1/PIGF pre-eclampsia ratio	CC-KIT-172 CC-KIT-173 CC-ROC-Imm-SOP-28 (calculated)
Serum	Syphilis TP	CC-KIT-115 CC-ROC-Sero-SOP-11
Serum	Testosterone	CC-KIT-117 CC-ROC-Imm-SOP-20
Serum	Theophylline	CC-KIT-118 CC-ROC-Chem-SOP-37
Serum	Thyroid Peroxidase Antibody (Anti-TPO)	CC-KIT-179 CC-ROC-Imm-SOP-29
Serum	Total Protein	CC-KIT-121 CC-ROC-Chem-SOP-38



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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)
Serum	Total Prostate Specific Antigen (PSA)	CC-KIT-138 CC-ROC-Imm-SOP-21
Serum	Toxoplasma IgM Antibody	CC-KIT-120 CC-ROC-Sero-SOP-12
Serum	Triglycerides	CC-KIT-123 CC-ROC-Chem-SOP-40
Plasma (Serum)	Troponin T	CC-KIT-119 CC-ROC-Imm-SOP-22
Serum	Thyroid Stimulating Hormone (TSH)	CC-KIT-125 CC-ROC-Imm-SOP-23
Serum	UIBC	CC-KIT-127 CC-ROC-Chem-SOP-41
Serum, Urine	Urate (Uric Acid)	CC-KIT-126 CC-ROC-Chem-SOP-43
Serum, Urine	Urea	CC-KIT-128 CC-ROC-Chem-SOP-42
Urine, CSF	Protein	CC-KIT-122 CC-ROC-Chem-SOP-39
Serum	Valproate	CC-KIT-129 CC-ROC-Chem-SOP-44
Serum	Vancomycin	CC-KIT-130 CC-ROC-Chem-SOP-45



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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, Urine	Osmolality	Vitech 3320 – Osmometer CC-SOP-AUT-012 CC-ESD-70
Faeces	Faecal Immunochemical Test (FIT)	MAST OC Sensor CC-MAST-SOP-1  Sebia Hydrasys 2 Gel electrophoresis analyser
Urine	Protein electrophoresis	CC-SOP-EPH-005
Serum, Urine	Paraproteins: Heavy chains: IgG, IgA, IgM, IgD, IgE Light chains: kappa, lambda, free kappa and free lambda	Immunofixation CC-SOP-EPH-006 LM-BIO-SOPS-150 LM-BIO-SOPS-151
Serum	Alkaline Phosphatase Isoenzymes: <ul style="list-style-type: none"> <li>Liver isoenzyme</li> <li>Bone isoenzyme</li> <li>Placental isoenzyme</li> <li>Intestinal isoenzyme</li> </ul>	CC-SOP-EPH-007 LM-BIO-SOPS-153 LM-BIO-SOPS-463
Serum	Protein Electrophoresis screen: <ul style="list-style-type: none"> <li>Alpha – 1 glycoprotein</li> <li>Alpha – 2 glycoprotein</li> <li>Beta 1-Globulin</li> <li>Beta 2-globulin</li> <li>Gamma Globulin</li> </ul>	Sebia Minicap Capillary zone electrophoresis separation method CC-Electro-SOP-2 LM-BIO-SOPS-528
Serum	Serum paraproteins: <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



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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	Varicella-Zoster IgG	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	Measles IgG Antibody	Direct competitive chemiluminescence LM-BS-BIO-74 LM-BIO-SOPS-385
Faeces	Faecal Calprotectin	Direct competitive chemiluminescence CC-DIA-SW-17
Serum	tTG	Sandwich chemiluminescent immunoassay (CLIA) SOP CC-DIA-SOP-2
Serum	HIV 1&2 antibody HIV 1 p24 antigen Syphilis total antibody Hepatitis B surface antigen	Indirect chemiluminescent immunoassay (CLIA) LM-BS-BIO-71  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  Cobas C8000 analyser SOPs CC-ROC-Sero-SOP-1; 2; 8; 11.



