


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|  |  |   |
|--|--|---|
| <br><b>UKAS</b><br>MEDICAL<br>8657<br><br>Accredited to<br>ISO 15189:2012 | <b>The Royal Wolverhampton NHS Trust operating as<br/>Black Country Pathology Services</b>   |   |
|  | Issue No: 004    Issue date: 14 February 2022  |   |
|  | Department of Haematology<br>Pathology Centre C37<br>New Cross Hospital<br>Wolverhampton Road<br>Wolverhampton<br>WV10 0QP<br>United Kingdom | Contact: Katy New<br>Tel: +44 (0)1902 307999 ext.88247<br>E-Mail: <a href="mailto:katy.new@nhs.net">katy.new@nhs.net</a><br>Website: <a href="http://www.royalwolverhampton.nhs.uk">www.royalwolverhampton.nhs.uk</a> |
| Testing performed at the above address only  |  |   |

### Site Activities performed away from the main Address:

| Location Details:   | Activities                           |
|---|--------------------------------------|
| CHU Fridge  | Blood and blood product issue fridge |
| Maternity Fridge  | Blood and blood product issue fridge |
| Critical Care   | Blood and blood product issue fridge |
| Cardiac Theatres  | Blood and blood product issue fridge |
| Emergency Department (A+E)                                      | Blood and blood product issue fridge |
| Cannock Chase Hospital<br>Brunswick Road<br>Cannock<br>WS11 5XY | Blood and blood product issue fridge |



8657

Accredited to  
ISO 15189:2012

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

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

### The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 004 Issue date: 14 February 2022

Testing performed at main address only

#### DETAIL OF ACCREDITATION

| Materials/Products tested  | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used   |
|--|--|--|
| <p>HUMAN BODY FLUIDS</p> <p>Venous whole blood: EDTA unless otherwise specified</p> <p>Whole Blood EDTA or Citrate</p> | <p><u>Haematology examination activities for the purpose of clinical diagnosis:</u></p> <p>FBC<br/>Haemoglobin<br/>Red cell count<br/>Haematocrit<br/>white blood cells (WBC)<br/>Differential WBC count<br/>Reticulocytes<br/>MCV<br/>MCH<br/>MCHC<br/>NRBC<br/>Platelets</p> | <p>Documented procedures &amp; manufacturer's instructions for Sysmex XN9000 track analyser with specific reference to:</p> <p>F2.H450P.HAE</p>  |
| <p>Human body fluids including ascitic and pleural fluids</p>  | <p>Quantification of white blood cells</p> <p>Film reporting and WBC Diff</p>  | <p>Documented procedures &amp; manufacturer's instructions for Sysmex XN9000 track analyser with specific reference to:</p> <p>F2H450P.HAE</p> <p>Automated preparation and May Grunwald and Giemsa staining<br/>F2.H480P.HAE<br/>Documented procedures &amp; manufacturer's instructions for SP10 slide maker/stainer</p> <p>Manual preparation of films<br/>F2.H050P.HAE<br/>F2.H060P.HAE (manual film review)</p> |



8657

Accredited to  
ISO 15189:2012

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

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

### The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 004 Issue date: 14 February 2022

Testing performed at main address only

| Materials/Products tested   | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used   |
|---|---|--|
| <p>HUMAN BODY FLUIDS (cont'd):</p> <p>Venous whole blood EDTA unless otherwise specified</p> <p>Films prepared as above</p> | <p><u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Digital scanning and review of blood films</p> <p>Erythrocyte Sedimentation Rate (ESR)</p> <p>Screening for abnormal haemoglobins A, A2 and F</p> <p>Detection and confirmation of abnormal haemoglobins A, A2, F (S,C,D,E)</p> <p>Detection of HbS solubility</p> <p>Detection of heterophile antibodies for infectious mononucleosis</p> | <p>Documented procedures &amp; manufacturer's instructions for digital imaging Sysmex DI60 analyser with specific reference to:</p> <p>F2.H490P.HAE (use of DI60)</p> <p>Documented procedures &amp; manufacturer's instructions for StaRRsed InteRRliner analyser (Westergren) with specific reference to:</p> <p>F2.H440P.HAE</p> <p>Documented procedures &amp; manufacturer's instructions for Sebia Cap 3 capillary zone electrophoresis with specific reference to:</p> <p>Capillary electrophoresis F2.I082P.HAE1 (Capillarys 3) screen)</p> <p>Documented procedures &amp; manufacturer's instructions for Hydrasys agarose gel electrophoresis with specific reference to:F2.E020P.HAE</p> <p>In house documented manual method with specific reference to:</p> <p>Sickle test F2.E010P.HAE</p> <p>F2.H330P.HAE</p> |



8657

Accredited to  
ISO 15189:2012

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

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

### The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 004 Issue date: 14 February 2022

Testing performed at main address only

| Materials/Products tested  | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used  |
|--|--|---|
| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous whole blood: EDTA unless otherwise specified</p> | <p><u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of combined HRP2 and pLDH P falciparum antigen and pan species plasmodial antigen (P. falciparum, P. vivax, P. malariae, P. ovale)</p> <p>Identification of malarial parasites:<br/>P. falciparum<br/>P. vivax<br/>P. malariae<br/>P. ovale<br/>P. knowlesi</p> <p>G6PD detection</p> | <p>Documented procedures &amp; manufacturer's instructions for ClearView II<br/>Immunochromatographic assay with specific reference to:</p> <p>Documented procedures &amp; manufacturer's instructions for Carestart Immunochromatographic assay with specific reference to</p> <p>F2.H081P.HAE</p> <p>Documented in house method Thick and thin blood film preparation, staining and microscopy</p> <p>F2.H080P.HAE</p> <p>In house documented manual method using qualitative fluorescent detection:<br/>F2.H325P.HAE</p> |
| Bone Marrow Trepphine  | Normal and abnormal morphologies   | In house documented method using manual staining and microscopy:<br>F2.BM030P.HAE   |
| Bone Marrow  | Bone marrow interpretation and reporting   | F2.BM035P.HAE   |
| Bone Marrow  | Detection of iron  | F2.BM030P.HAE   |
| Urine  | Detection of haemosiderin  | F2.BM030P.HAE   |



