


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8912</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Tameside and Glossop Integrated Care NHS Foundation Trust</b></p> <p><b>Issue No: 005    Issue date: 20 February 2021</b></p>	
	<p>Department of Blood Sciences Tameside General Hospital New Fountain House Ashton-under-Lyne OL6 9RW</p>	<p>Contact: Alison Shanahan Tel: +44 (0) 0161 922 6318 E-Mail: Alison.Shanahan@tgh.nhs.uk Website: www.tamesidehospital.nhs.uk</p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Tumour Markers</u>	
	Quantification of:	Beckman Coulter DXI 800 (1146065 & 1145792) using immunoassay with specific reference to:
Serum	AFP	SOP B021
	CA19-9	SOP B043
	CA 125	SOP B044
	CEA	SOP B022
	PSA	SOP B048
	<u>Endocrine</u>	
Serum	Cortisol	SOP B023
	Free T3	SOP B026
	FT4	SOP B027
	FSH	SOP B028
	Oestradiol	SOP B045



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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Endocrine</u> (cont'd)	
	Quantification of:	Beckman Coulter DXI (1146065 & 1145792) using immunoassay with specific reference to:
Serum	Parathyroid Hormone	SOP B049
	Progesterone	SOP B046
	Prolactin	SOP B047
	Total HCG	SOP B050
	TSH	SOP B057
	<u>Haematinics</u>	
Serum	Ferritin	SOP B024
	Folate	SOP B025
	Intrinsic Factor Antibodies	SOP B035
Blood	Red Cell Folate	SOP B033
	Vitamin B12	SOP B052
Blood	Iron (TIBC, SAT)	Beckman Coulter DXI using AU Photometric Colour TPTZ SOP B082
Serum	Total Vitamin D	Beckman Coulter Access 250h using DXI two step competitive binding immune enzymatic assay SOP B112



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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Serology</u>	
	Detection of:	Beckman Coulter DXI (1146065 & 1145792) using immunoassay with specific reference to:
Serum	Hepatitis A IgG Screen	SOP B011
	Hepatitis A IgM Screen	SOP B012
	Hepatitis B Surface Antigen Screen	SOP B013
	Hepatitis C Screen	SOP B016
	HIV Screening Test	SOP B010
	Rubella Immunity	SOP B017
	Hepatitis B Core Antibody	SOP B015
	Hepatitis B Surface Antibody	SOP B014
Serum	HIV-1 Antigen P-24 Antigen HIV1 Ab HIV2 Ab	DXI Combo assay chemiluminescent immunoassay Two step immune enzymatic sandwich method SOP B010
	<u>Cardiac Markers</u>	
Blood	Quantification of NT-pro BNP	Radiometer AQT90 using immunoassay SOP B009
Serum	Troponin I	Beckman Coulter DXI using immunoassay SOP B058





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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Drugs</u>	
	Quantification of:	Beckman Coulter AU AU5811 (2750403 & 23473305) using the following measurement principles with specific reference to:
Serum	Alcohol	Enzymatic SOP B087
	Paracetamol	Enzymatic SOP B095
	Salicylate	Enzymatic SOP B104
	<u>Enzymes</u>	
Serum	ALP	Kinetic colour IFCC SOP B069
	ALT	Kinetic UV IFCC (without PLP) SOP B070
Serum, Urine	Amylase	Kinetic colour- G7 IFCC SOP B075
	AST	Kinetic UV IFCC (without PLP) SOP B073
	CK	Kinetic UV NAC- IFCC SOP B074
	GGT	Kinetic colour IFCC SOP B071
	Lactate dehydrogenase	Kinetic UV- P to L SOP B101



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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Metabolites</u>	
	Quantification of:	Beckman Coulter AU5811 and AU5812 (2750403 & 23473305) using the following measurement principles with specific reference to:
Serum	Albumin	Photometric colour BCP SOP B067
	Bicarbonate	Enzymatic- PEP carboxylase SOP B064
	Bilirubin (direct)	Photometric colour- Diazo SOP B086
	Bilirubin (total)	Photometric colour test for the quantitative determination of total bilirubin. Bilirubin +DPD (diazonium salt) in the presence of an accelerator forms azobilirubin SOP B081
Serum, Urine	Calcium	Photometric colour- Arsenazo III SOP B065
	Creatinine (CRCL, eGFR, PCRAT, CCR)	Kinetic colour- compensated Jaffe SOP B063
Serum, Urine, CSF	Glucose	Enzymatic UV – hexokinase + G6PD SOP B066
Serum	Lipids (HDL, Cholesterol, Triglyceride, LDLC, Chol/HDL)	Enzymatic colour- Ag/Ab complex SOP B078
Serum, Urine	Inorganic Phosphorous	Photometric UV-phosphomolybdate SOP B072



