


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |  |  |
|---|--|--|
| <br><b>8146</b><br><b>Accredited to<br/>ISO 15189:2012</b> | <b>Northern Care Alliance NHS Foundation Trust</b>                                 |  |
|   | <b>Issue No: 008 Issue date: 01 October 2021</b>                                   |  |
|   | <b>Haematology Laboratory</b><br>Royal Oldham Hospital<br>Rochdale Road<br>OL1 2JD | <b>Contact: Michael Heaton</b><br><b>Tel: +44 (0)161 656 1678</b><br><b>Fax: +44 (0)161 627 8008</b><br><b>E-Mail: Michael.heaton@pat.nhs.uk</b> |
| <b>Testing performed by the Organisation at the locations specified below</b>   |  |  |

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

#### Laboratory locations:

| Location details   | Activity                               | Location code           |
|--|--|-------------------------|
| <b>Address</b><br>Haematology/BT Laboratory<br>Royal Oldham Hospital<br>Rochdale Road<br>OL1 2JH                             | <b>Local contact</b><br>Michael Heaton | Diagnostic testing<br>A |
| <b>Address</b><br>Essential Service Laboratory<br>North Manchester General Hospital<br>Delaunays Road<br>Crumpsall<br>M8 5RB | <b>Local Contact</b><br>Michael Heaton | Diagnostic testing<br>B |
| <b>Address</b><br>Essential Service Lab<br>Fairfield General Hospital<br>Rochdale Old Road<br>Bury<br>BL9 7TD                | <b>Local Contact</b><br>Michael Heaton | Diagnostic testing<br>C |



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

| Location details  | Activity                                      | Location code  |
|---|---|--|
| Blood issue fridge<br>Blood Transfusion Department, Pathology<br>Phase 1 Theatre<br>Central Delivery Unit | Storage and issue of blood and blood products | A  |
| Blood Issue Fridge<br>Essential Service Laboratory<br>Central Delivery Unit<br>Main Theatre               | Storage and issue of blood and blood products | B  |
| Blood Issue Fridge<br>Essential Service Laboratory  | Storage and issue of blood and blood products | C  |
| Blood Issue Fridge<br>Level B Blood Fridge Room   | Storage and issue of blood and blood products | Rochdale Infirmary<br>Whitehall Street<br>Rochdale<br>OL12 0NB |



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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         | <u>Haematology examinations for the purposes of clinical diagnosis</u>  | In-house documented procedures based on equipment manuals as relevant  |                        |
| Blood                     | Full Blood Count<br>Haemoglobin<br>White Blood Cell Count<br>Red Blood Count<br>Platelet Count<br>Haematocrit<br>Mean Cell Volume<br>Mean Cell Haemoglobin<br>Mean Cell Haemoglobin Concentration (MCHC)<br>Neutrophil count<br>Lymphocyte count<br>Monocyte count<br>Eosinophil count<br>Basophil count<br>Nucleated Red Cells | Sysmex XN-9000 (A), XN-3000 (B) and XN-2000 (C) by flow cytometry, impedance and Spectrophotometry<br>SOPs<br>HAE-SOP-SYS-1<br>HAE-SOP-SYS-3<br>HAE-SOP-SYS-5<br>HAE-SOP-SYS-6<br>HAE-SOP-SYS-10<br>HAE-SOP-SYS-11 | A, B, C                |
|                           | Reticulocyte count  |  | A & B                  |
| Serum                     | Ferritin<br>B12<br>Folate<br>Erythropoietin<br>Intrinsic Factor Antibody  | Beckman Coulter Dxl800 by immunoassay<br>SOPs<br>HAE-SOP-HTINICS-2<br>HAE-SOP-HTINICS-3<br>HAE-SOP-HTINICS-4<br>HAE-SOP-HTINICS-5  | A                      |
| Plasma                    | Viscosity   | Benson Viscometer by viscometry<br>SOP HAE-SOP-GEN-8   | A                      |
| Blood                     | ESR   | StaRRsed InteRRliner ESR (TROH) Inversa (NMGH)<br>Analyser by Westergren method<br><br>HAE-SOP-SYS-4 (InteRRliner)<br><br>HAE-SOP-SYS-7 (Inversa)  | A, B<br><br>A<br><br>B |



