Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9058

Accredited to ISO 15189:2012

The Mid Yorkshire Teaching NHS Trust

Issue No: 009 **Issue date**: 28 November 2023

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Blood Science Department Pathology Pinderfields Hospital Aberford Road Wakefield WF1 4DG	**Local contact** Janet English (details as above)	• Haematology • Blood Transfusion • Chemistry	A
Dewsbury and District Hospital Halifax Road Dewsbury WF13 4HS	Janet English (details as above)	• Haematology • Blood Transfusion • Chemistry	B

Site activities performed away from the locations listed above:

Location details	Activity
Pinderfields Hospital Maternity A&E Theatres Critical Care Haematology Outpatients Haematology Day unit	• Management of blood fridge • Phlebotomy
Dewsbury and District Hospital Ridings Theatres Ridings Ground Floor	• Management of blood fridge • Phlebotomy

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Testing performed by the Organisation at the locations specified

Location details	Activity
Pontefract Hospital Laboratory Haematology Day Unit	• Management of blood fridge • Phlebotomy

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of diagnosis:	Documented in house methods and manufacturer's instructions for	
	Quantitative determination of:	Roche Cobas c702 module SOP-BIO-037	A
		Roche Cobas c501 module SOP-BIO-039	B
		by photometry	
Serum	Alanine Transaminase		A, B
Serum	Albumin		A, B
Serum	Alkaline Phosphatase		A, B
Plasma	Ammonia		A & B
Serum	Amylase		A, B
Serum	Angiotensin Converting Enzyme (ACE)		A
Serum	AST		A
Serum	Bicarbonate		A & B
Serum	Bile acids		A
Serum	Bilirubin		A, B
Serum	Calcium		A, B
Urine	Calcium		A & B
Serum	Cholesterol (Total)		A & B
Serum	Creatine Kinase		A & B
Serum	Creatinine		A, B
Urine	Creatinine		A & B
Serum	Direct Bilirubin		A
Serum	Ethanol		A
Serum	Gamma-GT		A
Plasma	Glucose		A, B
CSF	Glucose		A
Serum	HDL		A & B
Serum	Iron		A
Plasma	Lactate		A
CSF	Lactate		A
Serum	LDH		A
Serum	Lipase		A
Serum	Lithium		A
Serum	Magnesium		A, B
Urine	Magnesium		A
Serum	Paracetamol		A, B
Serum	Phosphate		A, B
Urine	Phosphate		A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of diagnosis: (cont'd)	Documented in house methods and manufacturer's instructions for	
	Quantitative determination of: (cont'd)	Roche Cobas c702 module SOP-BIO-037	A
		Roche Cobas c501 module SOP-BIO-039	B
		by photometry	
Serum	Salicylate		A, B
Serum	Total Protein		A, B
Serum	Triglycerides		A, B
Serum and Urine	Urate		A
Serum and Urine	Urea		A, B
	Quantitative determination of:	Roche Cobas c702 module SOP-BIO-037	A
		Roche Cobas c501 module SOP-BIO-039	B
		by turbidmetry	
Urine	Albumin		B
Serum	Alpha-1-Antitrypsin		A
Serum	ASO		A
Serum/Plasma	Beta-2 Microglobulin		A
Serum	C3		A
Serum	C4		A
Serum	Caeruloplasmin		A
Serum	CRP		A, B
Serum	Gentamicin		A
Serum	Haptoglobin		A
Serum	IgA		A
Serum	IgG		A
Serum	IgM		A
Urine, CSF	Protein		A, B
Serum	Rheumatoid Factor		A, B
Serum	Total Immunoglobin E		A
Serum	Transferrin		A
Serum	Valproic Acid		A
Serum	Vancomycin		A
Faeces	Calprotectin		B
Faeces	Elastase		B
Faeces	Faecal immunochemical test (FIT)		B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of diagnosis: (cont'd)	Documented in house methods and manufacturer's instructions for	
	Quantitative determination of:	Roche Cobas e801 module SOP-BIO-037	A
		Roche Cobas e411 module SOP-BIO-039	B
		Measurement by electrochemiluminescence immunoassay (ECLIA)	
Serum	Alpha Feto protein		A
