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ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Wirral University Teaching Hospital NHS Foundation Trust

Issue No: 009 Issue date: 23 December 2024

Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

Location details	Activity	
Arrowe Park Theatres	Blood Fridges	
Arrowe Park Maternity	Blood Fridge	
Arrowe Park Ward 30	Blood Fridge	
Clatterbridge Ward M2	Blood Fridge	
Clatterbridge CCU	Blood Fridge	



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for :	
Serum/Lithium heparin plasma	ACE	Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using colorimetric methods: ALM-01-50	A
Serum/Lithium heparin plasma/fluid	Albumin	ALM-01-06 CCOM-06	A B
Serum/Lithium heparin plasma	Alkaline phosphatase	ALM-01-07 CCOM-07	A B
Serum/Lithium heparin plasma	Direct Bilirubin	ALM-01-11	A
Serum/Lithium heparin plasma	Iron	ALM-01-40	A
Fluoride Hepplasma/ CSF	Lactate	ALM-01-43	A
Serum	Lithium	ALM-01-44	A
Serum/lithium heparin plasma/urine	Magnesium	ALM-01-20 CCOM-15	A B
Serum/Lithium heparin plasma	Paracetamol	ALM-01-28	A
Serum/lithium heparin plasma/urine	Phosphate	ALM-01-21 CCOM-16	A B
Serum/Lithium heparin plasma	Total Bilirubin	ALM-01-12 CCOM-11	A B
Serum/lithium heparin plasma/urine/CSF/Fluid	Total Protein	ALM-01-30 CCOM-17	A B