8657

Accredited to  
ISO 15189:2012

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

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

### The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 004 Issue date: 14 February 2022

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 (cont'd)<br><br>Venous whole blood: EDTA unless otherwise specified | <u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd) | Manual techniques for slide preparation and staining using documented procedure:  |
|   | Coagulation  | Documented procedures & manufacturer's instructions for Sysmex CS5100i Analyser clot detection, latex agglutination and quantitative chromogenic assays with specific reference to: |
| Plasma: citrated  | Prothrombin time/INR   | F2.C632P.HAE (auto)   |
|   | APTT   | F2.C634P.HAE (auto)   |
|   | Clauss Fibrinogen  | F2.C636P.HAE (auto)   |
|   | Thrombin time  | F2.C652P.HAE (auto)   |
|   | D Dimer  | F2.C638P.HAE (auto)   |
|   | Anti-Factor Xa (LMWH assay)  | F2.C648P.HAE (auto)   |
|   | Anti-Factor Xa (UFH assay)   | F2.C648P.HAE (auto)   |
|   | Anti-Factor Xa (Rivaroxaban assay)   | F2.C648P.HAE (auto)   |
|   | Anti-Factor Xa (Orgaran assay)   | F2.C648P.HAE (auto)   |
|   | Intrinsic factor pathway studies (Factor VIII, IX, XI and XII)                           | F2.C644P.HAE (auto)   |
|   | Extrinsic factor pathway studies (Factor II, V, VII and X)                               | F2.C646P.HAE (auto)   |
|   | Lupus Anticoagulant  | D2.C640P.HAE (auto)   |
| Whole Blood (EDTA or citrate)   | Qualitative determination of:  | Preanalytical processing of blood samples and reporting of results for samples tested in UKAS 8655 laboratory using:  |
|   | Factor V Leiden G1691A and Prothrombin (FII) G20210A gene mutations                      | Manufacturer's instructions for the Cepheid GeneXpert Infinity 48 DX (PCR) with specific reference to: F2.044P.MIC  |



8657

Accredited to  
ISO 15189:2012

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

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

### The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 004 Issue date: 14 February 2022

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 (cont'd) | <u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)   | Documented procedures & manufacturer's instructions for Sysmex CS5100i Analyser with specific reference to:   |
| Plasma: citrated           | Protein C activity   | F2.C640P.HAE (auto)   |
|                            | free Protein S activity  | F2.C640P.HAE (auto)   |
|                            | Antithrombin activity  | F2.C640P.HAE (auto)   |
|                            | Von Willebrand factor activity   | F2.C642P.HAE (auto)   |
|                            | Von Willebrand Factor antigen  | F2.C642P.HAE (auto)   |
|                            | Coagulation Inhibitor screen   | F2.C634P.HAE (auto)   |
|                            | Factor VIII Inhibitor (Bethesda)   | F2.C501P,HAE (auto)<br>Manual dilutions and incubation and clotting measurement   |
|                            | <u>Blood Transfusion Testing for use in clinical diagnosis</u>   | Documented procedures & manufacturer's instructions for BioRad IH1000 analyser and manual techniques using Diamed cards with specific reference to: |
| Venous blood               | Blood grouping<br>ABO Rh (D C c E e)   | F2.BT500P.HAE (auto)<br>F2.BT030P.HAE (manual)  |
|                            | Antibody detection:  | Documented procedures & manufacturer's instructions for Diamed cards with specific reference to:  |
|                            | <ul style="list-style-type: none"> <li>• Rh (C D E c e)</li> <li>• K</li> <li>• Fya</li> <li>• Fyb</li> <li>• JKa</li> <li>• JKb</li> <li>• M S s</li> </ul> | F2.BT500P.HAE (auto)<br>F2.BT070P.HAE (manual)  |



8657

Accredited to  
ISO 15189:2012

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

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

### The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 004 Issue date: 14 February 2022

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 (cont'd)<br><br>Venous blood | <u>Blood Transfusion Testing for use in clinical diagnosis (cont'd)</u><br><br>Compatibility testing of patients plasma with donor cells<br><br>Direct antiglobulin test (DAT)<br><br>HDN investigation<br><br>Genotype. RC phenotype <ul style="list-style-type: none"> <li>• Rh (D C c E e)</li> <li>• K</li> </ul> Antibody investigation: <ul style="list-style-type: none"> <li>• Rh (C D E c e)</li> <li>• K</li> <li>• Fya</li> <li>• Fyb</li> <li>• JKa</li> <li>• JKb</li> <li>• M S s</li> </ul><br>Fetomaternal Haemorrhage estimation | F2.BT090P.HAE (manual)<br>F2.BT105P.HAE ( auto))<br><br>F2.BT500P.HAE (auto)<br>F2.BT070P.HAE (manual)<br><br>F2.BT500P.HAE (auto)<br>F2.BT070P.HAE (manual)<br>F2.BT160P.HAE<br><br>F2.BT500P.HAE (auto)<br>F2.BT070P.HAE (manual)<br><br>F2.BT500P.HAE (auto)<br>F2.BT070P.HAE (manual)<br><br>Documented in house procedure using manual acid elution and microscopy<br><br>Kleihauer<br>F2.BT160P.HAE |
| END  |   |   |