Schedule of Accreditation

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United Kingdom Accreditation Service

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Accredited to ISO 15189:2012

HSL Analytics LLP

Issue No: 010 **Issue date:** 10 May 2024

Pathology Department
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London
N19 5NF

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Testing performed at the above address only

Site activities performed away from the location listed above

Location details	Site Activity
Whittington Hospital Magdala Avenue London N19 5NF United Kingdom	
As above - Thalassemia Unit	Blood storage/issue
As above - Main Theatre	Blood storage/issue
As above - Labour Ward	Blood storage/issue

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS: Serum/ Plasma unless otherwise specified	<u>Biochemistry examination activities for the purpose of clinical diagnosis:</u>	Documented procedures & manufacturer's instructions for Roche Cobas 8000 analyser using manufacturers reagents unless otherwise specified with specific reference to: TP BS 300 004 - Roche Cobas 8000 Operating Procedure
	Albumin	photometric
	Alcohol	photometric
	ALP	photometric
	ALT	photometric
	Ammonia	photometric
	AST	photometric
	B12	photometric
	Bile acids	Photometric (Dialab 903120)
	Bilirubin	photometric
	C3	photometric
	C4	photometric
	Calcium	photometric
	Carbamazepine	photometric
	Chloride	Ion Selective Electrode
	Cholesterol	photometric
	CK	photometric
	Conjugated Bilirubin	photometric
	Creatinine	photometric
	CRP	photometric
	Digoxin	photometric
	estimated glomerular filtration rate (eGFR)	calculation
	Ferritin	photometric
	Folate	photometric
	Fructosamine	photometric
	gamma GT	photometric
	Gentamicin	photometric
CSF	Glucose	photometric
	HDL Cholesterol	photometric
	IgG	photometric
	IgM	photometric
	Ionised Calcium	photometric
	Iron	photometric

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd):	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd).	Documented procedures & manufacturer's instructions for Roche Cobas 8000 analyser with specific reference to: TP BS 300 004
Serum/ Plasma unless otherwise specified		
CSF	Lactate	photometric
	LDH	photometric
	LDL Cholesterol	Calculation: Freidwald Formula
	Lithium	photometric
	Magnesium	photometric
Urine	Microalbumin	photometric
	Paracetamol	photometric
	Phenytoin	photometric
	Potassium	Ion Selective Electrode
	Salicylate	photometric
Urine	Sodium	Ion Selective Electrode
	Theophylline	photometric
	Total Iron Binding Capacity (TIBC)	Calculation – FE + UIBC
	Total Bicarbonate	photometric
CSF	Total Protein	photometric
Urine	Uric Acid	photometric
	Valproic Acid	photometric
	Vancomycin	photometric
	Hepatitis B surface antibodies (HbsAb)	electrohemiluminiscence
	Hepatitis B surface antigen (HbsAg)	electrochemiluminescence
	Hepatitis C antibody	electrochemiluminescence
	HIV Ab/AG screen	electrochemiluminescence
	Syphilis Total antibody	chemiluminescence
Serum unless otherwise stated		Documented procedures & manufacturer's instructions for Roche Cobas e602 analyser with TP BS 300 004
	AFP	electrochemiluminescence
	CA125	electrochemiluminescence
	CEA	electrochemiluminescence
	Cortisol	electrochemiluminescence
	beta HCG	electrochemiluminescence
	Free T3	electrochemiluminescence
	Free T4	electrochemiluminescence
	FAI	Calculated
	NT pro BNP	electrochemiluminescence
	Oestradiol	electrochemiluminescence
	Progesterone	electrochemiluminescence