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for : Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using colorimetric methods: Using enzymatic/colorimetric methods:	
Serum/Lithium heparin plasma	GGT	ALM01-18 CCOM-14	A B
	HDL cholesterol	ALM-01-19	A
Serum/Lithium heparin plasma/fluid	Triglyceride	ALM-01-24	A
	Urate	ALM-01-25 CCCOM-18	A B
		Using Immunoassay methods:	
Serum/Lithium heparin plasma	Alpha-1-fetoprotein	ALM-01-56	A
Serum/Lithium heparin plasma	Beta HCG	ALM-01-70	A
Serum/Lithium heparin plasma	CA-125	ALM-01-58	A
	CA-153	ALM-01-59	A
	CA-199	ALM-01-60	A
	CEA	ALM-01-61	A
	Cortisol	ALM-01-62	A
	Digoxin	ALM-01-94	A
	Ferritin	ALM-01-64	A
	Folate	ALM-01-65	A
	Free PSA	ALM-01-66	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for :	
Serum/Lithium heparin plasma (cont'd)	Free T3	Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using Immunoassay methods: ALM-01-68	A
	Free T4	ALM-01-69	A
	FSH	ALM-01-67	A
	LH	ALM-01-71	A
	Oestradiol	ALM-01-63	A
	Pro-BNP	ALM-01-77	A
	Progesterone	ALM-01-73	A
	Prolactin	ALM-01-72	A
	PSA	ALM-01-66	A
	PTH	ALM-01-88	A
	SHBG	ALM-01-87	A
	Testosterone	ALM-01-75	A
	TPO Antibody	ALM-01-55	A
	Troponin T	ALM-01-76	A
	TSH	ALM-01-89	A
	Valproate	ALM-01-49	A
Vancomycin	ALM-01-27	A	
Vitamin B 12	ALM-01-57	A	
Vitamin D	ALM-01-78	A	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for :	
Serum/Lithium heparin plasma	Alpha-1-antitrypsin	Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using Immunoturbidometric assay methods:	A
	C3	ALM-01-37	A
	C4	ALM-01-39	A
Serum	Caeruloplasmin	ALM-01-91	A
Serum/Lithium heparin plasma	CRP	ALM-01-17	A
		CCCOM-13	B
Serum/Lithium heparin plasma	Haptoglobin	ALM-01-05	A
	IgA	ALM-01-42	A
	IgG	ALM-01-42	A
	IgM	ALM-01-42	A
Urine	Microalbumin	ALM-01-31	A
Serum/Lithium heparin plasma	Rheumatoid factor	ALM-01-29	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for : Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using enzymatic assay methods:	
EDTA plasma	Ammonia	ALM-01-36	A
Serum/Lithium heparin plasma	Alanine aminotransferase	ALM-01-29	A B
	Aspartate aminotransferase	ALM-01-29	A B
Serum/Lithium heparin plasma/urine/fluid	Amylase	ALM-01-09	A
		CCOM-09	B
Serum/Lithium heparin plasma	Bicarbonate	ALM-01-02	A
		CCOM-02	B
Fluoride EDTA/urine	Bile acids	ALM-01-29	A
Serum/Lithium heparin plasma/CSF/fluid	Cholesterol	ALM-01-14	A
Serum/Lithium heparin plasma	Ethanol	ALM-01-35	A
Serum/Lithium heparin plasma/CSF/fluid	Glucose	ALM-01-05	A B
Serum/Lithium heparin plasma	Lactate Dehydrogenase	ALM-01-33	A
		CCOM-19	B
	Salicylate	ALM-01-22	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for :	
Serum/Lithium heparin plasma/urine	Calcium	Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using photometric assay methods: ALM-01-13 CCOM-12	A B
Serum/Lithium heparin plasma	Creatine kinase	ALM-01-15	A
	Unsaturated Iron Binding Concentration	ALM-01-40	A
Serum/Lithium heparin plasma	Carbamazepine	Using agglutination immunoassay methods: ALM-01-38	A
Serum/Lithium heparin plasma/urine/fluid	Creatinine	Using Jaffe kinetic colorimetric methods: ALM-01-04 CCOM-04	A B
Serum/Lithium heparin plasma	Gentamicin	Using enzymatic immunoassay methods: ALM-01-41	A
Serum/Lithium heparin plasma/urine/fluid	Urea	Using kinetic photometric assay methods: ALM-01-03 CCOM-03	A B
Serum/Lithium heparin plasma	Phenytoin	Using KIMS methods: ALM-01-46	A
Serum/Lithium heparin plasma	Theophylline	ALM-01-47	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for :	
Serum/Lithium heparin plasma	Procalcitonin	Roche Cobas 8000 system (A) and Roche Cobas 6000 system(B) Using electrochemiluminescent immunoassay methods: ALM-01-101	A
Serum	Placental Growth Factor	ALM-01-100	A
Serum	Soluble fms-like tyrosine kinase-1	ALM-01-99	
		Using calculations:	
Serum/Lithium heparin plasma	Calcium (adjusted for albumin level)	ACB Guidance 2015 ALM-01-93	A B
	Cholesterol/HDL ratio	ALM-01-93	A
	eGFR	ALM-01-93	A B
	Globulin	ALM-01-93	A B
	Iron binding saturation	ALM-01-93	A
	Total iron binding concentration	ALM-01-93	A
	LDL	ALM-01-93	A
		Using ISE:	
Serum/Lithium heparin plasma	Chloride	ALM-01-01 CCOM-01	A B
Serum/Lithium heparin plasma/urine	Potassium	ALM-01-01 CCOM-01	A B
	Sodium	ALM-01-01 CCOM-01	A B



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for :	
Blood	HbA1c	Roche Cobas C513 using turbidimetric immunoassay SOP ALM-01-97	A
Sweat	Chloride	Sherwood Scientific Chloride Analyser 926S measuring conductivity: IP-03-03	A
	Conductivity	ALM-01-90	A
Urine	BHCG	BM-10-10	A
Serum	Monoclonal paraprotein identification and quantitation	Sebia Capillarys 2 Flex Piercing using capillary electrophoresis SOP CB-SP-02	A
Serum	ALP isoenzymes	Sebia Hydrasys 2 using zonal electrophoresis/lectin agglutination SOP CB-SP-05	A
Urine	Bence Jones protein	Sebia Hydrasys 2 using zonal electrophoresis SOP CB-SP-04	A
Serum, urine	Osmolality	Advanced Instruments Micro Osmometer 3320 using freezing point depression SOP BP-05-05	A
Blood (lithium heparin)	β Ketones	Nova Biomedical Stat Strip Ketone Meter using enzymatic method SOP ALP-02-05	A
Serum	Serum Free Light Chains	Binding Site Optilite using immunoturbimetry SOP CB-OPT-01	A



