

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8657

Accredited to
ISO 15189:2022

The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 009 Issue date: 04 March 2025

Department of Haematology
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Testing performed at the above address only

Site Activities performed away from the main Address:

Location Details:	Activities
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 Brunswick Road Cannock WS11 5XY	Blood and blood product issue fridge



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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 Haemoglobin Red cell count Haematocrit white blood cells (WBC) Differential WBC count Reticulocytes MCV MCH MCHC NRBC Platelets</p>	<p>Documented procedures & manufacturer's instructions for Sysmex XN9100 and XN3100 track analysers with specific reference to:</p> <p>HAE/SOP/051</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 & manufacturer's instructions for Sysmex XN9100 and XN3100 track analysers with specific reference to:</p> <p>HAE/SOP/051</p> <p>Automated preparation and May Grunwald and Giemsa staining HAE/SOP/075 Documented procedures & manufacturer's instructions for SP50 slide maker/stainer</p> <p>Manual preparation of films HAE/SOP/039 HAE/SOP/040 (Bloodfilm examination)</p> <p>Documented procedures & manufacturer's instructions for digital imaging Sysmex DI60 analyser with specific reference to:</p>
<p>Films prepared as above</p>	<p>Digital scanning and review of blood films</p>	<p>HAE/SOP/055(use of DI60)</p>



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HUMAN BODY FLUIDS (cont'd): Venous whole blood EDTA unless otherwise specified (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd) Erythrocyte Sedimentation Rate (ESR) Qualitative and quantitative detection of haemoglobin variants A, A2 and F Qualitative and quantitative confirmation of haemoglobin variants A, A2, F,S,C,D,E Detection of HbS solubility Detection of heterophile antibodies for infectious mononucleosis	Documented procedures & manufacturer's instructions for StaRRsed InteRRlinar analyser (Westergren) with specific reference to: HAE/SOP/050 Documented -in-house methods to meet the requirements of the NHS Sickle Cell and Thalassaemia Screening Programme as defined in the NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements Documented procedures & manufacturer's instructions for Sebia Cap 3 capillary zone electrophoresis with specific reference to: High Pressure Liquid Chromatography (HPLC) using TOSOH G11 and HAE/SOP/Hb2 Capillary zone electrophoresis using the Sebia Capillarys TERA and HAE/SOP/067 In house documented manual method with specific reference to: Sickle test HAE/SOP/068 HAE/SOP/046



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous whole blood: EDTA unless otherwise specified (cont'd)</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>G6PD detection</p>	<p>Documented procedures & manufacturer's instructions for ClearView II Immunochromatographic assay with specific reference to:</p> <p>Documented procedures & manufacturer's instructions for CareUS Rapydtest Immunochromatographic assay with specific reference to</p> <p>HAE/SOP/043</p>
Bone Marrow Trephine	Normal and abnormal morphologies	In house documented method using manual staining and microscopy: HAE/SOP/016
Bone Marrow	Bone marrow interpretation and reporting	HAE/SOP/017
Bone Marrow	Detection of iron	HAE/SOP/016
Urine	Detection of haemosiderin	HAE/SOP/016
Serum	Quantitative determination of: Erythropoietin (EPO)	Beckman Coulter Access Immunoenzymatic method HAE/SOP/H4



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HUMAN BODY FLUIDS (cont'd) Venous whole blood: EDTA unless otherwise specified (cont'd) Plasma: citrated	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> Prothrombin time/INR APTT Clauss Fibrinogen D Dimer Anti-Factor Xa (LMWH assay) Anti-Factor Xa (UFH assay) Anti-Factor Xa (Rivaroxaban assay) Anti Factor Xa (Apixaban assay) (Factor Assays for Factors III, IX, XI and XII, II, V, VII and X) Factor VIII Inhibitor (Bethesda) Lupus Anticoagulant (DRVVT and Lupus insensitive APTT) Protein C activity free Protein S activity Antithrombin III activity Coagulation Inhibitor screen	Documented procedures & manufacturer's instructions for Werfen ACL TOP 550 Analyser clot detection, latex agglutination and quantitative chromogenic assays with specific reference to: HAE/SOP/083 HAE/SOP/081 HAE/SOP/088 HAE/SOP/087 HAE/SOP/092 HAE/SOP/092 HAE/SOP/092 HAE/SOP/092 HAE/SOP/090 HAE/SOP/019 (manual dilutions, incubations and clotting measurements) HAE/SOP/085 HAE/SOP/085 HAE/SOP/085 HAE/SOP/085



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Werfen ACL Acustar Chemiluminescent assay and in house method HAE/SOP/089
Venous whole blood: EDTA unless otherwise specified (cont'd)		
EDTA Plasma	Quantitative determination of: Von Willebrand factor activity Von Willebrand Factor antigen	 HAE/SOP/089 HAE/SOP/089
Whole Blood (EDTA or citrate)	Qualitative determination of: Factor V Leiden G1691A and Prothrombin (FII) G20210A gene mutations	Preanalytical processing of blood samples and reporting of results for samples tested in UKAS 8655 laboratory using: Manufacturer's instructions for the Cepheid GeneXpert Infinity 48 DX (PCR) with specific reference to: MIC/SOP/057
	<u>Blood Transfusion Testing for use in clinical diagnosis</u>	Documented procedures & manufacturer's instructions for Ortho Vision Sprint analyser and manual techniques using Ortho cards with specific reference to:
Venous blood	Blood grouping ABO Rh (D C c E e)	BT/SOP/033 (Auto) BT/SOP/010 (Manual)
	Antibody detection:	Documented procedures & manufacturer's instructions for Ortho cards with specific reference to:
	<ul style="list-style-type: none"> • Rh (C D E c e) • K • Fya • Fyb • JKa • JKb • M S s 	BT/SOP/033 (auto) BT/SOP/011 (manual)



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion Testing for use in clinical diagnosis</u> (cont'd)	Documented procedures & manufacturer's instructions for Ortho Vision Sprint analyser and manual techniques using Ortho cards with specific reference to:
Venous blood	Compatibility testing of patient's plasma with donor cells	BT/SOP/012 (manual) BT/SOP/013 (auto)
	Direct antiglobulin test (DAT)	BT/SOP/033 (auto) BT/SOP/011 (manual)
	HDN investigation	BT/SOP/033 (auto) BT/SOP/010 and 011 (manual)
	Genotype. RC phenotype <ul style="list-style-type: none">• Rh (D C c E e)• K	BT/SOP/033 (auto) BT/SOP/011 (manual)
	Antibody investigation: <ul style="list-style-type: none">• Rh (C D E c e)• K• Fya• Fyb• JKa• JKb• M S s	BT/SOP/033 (auto) BT/SOP/011(manual)
END		