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd):Serum unless otherwise stated (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions for Roche Cobas e602 analyser with TP BS 300 004
	Prolactin	electrochemiluminescence
	PSA	electrochemiluminescence
	parathyroid Hormone (PTH)	electrochemiluminescence
	SHBG	electrochemiluminescence
	Testosterone	electrochemiluminescence
	Troponin T (high sensitivity)	electrochemiluminescence
	Vitamin D	electrochemiluminescence
Serum	Detection and identification of serum proteins	Serum Immunofixation Electrophoresis Documented procedures & manufacturer's instructions for SEBIA HYDRASYS (gel electrophoresis and immunofixation) with specific reference to: TP BS 300 036 – Serum Protein Electrophoresis and TP BS 300 038 – Serum Immunofixation
Urine	Detection of urine monoclonal proteins	Urine Immunofixation Electrophoresis (IFE) Documented procedures & manufacturer's instructions for SEBIA HYDRASYS (gel electrophoresis and immunofixation) with specific reference to: TP BS 300 037 – Urine Protein Electrophoresis and TP BS 300 039 – Urine Immunofixation

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd):	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	
Whole Blood (EDTA)	HbA1c	Documented procedures & manufacturer's instructions for Sebia Capillarys 3-Glycated Haemaoglobin SOP TI BS 300 565
	Haematology investigation activities for the purpose of clinical diagnosis	
Whole Blood (EDTA) unless otherwise stated	Full Blood Count using the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, HCT, MPV NEUT, LYMPH, MONO, EOS, BASO, NRBC	Documented procedures & manufacturer's instructions for Sysmex XN 2000 analyser with specific reference to: TP BS 300 016
Whole blood EDTA	Microscopic examination for evidence of haematological disease. Blood films	Documented procedures & manufacturer's instructions for Elitech Aerospray stainer with specific reference to: TP BS 300 001 – Blood Films and Staining Procedures TP BS 300 021 - FBC, Blood Film , Malaria Reporting Procedues
	Microscopic examination of thick and thin blood films for detection of malariaparasites	Giemsa staining Leishman Staining using SOP TP BS 300 030 – Malaria Parasite Detection

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology investigation activities for the purpose of clinical diagnosis (cont'd)	
Whole Blood (EDTA) unless otherwise stated	Erythrocyte Sedimentation Rate (ESR)	Documented procedures & manufacturer's instructions for Vitech StaRRsed Auto Compact ESR analyser (Westergren method) with specific reference to: TP BS 300 050 – Procedure for the Use of the StaRRsed Auto Compact ESR Analyser
Whole Blood (EDTA)	Detection of P falciparum HRP2 and pan specific plasmodium LDH	Documented procedures & manufacturer's instructions for CareUS malaria test with specific reference to: TP BS 300 030 – Malaria Parasite Detection
Plasma	Detection of igm heterophile antibodies	Documented procedures & manufacturer's instructions for Clearview IM II Immunochromatographic method with specific reference to: TP BS 300 053 – Glandular Fever Screen

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology investigation activities for the purpose of clinical diagnosis (cont'd)	
	Antenatal & Newborn Screening	Documented -in-house methods to meet the requirements of the Sickle Cell and thalassemia screening programme(s) as defined 'NHS Sickle Cell and thalassemia screening: laboratory QA evidence requirements"
	Detection of HbA2, HbF, HbA and other variants such as Hb S,C,D,G,E and other less common variants.	Documented procedures & manufacturer's instructions for Biorad Variant II HPLC with specific reference to: TP BS 300 048 – Procedure for the Use of the Bio-Rad Variant II Analyser Documented procedures & manufacturer's instructions for Helena Biosciences SAS MX (Agarose Gel electrophoresis) with specific reference to: TI BS 300 057 – Agarose Gel Hb Electrophoresis as confirmatory test detected by BioRad HPLC.
Whole Blood (EDTA) unless otherwise stated	Sickle solubility test	Documented procedures & manufacturer's instructions for Helena Sickle Solubility test kit Immunochromatographic method with specific reference to: TP BS 300 035 – Sickle Solubility Test