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HUMAN BODY FLUIDS (cont'd) Blood	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u> pH pCO ₂ PO ₂ tHb Met Hb COHb O ₂ Hb Base Excess Standard Bicarbonate K ⁺ , Na ⁺ , Ca ²⁺ , Cl ⁻	Documented in house methods and manufacturers instructions for : Radiometer- ABL 90 Flex Blood Gas Analyser all using SOP RG-01-13 Using potentiometric measurement Using optical measurement Using spectrophotometric principles Using derived measurements Using potentiometric measurement	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
	Quantitative determination of:	Sysmex XN 9000 and Sysmex XN10: Sysmex XN 9000 and XN10-A Sysmex XN 10 - B Using Flow Cytometry Method/Calculation: H-A-XN-001	
EDTA whole blood	Auto differential (percentage) (absolute): Basophils Neutrophils Lymphocytes Monocytes Eosinophils Nucleated RBCs		C D
EDTA whole blood	FBC Platelet	Using Impedance Flow Cytometry: H-A-XN-001	C D
	FBC Platelet-F	H-A-XN-001	C D
EDTA whole blood	FBC Red blood count	Using Impedance Method: H-A-XN-001	C D
	FBC White Cell count	H-A-XN-001	C D
EDTA whole blood	FBC Haemoglobin	Using Photometric Method: H-A-XN-001	C D
EDTA whole blood	FBC MCHC	Using Calculations: H-A-XN-001	C D
	FBC MCV	H-A-XN-001	C D
	FBC MCH	H-A-XN-001	C D



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HUMAN BODY FLUID (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods:	
	Quantitative determination of: (cont'd)	Sysmex XN 9000 and Sysmex XN10: Sysmex XN 9000 and XN10-A Sysmex XN 10 - B Using Cumulative Pulse Measurement: H-A-XN-001	C D
EDTA whole blood	FBC HCT		
EDTA whole blood	Reticuloctye (percentage) (absolute)	Using flow cytometry calculation: HA-XN-001	C
EDTA whole blood	Quantitative determination of: Blood cells - Identification of cell types, cell contents and structures	Manual blood film reporting. Using microscopy: H-M-BF-002	C
EDTA whole blood	Extended differential (percentage)(absolute): Basophils Neutrophils Lymphocytes Monocytes Eosinophils Blasts Myelocytes Promyelocytes Metamyelocytes Nucleated RBC	Using microscopy/calculations: PN-HE-001	C
EDTA whole blood	Quantitative determination of: ESR	Sysmex Interrliner: Automated Using Optical Measurement and calculation: H-A-XN-008	C



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for:	
EDTA whole blood	ESR	Manual method H-A-001	C
Whole Blood and CSF cytopsin deposit	Qualitative determination of: Blood cells	Manual slide preparation and Sysmex SP-50 automated slide staining H-M-RH-037	C
EDTA whole blood	Qualitative determination (if none seen) or Quantitative determination (if positive) of: Malaria parasites • P.falciparum • P.vivax • P.ovale • P.malariae • P knowlesi	Microscopy: H-M-BF-007	C
EDTA whole blood	Malarial Parasite Screen for detection of histidine-rich protein II antigen: <i>Plasmodium falciparum</i> And a pan-malarial antigen common to pan-detection of: <i>Plasmodium falciparum</i> <i>Plasmodium ovale</i> <i>Plasmodium malariae</i> <i>Plasmodium vivax</i>	BinaxNOW Immunochromatographic assay (manual) H-M-BF-016	C
EDTA whole blood	Qualitative determination of: Infectious mononucleosis heterophile antibodies	Clearview IM II - Cassette Using Immunoassay: H-M-RH-012	C
Sodium citrate plasma	APTT Prothrombin Time	Using Manual Tube Turbidimetric Method: H-LP-025 H-LP-020	C C
Sodium citrate plasma	INR	Using Manual Tube Calculation: H-LP-020	C



