


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL 9733 Accredited to ISO 15189:2012	<b>Frimley Health NHS Foundation Trust</b>	
	Issue No: 005    Issue date: 01 June 2022	
	<b>Blood Science Department</b> <b>Pathology Department</b> <b>Wexham Park Hospital</b> <b>Wexham</b> <b>Slough</b> <b>SL2 4HL</b>	<b>Contact: Elaine Inglis</b> <b>Tel: +44 (0) 1932 723042 / 01753 633098</b> <b>Fax: +44 (0) 1932 875129</b> <b>E-Mail: <a href="mailto:fph-tr.bspsquality@nhs.net">fph-tr.bspsquality@nhs.net</a></b> <b>Website: <a href="http://www.nhspathology.fph.nhs.uk">http://www.nhspathology.fph.nhs.uk</a></b>
<b>Testing performed at the above address only</b>		

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

Location details	Activity
Wexham Park Hospital Main Lab	Blood storage & issue Fridge managed by Blood Sciences
Wexham Park Hospital Theatres	Blood storage & issue Fridge managed by Blood Sciences
Wexham Park Hospital Accident & Emergency Ward	Blood storage & issue Fridge managed by Blood Sciences
Wexham Park Hospital Eden Ward	Blood storage & issue Fridge managed by Blood Sciences
Heatherwood Hospital Pathology Ascot	Blood storage & issue Fridge managed by Blood Sciences Specimen reception



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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	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood EDTA	Blood Group by detection and identification of antigens: ABO and RhD	Automated using Immucor Neo analyser and Immucor Echo analyser: BTR-WPH-SOP-T012 BTR-WPH-SOP-T013  Manual tube spin agglutination and manual Diamed gel IAT technology: BTR-WPH-SOP-T032
Plasma EDTA	Antibody Screen by detection of antibodies to: Cc,E,e K Jka, Jkb Fya, Fyb M, N, S, s Kpa	Automated using Immucor Neo analyser and Immucor Echo analyser: BTR-WPH-SOP-T012 BTR-WPH-SOP-T013  Manual gel IAT technology BTR-WPH-SOP-T032
Whole Blood EDTA	Antigen phenotyping: Rh C, c, E, e K	Automated using Immucor Neo analyser BTR-WPH-SOP-T033  Manual gel IAT technology BTR-WPH-SOP-T033



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Plasma EDTA	Antibody investigation by detection, identification and quantification of: C,c,E,e K Jka, Jkb Fya, Fyb M, N, S, s Kpa	Automated using Immucor Neo analyser and Immucor Echo analyser: BTR-WPH-SOP-T017  Manual gel IAT technology BTR-WPH-SOP-T017
Whole Blood EDTA	Direct Antiglobulin Test (DAT)	Automated using Immucor Neo analyser and Immucor Echo analyser: BTR-BSPS-SOP-012  Manual column gel IAT technology BTR-WPH-SOP-T031



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood EDTA	Foetal Maternal Haemorrhage	Clin Tech Shepard kits Kleihauer Acid Elution Technique BTR-WPH-SOP-T043
Whole Blood EDTA	Compatibility testing of patients' plasma with donor cells	Cross matching using column gel IAT technology BTR-WPH-SOP-T021
	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
EDTA Whole Blood	Full Blood Count (FBC) analysis of the following parameters: Hb WBC PLT RBC Hct MCH MCH MCHC RDW Neutrophils (absolute) Lymphocytes (absolute) Monocytes (absolute) Eosinophils (absolute) Basophils (absolute)	Sysmex XN automated analysers differential laser light scatter HAE-WPH-SOP-H.01 Sysmex XN Use of HAE-WPH-SOP-H.02 – Sysmex XN Maintenance
EDTA Whole Blood	Screening test for Glucose 6 phosphate dehydrogenase deficiency	Trinity Biotech kit, visual qualitative fluorescence HAE-WPH-SOP-S.82
EDTA Whole Blood	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	RDT Carestart and malaria thick and thin films HAE-WPH-SOP-H.25