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|----------------------------|---|---|--------------------------|
| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination for the purposes of clinical diagnosis (cont'd)</u>  | In-house documented procedures based on equipment manuals as relevant   |                          |
| Blood                      | Blood film assessment for detection of abnormal cell types, morphology and numbers  | Blood film assessment using SP10 automated slide maker stainer and May Grunwald and Giemsa stain examined by light microscopy.<br>HAE-SOP-SYS-2 (SP-10 TROH, NMGH)<br>RAL staining machine<br>HAE-SOP-SYS-10 (RAL -FGH)<br>HAE-SOP-GEN-6 -microscopes<br>HAE-SOP-GEN-7-film examination | A, B<br><br>C<br>A, B, C |
| Bone marrow                | Bone marrow assessment for detection of abnormal cell types, morphology and numbers   | Bone marrow assessment using RA Lamb Stainmate and May Grunwald and Giemsa stains and examined by light microscopy<br>SOP HAE-SOP-GEN-14, HAE-SOP-LabCentre-6   | A,                       |
| Blood                      | Iron stain  | Manual Perl's Prussian Blue stain examined by light microscopy<br>SOP HAE-SOP-GEN-13  | A, B                     |
| Plasma                     | Coagulation-<br>Prothrombin time/INR<br>APTT<br>Fibrinogen (Derived)<br>Fibrinogen Clauss<br>D Dimer<br>Thrombin Time<br>Factor Assays : FII, FV, FVII, FVIII, FIX, FX, FXI, FXII<br>Lupus anticoagulant<br>APCR<br>AT3<br>Protein C<br>Protein S<br>Heparin assay<br>VW screen<br>vWF Ag | Werfen IL TOP 550 series analyser using immunoassay, turbidimetry, chromogenic and agglutination.<br>SOPs HAE-SOP-COAG-4, 8, 9, 10, 11, 14, 17, 19, 20, 22, 24, 37,40, 46, 48, 50, 51, 53   | A                        |



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|----------------------------|--|---|---------------|
| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination for the purposes of clinical diagnosis (cont'd)</u>       | In-house documented procedures based on equipment manuals as relevant   |               |
|                            | Prothrombin time/INR<br>APTT<br>Fibrinogen (Derived)<br>Fibrinogen Clauss<br>D-Dimer | Werfen IL TOP 350 series analyser using immunoassay, turbidimetry, chromogenic and agglutination: SOP   | B, C          |
| Blood Plasma               | Factor V Leiden<br>Prothrombin Gene Variant  | Cepheid GeneXpert PCR analyser<br>SOP HAE-SOP-COAG-35   | A             |
|                            |  | Documented in-house methods to meet the requirements of the Sickle Cell and Thalassemia screening programme(s) as defined in the July 2018 'NHS Sickle Cell and thalassemia screening: Laboratory QA evidence requirements. |               |
| Blood                      | Antenatal Haemoglobinopathy screening<br>HbA2/F/S                                    | BioRad Variant II using HPLC<br>SOP HAE-SOP-HPLC-1, 2, 3  | A             |
|                            | Haemoglobinopathy detection  | BioRad Variant II using HPLC<br>SOP HAE-SOP-HPLC-1, 2, 3  | A             |
| Blood                      | Sickle cell screen   | Streck Sickledex qualitative solubility test<br>SOP HAE-SOP-HPLC-4  | A, B, C       |
| Blood                      | G6PD screen  | G6PD Trinity Biotech using red cell enzyme rate reaction<br>SOP HAE-SOP-HPLC-7  | A             |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination for the purposes of clinical diagnosis (cont'd)</u>                    | In-house documented procedures based on equipment manuals as relevant   |               |
| Blood                      | Malaria screen  | MGG stained thin films prepared using SP10 automated slide maker stainer (A and B) and RAL staining machine (C) for preliminary malaria screen:<br>HAE-SOP-GEN-6 -microscopes<br>HAE-SOP-GEN-7-film examination | A, B, C       |
| Blood                      | Malarial confirmation and species identification<br>• P.Falciparum<br>• Non-falciparum            | BinaxNOW malaria kit using immunochromatographic membrane assay<br>SOP HAE-SOP-GEN-3  |               |
| Blood                      | IM screen   | Clearview IM kit using immunoassay<br>SOP HAE-SOP-GEN-1   | A, B, C       |
| Blood                      | <u>Blood Transfusion</u>  |   |               |
| Blood                      | Cross match   | Ortho Vision analyser using column agglutination technology<br>SOP BT-SOP-TRANS-20  | A, B, C       |
| Blood                      | Direct antiglobulin test  | Ortho Vision analyser using column agglutination technology SOP BT-SOP-TRANS-21   | A, B, C       |
| Blood                      | Antibody panels of the following systems:<br>Rh-hr, KELL, DUFFY, KIDD, LEWIS, MNS, P and LUTHERAN | Ortho Vision analyser using column agglutination technology Resolve Panel C and Resolve Panel B SOP BT-SOP-TRANS-5<br><br>Manual method using Ortho Resolve Panel C<br>SOP BT-SOP-TRANS-24                      | A, B, C       |
| Blood                      | Blood Group, A, B, O and AB groups<br>Rh groups, antigen D  | Ortho Vision analyser using column agglutination technology<br>SOP BT-SOP-TRANS-19  | A, B, C       |
| Blood                      | Kleihauer   | CLIN-TECH LTD Shepard's stain kit using acid elution.<br>SOP BT-SOP-TRANS-27  | A, B          |
| END                        |   |   |               |