


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL 8382  Accredited to ISO 15189:2012	<b>University Hospitals Bristol and Weston NHS Foundation Trust</b>	
	<b>Issue No: 008    Issue date: 14 February 2022</b>	
	<b>Pathology Laboratory Weston General Hospital Grange Road, Uphill Weston-super-Mare North Somerset BS23 4TQ</b>	<b>Contact: Mrs Elizabeth Worsam Tel: +44 (0) 117 3422575 E-Mail: Elizabeth.worsam@uhbw.nhs.uk</b>
<b>Testing performed at the above address only</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity
<b>Address:</b> Pathology Laboratory Weston General Hospital Grange Road, Uphill Weston-super-Mare North Somerset BS23 4TQ  <b>Local contact:</b> Elizabeth Worsam	Clinical Biochemistry Coagulation Haematology Microbiology Transfusion



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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>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented In-house Methods and Manufacturer's instructions for Advanced Instruments Micro Osmometer 3320OSMO1™
Serum, plasma, urine	Osmolality – Osmolar gap	Osmolality: SOP C071 and Osmolar Gap: SOP C071  <i>Calculations in Biochemistry SOP (Chem 1421)</i>
CSF	Glucose	Documented In-house Methods and Manufacturer's instructions for Roche COBAS 6000 to COBAS 6000 Operation: SOP Chem 53500  Cobas Glucose (GLUC3) (Hexokinase method)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Albumin	Cobas Albumin (ALBP) (by BCP)
Serum, Li-Hep plasma	Alkaline Phosphatase	Cobas Alkaline Phosphatase (ALP2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	ALT	Cobas Alanine AminoTransferase (ALTLP)
Serum, Li-Hep plasma	Amylase	Cobas Amylase (AMYL2)
Serum, Li-Hep plasma	Bicarbonate	Cobas Bicarbonate (CO2-L)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Bilirubin (Total)	Cobas Total Bilirubin – Tbil (BILT3)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	CA125	Cobas (CA125 II)



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HUMAN BODY FLUIDS: (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for Roche COBAS 6000 to COBAS 6000 Operation: SOP Chem 53500
Serum, Li-Hep plasma	Calcium	Cobas Calcium (CA2)
	Adjusted Calcium (calculation)	Calculations in Biochemistry SOP (Chem 1421)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Carbamazepine	Cobas Carbamazepine (CARB2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	CEA	Cobas Carcinoembryonic Antigen (CEA)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Cholesterol	Cobas Cholesterol (CHOL2)
	Non-HDL Cholesterol (calculation)	Calculations in Biochemistry SOP (Chem 1421)
Serum, Li-Hep plasma	Chloride	Cobas Electrolytes (ISE indirect Na, K, Cl)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, citrate plasma, fluoride plasma	Cortisol	Cobas Cortisol (CORT III)
Serum, Li-Hep plasma	Creatine Kinase	Cobas Creatine Kinase - CK (CK)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Creatinine	Cobas Creatinine (CREP2)
	AKI Alerts (calculation) eGFR (calculation)	Calculations in Biochemistry SOP (Chem 1421)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	CRP	Cobas C Reactive Protein (CRPL4)



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Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, citrate plasma, fluoride plasma	Digoxin	Cobas Digoxin (Digoxin)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Direct Bilirubin	Cobas Direct Bilirubin (DBIL) SOP: Chem 406
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Ferritin	Cobas Ferritin (Ferritin)
Serum, Li-Hep plasma	Folate	Cobas Folate (FOLATE III)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	FSH	Cobas Follicle Stimulating Hormone (FSH)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, fluoride plasma	Free T4	Cobas Free Thyroxine (FT4 III)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, fluoride plasma	Free T3	Cobas Free Triiodothyronine (FT3 III)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Gamma Glutamyltransferase	Cobas Gamma Glutamyl Transferase (GGT-2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Gentamicin	Cobas Gentamicin (GENTC)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, fluoride plasma	Glucose	Cobas Glucose (GLUC3) (Hexokinase method)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	HDL Cholesterol	Cobas HDL Cholesterol (HDLC4)
Serum, Li-Hep plasma	Iron	Cobas Iron – Fe (IRON2)



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Serum, Li-Hep plasma	Lactate Dehydrogenase	Cobas Lactate Dehydrogenase – (LDHI2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, fluoride plasma	LH	Cobas Luteinising Hormone (LH)
Serum, K <sub>2</sub> EDTA plasma	Lithium	Cobas Lithium (LI)
Serum, Li-Hep plasma	Magnesium	Cobas Magnesium (MG2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, citrate plasma, fluoride plasma	Oestradiol	Cobas Oestradiol (E2 III)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Paracetamol	Cobas Paracetamol (ACET2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Phenytoin	Cobas Phenytoin (PHNY2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Phosphate	Cobas Phosphate (PHOS2)
Serum, Li-Hep plasma	Potassium	Cobas Electrolytes (ISE indirect Na, K, Cl)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, fluoride plasma	Progesterone	Cobas Progesterone (Progesterone II)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma,	Procalcitonin	Cobas Procalcitonin (BRAHMS PCT)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Prolactin	Cobas Prolactin (Prolactin II)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	PSA	Cobas Prostate Specific Antigen (Total PSA)
Serum, K <sub>2</sub> EDTA plasma	PTH	Parathyroid Hormone (PTH)