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
EDTA Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Automated Starrsed analysers, modified Westergren method HAE-WPH-SOP-H.26
EDTA Whole Blood		Manual ESR method HAE-WPH-SOP-H.27
EDTA Whole Blood	Glycated Hb (HbA1c)	Sebia 3 Capillary Flex - Electrophoresis HAE-WPH-SOP-S.39
EDTA Whole Blood	HbF quantitation	Biorad variant HPLC HAE-WPH-SOP-S.31 HAE-WPH-SOP-S.30
EDTA Whole Blood	Blood film analysis for: Differential leucocyte count and morphology of the leucocytes, erythrocytes and platelets	Automated using SP10 slide preparation, staining using May-Grunwald-Giemsa and Giemsa stain HAE-WPH-SOP-H.03
EDTA Whole Blood Bone Marrow aspirate		Manual staining using May Grunwald Giemsa and Diff Quick stains HAE-WPH-SOP-H.14 HAE-WPH-SOP-H.23 HAE-WPH-SOP-H.24
		Manual Perl's stain HAE-WPH-SOP-H.15
		Documented -in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements
EDTA Whole Blood	Sickle cell solubility	Sickle solubility assay by Microgen Bioproducts HAE-RBH/WPH-SOP-014
EDTA Whole Blood	Haemoglobinopathy screen for Hb variants: HbA, A2, F, S, C, D, E	Sebia 3 Capillary Flex - Electrophoresis HAE-WPH-SOP-S.30 HAE-WPH-SOP-S.31



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Sodium Citrate Plasma	Blood coagulation <ul style="list-style-type: none"> <li>• Prothrombin Time (PT)</li> <li>• INR</li> <li>• APTT</li> <li>• Fibrinogen</li> <li>• Factor VIII and Factor IX</li> <li>• D-Dimer</li> <li>• APTT mix</li> </ul>	Stago STA-R Evolution Mechanical clot detection HAE-WPH-SOP-C001, HAE-WPH-SOP-C002, HAE-WPH-SOP-C005, HAE-WPH-SOP-C006, HAE-WPH-SOP-C007, HAE-WPH-SOP-C009, HAE-WPH-SOP-C0013, HAE-WPH-SOP-C0022
Sodium Citrate Plasma	<ul style="list-style-type: none"> <li>• Anti Xa</li> </ul>	Chromogenic Assay: WPH-SOP-C0013
Serum, EDTA plasma EDTA whole blood NaHep plasma	Detection of infectious mononucleosis heterophile antibodies	Inverness medical Clearview IM II test chromatographic immunoassay kit HAE-WPH-SOP-S77
	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>  Quantitative determination of:	Documented in house methods and manufacturer's instructions for:  <b>Roche Cobas 8000</b> Associated SOPs: BIO-WPH-SOP-009 BIO-WPH-SOP-011 BIO-WPH-SOP-004 BIO-WPH-SOP-013BIO-WPH-SOP-005BIO-WPH-SOP-003 BIO-RBH/WPH-SOP-001
Serum, plasma	ACE	Enzymatic kinetic assay
Serum Serum, plasma Serum, plasma Serum, plasma Serum, plasma Serum, plasma Serum, plasma	AFP CA-125 CA-153 CA-199 CEA Hcg LH	Sandwich immunoassay



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:
Serum, plasma	Quantitative determination of (cont'd): Albumin	<b>Roche Cobas 8000</b> Colorimetric BCG assay
Serum, plasma	ALP	Colorimetric assay
Serum, plasma	Iron	
Plasma, CSF	Lactate	
Serum, plasma	Lithium	
Serum, plasma	Total bilirubin	
Serum, plasma	Total protein	
Serum, urine, plasma	Magnesium	Colorimetric endpoint assay
Serum, plasma	Alpha 1 Antitrypsin	Immunoturbidimetric assay
Serum, plasma	Haptoglobin	
Urine	Microalbumin	
Serum, plasma	Transferrin	
Urine, CSF	total protein	Turbidimetric assay
Serum, plasma	ALT	UV-kinetic assay
Serum, plasma	AST	
Serum, plasma	CK	
Serum, plasma	LDH	
Serum, urine, plasma	Urea	Kinetic assay
Plasma	Ammonia	Enzymatic assay
Serum, plasma	Bicarbonate	
Serum, plasma	Bile acids	
Serum, urine, plasma	Enzymatic Creatinine	
Serum, plasma	Paracetamol	
Serum, plasma	Salicylate	
Serum, plasma	Ethanol	Enzymatic alcohol dehydrogenase assay