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for: Documented in-house methods to meet the requirements of the Sickle cell and thalassaemia screening programme as defined in the July 2018 'Sickle cell and thalassaemia screening: laboratory QA requirements'	
EDTA Whole Blood	Qualitative determination of: Hb A2 Hb F HbC HbD HbE HbO HbS	TOSOH G8 Analyser Using HPLC: H-ST-002 / H-ST-004	C
EDTA Whole Blood	HbS (Sickle cell screening)	CliniTech Sickle Test Manual qualitative solubility test H-M-RH-054	C
Sodium citrate plasma	Quantitative determination of: Anti-Xa Antithrombin Protein C	Werfen TOP 550 by chromogenic assay H-A-T 010 H-A-T 006 H-A-T 006	A
Sodium citrate plasma	Quantitative determination of: APTT Fibrinogen Prothrombin Time Factor VIII Factor IX Factor XI Factor XII Factor II Factor V Factor VII Factor X Lupus Anticoagulant	Werfen TOP 550 by turbidimetric assay H-A-T 002 H-A-T 002 H-A-T 002 H-A-T 007 H-A-T 007 H-A-T 007 H-A-T 007 H-A-T 008 H-A-T 008 H-A-T 008 H-A-T 008 H-A-T 005	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for:	
Sodium citrate plasma	Quantitative determination of: APTT INR	Werfen TOP 550- Correction test using turbimetric method / mixing studies. H-A-T 014 H-A-T 014	A
Sodium citrate plasma	Quantitative determination of: vonWillebrand Rag vonWillebrand RicoF	Werfen TOP 550 by latex particle enhanced immune turbimetric assay. H-A-T-009 H-A-T-009	A
Sodium citrate plasma	Quantitative determination of: D-dimer Protein-S	Werfen TOP 550 using latex agglutination. H-A-T-002 H-A-T-006	A
	Calculation of: INR Lupus Corrected Ratio Lupus Ratio	Werfen TOP 550 by calculation H-A-T 002 H-A-T 005 H-A-T 005	A
Sodium citrate Plasma	Thrombophilia Screen	Werfen TOP 550 by manual interpretation of assay results C-A-006	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities to enable the provision of compatible blood components</u>	Documented in house methods and manufacturer's instructions for:	
EDTA Plasma / Red blood cells	Qualitative determination of: Anti-A Anti-B Anti-D Anti-D2 A Cells B Cells Red cell Ab screen DAT (neonatal poly specific)	Biorad Diamed Automated Blood Group Analyser: Using Gel column agglutination: IH-1000 T-A-007 IH-1000 T-A-007 IH-1000 T-A-007 IH-1000 T-A-007 IH-1000 T-A-007 IH-1000 T-A-007 IH-1000 T-A-007 IH-1000 T-A-007	C C C C C C C C
EDTA Plasma / Red blood cells	Qualitative determination of: Anti-A Anti-B Anti-D Red cell ab screen DAT Anti C3d Anti IgG Red Cell Ab identification Crossmatch IAT Auto IAT Red cell phenotyping	Biorad Diamed Manual system Using Gel column agglutination: T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-M-006 T-M-006 / T-PD-01 T-M-011	C C C C C C C C C C
EDTA Plasma / Red blood cells	Qualitative determination of: Anti-A Anti-B Anti-D A Cells B Cells Red cell phenotyping Crossmatch Crossmatch auto	Manual tube techniques: Using Visual Agglutination: T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-PD-01 T-M-011 T-M-001 T-M-001	C C C C C C C C



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EDTA Whole Blood	Quantitative determination of: Foetal cells	Manual slide / Microscope: Using Elution and Counterstain: T-M-002	C
END			