Plasma	NT – Pro Brain Natriuretic Peptide		A
Serum	C.E.A.		A
Serum	CA125		A
Serum	CA153		A
Serum	CA199		A
Serum	Cortisol		A
Serum, Plasma	Digoxin		A
Serum	Ferritin		A
Serum	Folate		A
Serum	Follicle Stimulating Hormone		A
Serum	Free T3		A
Serum	Free T4		A, B
Serum	Human Chorionic Gonadotrophin		A, B
Serum/plasma	Human growth hormone		B
Serum/plasma	Insulin like growth factor 1		B
Serum	Luteinising Hormone		A
Serum	Macroprolactin		A
Serum	Oestradiol		A
Serum	Placental like growth factor		A
Serum	Progesterone		A
Serum	Prolactin		A
Serum	Prostatic Specific Antigen		A
Plasma	PTH		A
Serum	Sex hormone binding globulin		A
Serum	Soluble fms-like tyrosine kinase-1		A
Serum	Testosterone		A
Serum	TPO Antibodies		A
Serum	Troponin-T (high sensitivity)		A, B
Serum	TSH		A, B
Serum	Vitamin B12 (total)		A
Serum	Vitamin D		A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of diagnosis: (cont'd)	Documented in house methods and manufacturer's instructions for	
	Quantitative determination of:	Roche Cobas c702 SOP-BIO-037	A
		Roche Cobas c501 SOP-BIO-039	B
		Measurement by enzyme immunoassay	
Serum	Phenytoin		A
Serum	Theophylline		A, B
		Roche Cobas c702 using suppliers methods and measurement by microparticle agglutination immunoassay	A
Serum	Carbamazepine	SOP-BIO-082	
		Roche Cobas C702 module SOP-BIO-37	A
		Roche Cobas c501 module SOP-BIO-039	B
		by indirect ion selective electrode	
Serum, Urine	Chloride		A, B
Serum, Urine	Potassium		A, B
Serum, Urine	Sodium		A, B
CSF	Xanthochromia	Uvikon XL Spectrophotometer using measurement by spectrophotometry SOP-BIO-057	A
Whole Blood	HbA1C IFCC Standardised	Tosoh G11 Analyser using high pressure cation exchange chromatography SOP-BIO-201	A
Urine	pH	Mettler Toledo Five Easy F20 pH meter using suppliers methods and measurement by potentiometry SOP-BIO-027	A & B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of diagnosis: (cont'd)	Documented in house methods and manufacturer's instructions for	
	Quantitative determination of:		
Serum and Urine	Osmomolality	Advanced Instruments Osmo Pro Osmometer – using freezing point depression SOP-BIO-177	A
Urine	Bence-Jones protein (Kappa and lambda free light chains)	Helena SAS 3 and V8 Nexus software by Gel immunofixation SOP-BIO-169	A
Serum	Identification of heavy and light chain components of monoclonal protein	Helena SAS 3 and V8 Nexus Gel immunofixation and capillary immunotyping SOP-BIO-167 SOP-BIO-169	A
Urine	Identification of free light chain and potential heavy chain components	Helena SAS 3 Gel immunofixation SOP-BIO-167	A
	Calculated tests:	Calculated parameters/derived results from Roche Cobas SOP-BIO-205	
Serum/plamsa	Acute kidney injury stage Adjusted calcium eGFR Liver fibrosis score (FIB-4) Globulin Low density lipoprotein Non HDL Cholesterol Total HDL:Cholesterol ratio Transferrin saturation Free androgen index Free testosterone		A & B A & B A & B A A & B A & B A & B A & B A A A
Serum	sFlt-1:PIGF ratio		A
Urine	Albumin 24hr output Albumin:creatinine ratio Calcium 24 hr output Calcium:creatinine ratio		B B A & B A & B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of diagnosis: (cont'd)	Documented in house methods and manufacturer's instructions for	
	Calculated tests:	Calculated parameters/derived results from Roche Cobas SOP-BIO-205	
Urine	Creatinine 24hr output		A & B
	Potassium 24hr output		A & B
	Magnesium 24hr output		A
	Sodium 24hr output		A & B
	Phosphate 24hr output		A & B
	Protein 24hr output		A & B
	Protein:creatinine ratio		A & B