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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  HM-GENH-SOP-6
Whole Blood (EDTA or citrate)	Erythrocyte sedimentation rate	Automated - Starssed Inversa ST Westergren methodology  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 3000 stainer  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 3000 stainer and manual Giemsa stain  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  LM-HM-SOP-30
Whole Blood	Glucose 6 phosphate dehydrogenase (G6PD)	Alere Binax NOW enzyme chromatographic test for qualitative detection of G6PD enzyme activity  LM-HM-SOP-88
Whole Blood	Detection and identification of Plasmodium species: - <i>P. falciparum</i> <i>P. vivax</i> <i>P. ovale</i> <i>P. malariae</i>	Carestart Malaria Rapydtest. HRP2/pLDH Combo Test. HM-SOP-GENH-025
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 VIIIC</li> <li>Factor X</li> <li>Factor XI</li> <li>Factor XII</li> </ul>	Werfen ACL TOP 550 turbidimetric clot detection  HM-SOP-COA-032 LM-HM-SOP-41 HM-SOP-COA-008  Werfen ACL TOP 550  HM-SOP-COA-034



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Citrated Plasma	D-dimer	Werfen ACL TOP 550 HM-SOP-COA-037
Plasma	Thrombophilia tests: <ul style="list-style-type: none"><li>• Free protein S</li><li>• Functional antithrombin</li><li>• Functional protein C</li><li>• Lupus inhibitor</li></ul>	Werfen ACL TOP 550 S LM-HM-SOP-17 HM-SOP-COA-039 LM-HM-SOPS-4 HM-SOP-COA-036
Plasma	Heparin Anti Xa assay	Werfen ACL TOP 550 analyser using chromogenic assay HM-COAG-SOP-1 SOP



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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:  Documented -in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme screening programme(s) as defined in the July 2018 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements':*
Whole Blood	Haemoglobin screen: * <ul style="list-style-type: none"> <li>• Haemoglobin A2</li> <li>• Haemoglobin F</li> </ul>	Tosoh G11 high performance liquid chromatography analyser  LM-HM-SOPS-23 LM-HM-SOPS-20
Whole Blood	Haemoglobin S	Sickledex Kit Solubility Test  LM-HM-SOP-23
Whole Blood	Haemoglobin A1c	Tosoh G11 high performance liquid chromatography  LM-HM-SOPS-24
Whole Blood	<u>Molecular haematology:</u> 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 LM-MOL-SW-15
Whole Blood	Factor V Leiden (G1691A)	Cepheid GeneXpert® Dx System using the Xpert® Factor V Assay MD-SOP-1 SOP
Whole Blood	Factor II/Prothrombin (G20210A) Mutations	Cepheid GeneXpert® Dx System using the Xpert® Factor II Assay





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15189:2012**Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service**

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

**Bolton NHS Foundation Trust****Issue No:** 010 **Issue date:** 26 March 2025**Testing performed at main address only**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<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:  Automated testing on Ortho Clinical Diagnostics (OCD) Vision Swift Analyser and Manual Biovue Column Agglutination Technique Indirect Antiglobulin Test
Blood (red cells)	Blood Grouping by antigen detection: <ul style="list-style-type: none"><li>• A, B and O groups</li><li>• Rh C, c, D, E,e</li></ul>	
Blood (plasma)	Antibody Screening and identification: <ul style="list-style-type: none"><li>• Rh</li><li>• Kell</li><li>• Duffy</li><li>• Kidd</li><li>• Lewis</li><li>• P</li><li>• MNS</li><li>• Lutheran</li><li>• Lewis</li></ul>	BT-SOP-1 HM-SOP-BT-061
Blood (red cells)	Direct Antiglobulin Test	
Blood (red cells)	Phenotype testing: <ul style="list-style-type: none"><li>• Rh</li><li>• Kell</li></ul>	HM-SOP-BT-061
Blood (red cells)	Feto-maternal haemorrhage (FMH)	Kleihauer Acid Elution Technique Clin-Tech Shepards Stain HM-SOP-BT-014



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## Schedule of Accreditation

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### United Kingdom Accreditation Service

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

### Bolton NHS Foundation Trust

Issue No: 010 Issue date: 26 March 2025

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Antenatal Screening activities for the purpose of clinical diagnosis</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:  Documented -in-house methods to meet the requirements of the FASP screening programme as defined in the April 2019 'FASP screening: laboratory QA evidence requirements':
Serum	Down's, Edwards' and Patau's syndromes: Papp-A Free beta HCG	First trimester screening antenatal screening Perkin Elmer AutoDELFIA (fluorometric immunoassay) SOP LM-BIO-SOPS-466
Serum	Down's syndrome: AFP Total HCG UE3 Inhibin A	Second trimester screening Perkin Elmer AutoDELFIA (fluorometric immunoassay) SOP LM-BIO-SOPS-466
Serum	Down's, Edwards' and Patau's syndromes: Papp-A Free beta HCG	Fast track first trimester screening - Perkin Elmer Delfia Xpress (fluorometric immunoassay) SOP ANS-SW-6

END