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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Metabolites</u> (cont'd)	Beckman Coulter AU5811 and AU5812 (2750403 & 23473305) using the following measurement principles with specific reference to:
Plasma, CSF	Lactate	Enzymatic colour- lactate dehydrogenase SOP B083
Serum, Urine	Magnesium	Photometric- colour-xylidyl blue SOP B080
Serum	Total Protein	Photometric colour- Biuret SOP B068
Serum, Urine	Urea	Kinetic UV- urease SOP B062
	Uric Acid	Enzymatic colour- uricase SOP B079
Urine, CSF	Protein	Photometric colour- Pyragallo red SOP B090
CSF	Xanthochromia	Uvikon XS Spectrophotometry B114
	<u>Specific Proteins</u>	
	Quantification of:	Beckman Coulter AU5811 and AU5812 (2750403 & 23473305) using the following measurement principles with specific reference to:
Serum	CRP	Immuno-turbidimetric-latex/norm app SOP B056
	Haptoglobin	Immuno-turbidimetric SOP B102



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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Specific Proteins</u>	
	Quantification of:	Beckman Coulter AU5811 and 5812 (2750403 & 23473305) using the following measurement principles with specific reference to
Serum	Immunoglobulins A, G, M	Immuno-turbidimetric SOP B084
Urine	Microalbumin	Immuno-turbidimetric SOP B089
Serum	Prealbumin	Immuno-turbidimetric SOP B098
Serum	Transferrin	Beckman Coulter AU5811 (2750403 & 23473305) using Immuno-turbidimetric SOP B105
Blood	HbA1c	TOSOH G8 (56214) using HPLC SOP B004
	<u>Immunology</u>	
	Quantification of:	Beckman Coulter AU5811 and 5812 (2750403 & 23473305) using the following measurement principles with specific reference to:
Serum	Rheumatoid Factor	Immuno- turbidimetric- latex SOP B085
	Thyroid Antibodies	Two step enzymatic sandwich assay DXI SOP B051





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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>Electrolytes</u>	
Serum, Urine	Quantification of:	Beckman Coulter AU5811 and AU5812 (2750403 & 23473305) using Indirect ISE SOP B061
	Chloride	
	Potassium	
	Sodium	
	<u>Myeloma Screening</u>	
Urine	Detection/ Quantification of:	Interlab G26 (36107173) using the following measurement principles with specific reference to:
	Bence Jones Protein	Immunofixation electrophoresis SOP B007
Serum	Detection of normal and abnormal proteins	Electrophoresis- agarose gel SOP B006 Immunofixation electrophoresis SOP B007
	<u>Inborn Errors</u>	
Plasma (EDTA)	Detection/ Quantification of:	
	Ammonia	Beckman Coulter AU5811 and AU5812 (2750403 & 23473305)  Direct Enzymatic Test SOP B088
Urine	Detection of Urine Reducing Substances	Manual Benedict's Test SOP B037



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HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
Other (cont'd)		
Serum	Bile Acids	Beckman Coulter AU Enzymatic SOP B100
Serum, Urine	Osmolality	Vitec 3320 Micro- Osmometer using freezing point depression SOP B029
Urine	HCG (Pregnancy Test)	Launch Accusay using immunochromatography SOP B002
Serum	Globulin GAP	Using Beckman Coulter AU and DXC iLab TP (CSC telepath system) SOP B116
Serum	Corrected calcium	
Serum	AKI stages	
Serum	Estimated GFR	



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HUMAN BODY FLUIDS	<u>Haematological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
Blood	<u>General Haematology</u> Quantification of: WBC RBC MCV Platelets	Beckman Coulter DxH800 (AW31168 & AW33185) FBC using impedance SOP H032 H058
Blood	Haemoglobin	Beckman Coulter DxH800 FBC using photometric SOP H032 H058
Blood	Quantification of: Neutrophil Lymphocyte Monocyte Eosinophil Basophil Nucleated Red Cell Reticulocytes	Beckman Coulter DxH800 Automated Differential using flow cytometry SOP H032 H058





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HUMAN BODY FLUIDS	<u>Haematological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
Urine	<u>General Haematology (cont'd)</u> Detection of Haemosiderin	Microscopical detection Urine Haemosiderin using Perl's Prussian Blue Microscopes: Nikon Eclipse E400 S/N - 676157 (Haematology) Zeiss Standard 25 S/N - 095622 (Haematology Transfusion) Nikon Eclipse E80i - S/N - 450055 (Haematology) Nikon Eclipse E400 S/N - 678302 (Haematology/ consultant SOP H022, H027, H028
Blood	ESR	Sediplus S2000 IR- Transmission Sedimentation SOP H033
Bone Marrow Aspirates	Microscopic examination of stained films (peripheral blood & bone marrow) for evidence of haematological disease.	Manual Differential using Romanowsky Stain Perl's Prussian Blue Microscopes: Nikon Eclipse E400 S/N - 676157 (Haematology) Zeiss Standard 25 S/N - 095622 (Haematology Transfusion) Nikon Eclipse E80i - S/N - 450055 (Haematology) Nikon Eclipse E400 S/N - 678302 (Haematology/ consultant SOP H022 H023 H024, H028