	Urate 24hr output		A
	Urea 24hr output		A & B
Serum/plasma/Urine	Calcium:creatinine clearance ratio		A & B
	Creatinine clearance		A & B
	Tubular reabsorption of phosphate		A
	TMP:GFR (phosphate threshold)		A
Sweat	Conductivity & chloride measurement.	Wescor 3700 SYS Macroduct Sweat Collection System using supliers methods by pilocarpine iontophoresis BIO_SOP_LPT_Man_132 Sherwood MK2 926S chloride meter by suppliers methods and measurement by Argentimetry BIO_SOP_LPT_Man_134 Wescor 3120 Sweat•Chek Conductivity Analyser using suppliers methods and measurement by conductivity BIO_SOP_LPT_Man_133	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination for the purpose of clinical diagnosis</u>	Documented procedures and manufacturer's instructions for	
Blood	Full Blood Count (FBC) analysis for the following parameters:	Sysmex XN Series analyser using fluorescence flow cytometry XN 9000	A
	Haemoglobin	Sysmex XN Series analyser using fluorescence flow cytometry XN 2000	B
	WBC – differential neutrophils, lymphocytes, monocytes, basophils, eosinophils Retics Nucleated Red Blood cell count Platelets MCV MCH MCHC RDW	SOP-HAEM-001 SOP-HAEM-002 SOP-HAEM-005 SOP-HAEM-012	
Plasma	Manual coagulation testing for PT, APTT	KC1 manual mechanical clotting time SOP-HAEM-089	A, B
		Sysmex CS-2500i Sysmex CS-5100 Optical analysis of turbidimetric and colorimetric changes SOP-HAEM_062 overview of analysers SOP_HAEM_064 Processing QC and changing reagents	A & B A
	Prothrombin time INR APTT/ APTT ratio Fibrinogen Thrombin Time D-dimer Anti-Xa	SOP_HAEM_074 SOP_HAEM_074 SOP_HAEM_075 SOP_HAEM_076 SOP-HAEM_078 SOP-HAEM_077 SOP_HAEM_098	A, B A, B A, B A, B A A, B A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematological examination for the purpose of clinical diagnosis (cont'd)	Documented procedures and manufacturer's instructions for	
Blood	Plasma Viscosity	Benson plasma viscometer SOP-HAEM-228 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.	A
Blood	Hb variant screening percent HBA2 and HBF	Bio-rad variant II HPLC SOP_HAEM_179 Sample analysis SOP_HAEM_184 antenatal processing	A
Blood	Blood film analysis: White cell differential Immature leucoytes Red cell structural abnormality Platelet structure and number	Blood smears – light microscopic identification of pathological processes SOP-HAEM-115 SOP-HAEM-116 Using Aerospray slide stainer for May-Grunwald-Giemsa SOP-HAEM-113 RAL Stainer for May-Grunwald Giemsa SOP-HAEM-225 SP-10 Wright single stain May-Giemsa stain Wright-Giemsa stain SOP-HAEM-226	A & B
Blood	Detection of malaria parasites: Plasmodium falciparum Plasmodium vivax Plasmodium malariae Plasmodium ovale	Immunochromatographic assay using Humasis Malaria Antigen Kit Thin film light microscopic analysis with May-Giemsa Stain and thick blood film using Fields stain A and B SOP –HAEM- 111 SOP-HAEM-112	A & B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematological examination for the purpose of clinical diagnosis (cont'd)	Documented procedures and manufacturer's instructions for	
Blood	Infectious mononucleosis	Clearview IM screening Kit for infectious mononucleosis detection Sandwich ELISA SOP-HAEM-122	A & B
Blood	G6PD	Trinity Biotech G6PD screening kit Production of a fluorescence or its absence under UV light SOP-HAEM-121	A & B
Blood	Sickle cell test	Clin-tech Sickle test SOP-HAEM-186 based on deoxy-HbS solubility in phosphate buffers	A