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology investigation activities for the purpose of clinical diagnosis (cont'd)	
Plasma (citrated)	Coagulation	Documented procedures & manufacturer's instructions for Sysmex CS-2100i using scattered light detection method with specific reference to: TP BS 300 012 – Procedure for the use of CS-2100i Analyser
	Prothrombin Time (PT) INR Activated partial thromboplastin time (APPT) Fibrinogen Partial Thromboplastin Time (PTT) Lupus anticoagulant D-Dimer	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Transfusion investigation activities for the purpose of clinical diagnosis:</u>	Documented procedures & manufacturer's instructions for IBG Immucor ECHO Lumena analyser, NHSBT Reagents and Lorne Reagents. Solid and liquid phase and haemagglutination assays and manual analyses with specific reference to: TP BT 400 001 – Procedure for the use of the Echo Lumena
Whole Blood (EDTA) unless otherwise stated	Group and antibody screen - Automated Blood Groups - ABO and RhD systems: - RhD positive - A RhD positive - B RhD positive - AB RhD positive - RhD negative - A RhD negative - B RhD negative AB RhD negative	TP BT 400 001 – Procedure for the use of the Echo Lumena (Automated) TP BT 400 011 – Blood Grouping (Automated) TP BT 400 002 – Blood Grouping (Manual) using NHSBT reagents TP BT 400 004 – Antibody Investigations (Manual tube method using NHSBT 3-cell screen and Lorne reagent)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Transfusion investigation activities for the purpose of clinical diagnosis: (cont'd)</u>	
	Antibody identification (C, c, D, E, e, K, k, Fya, Fyb, Jka, Jkb, S, s, M, N, P1, Lea, Leb, Lu(a), Kp(a)	TP BT 400 004 – Antibody Investigations (Manual tube method using Lorne reagents) TP BT 400 001 – Procedure for the use of the Echo Lumena (Automated)
	Red cell phenotyping - Blood Groups (phenotyping) (C, c, E, e, K, k, Fya, Fyb, Jka, Jkb, S, s, M, N, P1, Lea, Leb, Lu(a), , Kp(a)	TP BT 400 014 – Red Blood Cell Phenotyping by manual tube method using Lorne and NBS reagents
	Cross match-manual	TP BT 400 025 – Cross Matching Serology and TI BT 400 293 – Cross Matching and Red Cell Antibodies
	Direct antiglobulin test (DAT) (C3d, IgG)	TP BT 400 001 – Procedure for the use of the Echo Lumena (Automated) TP BT 400 012 – Direct Antiglobulin Test (Automated) TP BT 400 003 – Direct Antiglobulin Test (Manual)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Transfusion investigation activities for the purpose of clinical diagnosis: (cont'd)	
Whole Blood (EDTA) unless otherwise stated	Determination of fetomaternal haemorrhage (Kleihauer)	Clin-Tech Kit manual haemagglutination assay TP BT 400 028 – Kleihauer Test

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Serology examination activities for the purposes of clinical diagnosis</u>	Documented procedures & manufacturer's instructions for BioMerieux Vidas analyser (EIA) with specific reference to: TP MIC 702 320 Vidas Operation
Serum unless otherwise stated	CMV IgM/IgG EBNA IgG EBV VCA IgM EBV VCA IgG Hepatitis C antibody confirmation Lyme IgM/IgG Toxoplasma IgG VZV IgG	 TI MIC 702 327 TI MIC 702 323 TI MIC 702 322
	<u>Antenatal &Newborn Screening</u>	Documented -in-house methods to meet the requirements of the *IDPS programme as defined in 'Infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening using the following equipment and SOPs
	HIV Ab/AG confirmation Hepatitis B core total antibody Hepatitis B e antigen Hepatitis B e antibody Hepatitis B core IgM Hepatitis surface antigen (HBsAg)	TI MIC 702 326 TI MIC 702 329 Hep B Markers on VIDAS
	Syphilis IgM	Documented procedures & manufacturer's instructions for Launch DS2 analyser (EIA) with specific reference to: TP MIC 700 615 Operation of DS2 TP MIC 702 335 Syphilis IgM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Antenatal &Newborn Screening (cont'd)	Documented -in-house methods to meet the requirements of the *IDPS programme as defined in the April 2019 version of 'Infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening using the following equipment and SOPs (cont'd)
	TPPA Syphilis confirmation test	Documented procedures & manufacturer's instructions for manual agglutination. – TP MIC 702 333 TPPA
	Semi-quantitative detection of RPR	Documented procedures & manufacturer's instructions for manual agglutination Randox SYP RPR – MS 017
END		