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p> <p>Blood</p> <p>Blood Films</p>	<p><u>Haematological examination activities for the purposes of clinical diagnosis</u></p> <p><u>General Haematology (cont'd)</u></p> <p>Infectious Mononucleosis Screening Test (EBV IgM)</p> <p>Detection of <i>P. falciparum</i> (HRP II) and pLDH (<i>P. falciparum</i>, <i>P. vivax</i>, <i>P. ovale</i>, <i>P. malariae</i>)</p> <p>Detection of malarial parasites</p>	<p>In-house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Accusay (MONO) Launch using solid phase immunoassay SOP H036</p> <p>HUMASIS Malaria P.f/Pan Antigen Test Launch Kit immuno-chromatographic H031</p> <p>Microscopical detection malarial parasites using R66 Giemsa Stain Microscopes: Nikon Eclipse E400 S/N - 676157 (Haematology) Zeiss Standard 25 S/N - 095622 (Haematology Transfusion) Nikon Eclipse E80i - S/N - 450055 (Haematology) Nikon Eclipse E400 S/N - 678302 (Haematology/ consultant SOP H030</p>



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HUMAN BODY FLUIDS	Haematological examination activities for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals and standard methods as specified below:
	<u>General Haematology (cont'd)</u>	
	<u>Coagulation</u>	Sysmex CS2100i using the following measurement principles with specific reference to:
Plasma	APTT	Clotting SOP H003, H051
Plasma	PT and INR	Clotting SOP H002, H051
Plasma	D-Dimer	Immunoturbidimetric Assay SOP H005, H051
Plasma	Lupus Inhibitor	Dilute Russell's Viper Venom SOP H013
Plasma	Fibrinogen	Claus SOPs H004, H051
Plasma	Factor VIII Assay	Clotting SOP H007, H051
Plasma	Factor IX Assay	Clotting SOP H007, H051
Whole Blood	Capillary PT	Thrombotrack SOLO Clotting time SOP H009, H011



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HUMAN BODY FLUIDS	<u>Haematological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
Blood	<u>Inborn Errors</u> G6PD Screen	Trinity Biotech Kit Visual semi quantitative SOP H034  Documented in-house methods to meet the requirements of the SCT Screening Programme as defined in the July 2018 version of "Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements
Blood	Abnormal Haemoglobin Screen (A, A2, S, F, D, E, C)	Launch Interlab G26 Electrophoretic separation using agarose gel SOP H061
Blood	Haemoglobin Variant Analysis (confirmatory testing of above)	Menarini HA8160 HPLC SOPs H014, H015, H016
Blood	Hb Sickle Screen	Microgen Solubility Kit SOP H020





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HUMAN BODY FLUIDS	<u>Blood Transfusion examinations to assist in clinical investigations and treatment</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:
Blood	Blood group (manual) Adult (anti-A, anti-B, Anti-D, A1 cells, B cells)	Ortho Manual SOP T055
Blood	Paediatric (anti-A, anti-B, AntiAB, Anti-IgG)	
Blood	Antibody detection screen (manual) Rh: D, C, E, c, e, cw Kell: K, k, Kpa, Kpb, Jsa, Jsb Duffy: Fya, Fyb Kidd: Jka, Jkb Lewis: Lea, Leb P: P1 MNS: M, N, S, s Lutheran: Lua, Lub Xg: Xga	Ortho Manual SOP T055
Blood	Direct antibody test	Ortho Manual SOP T055
Blood	Red Cell phenotyping (C, E, c, e, K)	Ortho Vision Analyser SOP T054
Blood	Antibody investigation and identification	AHG and enzyme panels Ortho BioVue Cassettes- Automated or Manual SOPs T030 T053 T055 T054
Blood	Serological Cross match	Ortho Vision Analyser SOP T055 T054
Blood	Measurement of Foetal RBC in maternal blood for FMH determination (Kleihauer)	ClinTech Acid Elution SOP T006
Blood	Rapid blood grouping (anti-A, anti-B, anti-AB, anti-D, A cells B cells)	Manual method using Lorne anti SOP T024 sera



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<p>HUMAN BODY FLUIDS</p> <p>Blood</p> <p>Blood</p>	<p><u>Blood Transfusion examinations to assist in clinical investigations and treatment</u></p> <p>Manual red cell phenotyping</p> <p>ABO &amp; Rhesus D Blood group (automated)</p> <p>Direct antibody test (IgG, C3d, CTL)</p> <p>Antibody screen – antigens of the following systems Rh: D, C, E, c, e, f, c<sup>w</sup>, v Kell: K, k, Kp<sup>a</sup>, Kp<sup>b</sup>, Js<sup>a</sup>, Js<sup>b</sup> Duffy: Fy<sup>a</sup>, Fy<sup>b</sup> Kidd: Jk<sup>a</sup>, Jk<sup>b</sup> Lewis: Le<sup>a</sup>, Le<sup>b</sup> P: P1 MNS: M, N, S, s Lutheran: Lu<sup>a</sup>, Lu<sup>b</sup> Xg: Xg<sup>a</sup></p>	<p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Manual methods using Ortho BioVue Cassettes or tube techniques SOP T050</p> <p>Ortho BioVue cassettes on Ortho Vision SOP T052, T053, T054</p>
END		