Bone Marrow	Reporting of normal and abnormal morphologies	Jenner and Giemsa stain and Perls Iron Stain SOP-HAEM-117 SOP-HAEM-118 SOP-HAEM-119 SOP-HAEM-120 SOP-HAEM-243	A & B
Blood	Antiphospholipid Antibody screen: Dilute Russell's Viper Venom (DRVVT) APTTSP/Actin FSL Anti-cardiolipin assay Beta-2 glycoprotein I assay	Sysmex CS2500 SOP-HAEM-247 SOP-HAEM-250	A
Blood	Thrombophilia screening: Protein C Free Protein S Antithrombin III	Sysmex CS2500 SOP-HAEM-248	A
Blood	Thrombophilia Screening: DNA extraction and PCR for Factor II Prothrombin Gene and Factor V Leiden Mutations	Duplica Prep DNA extraction & ABI 7500 PCR system SOP-HAEM-249	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematological examination for the purpose of clinical diagnosis (cont'd)	Documented procedures and manufacturer's instructions for	
Blood	Antiphospholipid Antibody screen: Dilute Russell's Viper Venom (DRVVT) APTTSP/Actin FSL Anti-cardiolipin assay Beta-2 glycoprotein I assay	Stratec Gemini ELISA anayser SOP-HAEM-253 SOP-HAEM-250	A
Serum	Coeliac Screening	Stratec Gemini ELISA analyser SOP-HAEM-253 SOP-HAEM-256	A
Serum	Intrinsic Factor antibody screening	Stratec Gemini ELISA analyser SOP-HAEM-253 SOP-HAEM-251	A
Blood	HLA B27 screening	DNA extraction and PCR Duplica Prep DNA extraction system ABI 7500 PCR system SOP-HAEM-254	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood transfusion examinations to assist in clinical investigations	Documented procedures and manufacturer's instructions for	
Blood Plasma	Compatibility testing of patients plasma with donor cells	Manual Cross matching using Bio-Rad Column gel IAT technology/saline spin technique SOP_BT_030 SOP_BT_062 SOP_BT_049	A & B
Blood Plasma	Compatibility testing of patients plasma with donor cells	Automated Cross matching using Bio-Rad IH-1000 SOP_BT_062 SOP_BT_049	A & B
Blood Plasma	Blood group by detection and identification of antigens : AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B Rh D Negative O Rh D Negative A Rh D Positive Including the presence of A2 antigens	Automated using Bio-Rad IH-1000 analyser SOP_BT_AUTO_018	A & B
Blood Plasma	Antibody screen by detection of antibodies to: Rh – C, c, D, E, e, Cw Kell – K, k, Kpa Duffy – Fya, Fyb MNSs – M, N, S, s Kidd – Jka, Jka Lewis – Lea, Leb Lutheran – Lua P – P1	Automated using Bio-Rad IH-1000 analyser SOP_BT_AUTO_018	A & B
Blood	Direct Antiglobulin Test (DAT)	Automated method using Bio-Rad IH-1000 analyser SOP_BT_AUTO_018	A & B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood transfusion examinations to assist in clinical investigations (cont'd)	Documented procedures and manufacturer's instructions for	
Blood Plasma	Blood group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B Rh D Negative O Rh D Negative Including the presence of A2 antigens	Manual Bio-Rad Column gel IAT technology SOP_BT_074 SOP_BT_026	A & B
Blood Plasma	Antibody screen by detection of antibodies to: Rh – C, c, D, E, e, Cw Kell – K, k, Kpa Duffy – Fya, Fyb MNSs – M, N, S, s Kidd – Jka, Jka Lewis – Lea, Leb Lutheran – Lua P – P1	Manual Bio-Rad Column gel IAT SOP_BT_027 SOP_BT_076	A & B
Blood	Direct Antiglobulin Test (DAT)	Manual method Bio-Rad Column gel IAT technology SOP_BT_025	A & B
Blood Plasma	Antibody investigation by detection and identification of: Rh- C, c, D, E, e, Cw Kell – K, k, Kpa Duffy – Fya, Fyb MNSs – M, N, S, s Kidd – Jka, Jkb Lewis – Lea, Leb Lutheran - Lua	Bio-Rad Column gel IAT technology/tube spin agglutination SOP_BT_027 SOP_BT_072 SOP_BT_076 SOP_BT_078	A & B
END			