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:
Serum, urine, plasma	Quantitative determination of (cont'd):	<b>Roche Cobas 8000</b>
Serum, plasma	Amylase	Enzymatic colorimetric assay
Serum, plasma	Cholesterol	
Serum, plasma	gGT	
Serum, plasma	HDL	
Serum, plasma	Triglyceride	
Serum, urine, plasma	Uric Acid	
Serum, plasma, CSF	Glucose	Enzymatic Hexokinase UV assay
Serum, plasma	Anti-Mullerian Hormone	Sandwich immunoassay
Serum, plasma	Ferritin	
Serum, plasma	Folate	
Serum, plasma	FSH	
Serum, plasma	hs Troponin T	
Serum, plasma	Nt Pro BNP	
Serum, plasma	Prolactin	
Serum, plasma	PSA	
Serum, plasma	PTH	
Serum, plasma	SHBG	
Serum, plasma	TSH	
Serum, plasma	Vitamin D (Total)	
Serum, urine, plasma	Calcium	Colorimetric NM-BAPTA assay
Serum, plasma	Carbamazepine	KIMS assay
Serum, plasma	Digoxin	
Serum, plasma	Phenytoin	
Serum, plasma	Theophylline	
Serum, plasma	Amikacin	
Serum, urine, plasma	Chloride	ISE assay
Serum, urine, plasma	Potassium	
Serum, urine, plasma	Sodium	
Serum, plasma	Cortisol	Competitive immunoassay
Serum, plasma	Free T3	
Serum, plasma	Free T4	
Serum, plasma	Methotrexate	





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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:
Serum, plasma	Quantitative determination of (cont'd):	<b>Roche Cobas 8000</b>
Serum, plasma	Oestradiol	Competitive immunoassay
Serum, plasma	Progesterone	
Serum, plasma	Testosterone	
Serum, plasma	Vitamin B12	
Serum, plasma	CRP	Particle enhanced immunoturbidimetric assay
Serum, plasma	Direct bilirubin	Diazo method
Serum, urine, plasma	Phosphate	Molybdate UV assay
Serum, plasma	Tobramycin	Homogeneous enzyme immunoassay
Serum, plasma	Vancomycin	
Serum, plasma	Gentamicin	
Urine	24-hour urine calcium output	Calculated test
Urine	24-hour urine creatinine output	
Urine	24-hour urine magnesium output	
Urine	24-hour urine phosphate output	
Urine	24-hour urine potassium output	
Urine	24-hour urine protein output	
Urine	24-hour urine sodium output	
Urine	24-hour urine urate output	
Urine	24-hour urine urea output	
Urine	Albumin:Creatinine Ratio	
Urine	Protein:Creatinine Ratio	
Serum, plasma	Adjusted calcium	
Serum, plasma	Creatinine Clearance	
Serum, plasma	eGFR	
Serum, plasma	Free Androgen Index	
Serum, plasma	Globulin (Calculated)	
Serum, plasma	LDL	
Serum, plasma	Transferrin Saturation	
Serum, plasma	AKI alerts	Alert 1, 2 or 3 based on creatinine results



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:
Sweat	Sweat test Chloride	Sweat Chloride testing using Sherwood Sweat Chloride meter (BIO-WPH-SOP-014)
Serum, plasma	Macroprolactin	Automated using Roche Cobas (Sandwich immunoassay) and manual method BIO-WPH-SOP-020
Serum, urine, plasma	Osmolality	Advanced Osmometer 3320, freezing point depression method BIO-WPH-SOP-022
	Quantitative determination of:	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'. Accreditation for 1 <sup>st</sup> Trimester screening:
		<b>Roche Cobas 8000</b> Associated SOPs: BIO-WPH-SOP-009 BIO-WPH-SOP-011 BIO-WPH-SOP-004 BIO-WPH-SOP-013BIO-WPH-SOP-005BIO-WPH-SOP-003 BIO-RBH/WPH-SOP-001
Serum	Alpha-fetaprotein (AFP)	Sandwich immunoassay
Serum, plasma	Free B human Chorionic Gonadotrophin (B-hCG)	
Serum	Free Beta hCG	Brahms Kryptor – TRACE immunofluorescent assay HAE-WPH-SOP-S80
	PAPP-A	
END		