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HUMAN BODY FLUIDS: (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for Roche COBAS 6000 to COBAS 6000 Operation: SOP Chem 53500
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Rheumatoid factor	Cobas Rheumatoid Factor (RF II)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Salicylate	Cobas Salicylate (SALI)
Serum, Li-Hep plasma	Sodium	Cobas Electrolytes (ISE indirect Na, K, Cl)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Testosterone	Cobas Testosterone (Testosterone II)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Theophylline	Cobas Theophylline (THEO2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Total Protein	Cobas Total Protein (TP2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Triglycerides	Cobas Triglycerides (TRIGL)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Troponin T	Cobas Troponin T (Troponin T hs)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma, fluoride plasma	TSH	Cobas Thyroid Stimulating Hormone (TSH)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Urate	Cobas Urate – Uric acid (UA2)
Serum, K <sub>2</sub> EDTA plasma, Li-Hep plasma	Urea	Cobas Urea (UREAL)
Serum, K <sub>2</sub> EDTA plasma, citrate plasma, fluoride plasma	Vancomycin	Cobas Vancomycin (VANC3)
Serum, Li-Hep plasma	Vitamin B12	Cobas Vitamin B12 (Vitamin B12 II)
Serum, Li-Hep plasma	Total Vitamin D	Cobas Vitamin D (Vitamin D Total II)



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HUMAN BODY FLUIDS: (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for Roche COBAS 6000 to COBAS 6000 Operation: SOP Chem 53500
Urine	Amylase	Cobas Amylase (AMYL2)
	Calcium	Cobas Calcium (CA2)
	Chloride Potassium Sodium	Cobas Electrolytes (ISE indirect Na, K, Cl)
	Creatinine	Cobas Creatinine (CREP2)
	Microalbumin	Cobas Albumin (ALBT2) (Immunoturbidometric)
	Phosphate	Cobas Phosphate (PHOS2)
	Urea	Cobas Urea (UREAL)
	Urate	Cobas Urate – Uric acid (UA2)
Urine, CSF	Protein	COBAS Urine Protein & CSF Protein (TPUC3) by turbidimetric method: SOP Chem 53498 and CSF in Chemical Pathology: SOP Chem 122  Documented In-house Methods and Manufacturer's instructions for Menarini Premier Hb9210 Analyser to SOPs
Whole Blood (EDTA, Heparin, Fluoride)	HbA1c	Haemoglobin A1c: SOP Chem 459
Capillary Blood	Paediatric Bilirubin	Documented In-house Methods and Manufacturer's instructions for Das Neo-Bil Plus to Paediatric Bilirubin: SOP C047



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HUMAN BODY FLUIDS: (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u>	
Whole Blood (EDTA)	Full Blood and Reticulocytes: Includes the following parameters: -  WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, PDW, IPF, NEUT, LYMPH, MONO, EOS, BASO, NRBC, MPV, P-LCR, PCT, RET, IRF, LRF, MFR, HFR, RET-He, IPF, IG	Documented in-house Methods and Manufacturer's instructions for SOP XN-9000 Haem 2634 that includes Sysmex XN 10 analytical unit
Whole Blood:EDTA	Erythrocyte Sedimentation Rate  Blood Films - morphology of the red cells, platelets and white cells. Manual differential of white cells  Detection of malarial parasites: Plasmodium falciparum, Plasmodium malariae, Plasmodium ovale & Plasmodium vivax & Plasmodium knowlesi	Documented In-house Methods and Manufacturer's instructions for Diesse Vescube 200 to SOP Haem 47694  Documented in-house visual examination method using microscopy to SOP H5004, May-Grünwald-Giemsa Staining H5019 or automated slide making and staining using Sysmex SP 10  Documented in-house for staining and microscopical examination of Blood Films for Malarial Parasites to SOP: H5022
Plasma:EDTA	Malarial Parasite Antigen for pLDH (plasmodium Lactate Dehydrogenase). Detects Plasmodium +/- Falciparum  Detection of heterophile antibodies in Infectious Mononucleosis	Documented In-house Methods and Manufacturer's instructions for Carestart Malaria Screening Test: SOP H5021  Documented In-house Methods and Manufacturer's instructions for Monogen Biokit Glandular Fever Screening Test: SOP H5067





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<p>HUMAN BODY FLUIDS: (cont'd)</p> <p>Whole Blood:EDTA</p>	<p><u>Haematology examination activities for the purposes of clinical diagnosis:</u></p> <p>Haemoglobinopathy screen to confirm or exclude presence of haemoglobin variant and / or thalassaemia:</p> <p>Haemoglobin S</p> <p>Ante natal Sickle Cell and Thalassaemia Screening</p> <p>Coagulation examination activities for the purposes of clinical diagnosis:</p>	<p>Documented In-house Methods and Manufacturer's instructions for Sickledex Whole Blood Solubility Test for Haemoglobin S: SOP H5069</p> <p>Documented -in-house methods to meet the requirements of the Sickle Cell and Thalassaemia screening programme as defined in the July 2018 'SCT screening: laboratory QA evidence requirements'</p> <p>Documented In-house Methods and Manufacturer's instructions for Haemoglobinopathy Screening on the Menarini HA-8180: SOP H5060: SOP H5035</p> <p>Documented In-house Methods to Manufacturer's instructions for Sysmex CS2100i – Basic Operation: SOP Haem 47688</p>
<p>Citrated Blood</p>	<p>Coagulation Screen: D-Dimer APTT Fibrinogen INR/ PT</p>	<p>SOP Haem 47696</p>



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HUMAN BODY FLUIDS: (cont'd)	<u>Transfusion examination activities for the purposes of clinical diagnosis:</u>	
Whole Blood:EDTA	ABO & Rh D & DAT Grouping  Antibody screening and identification of: anti-D, C, E, c, e, Cw, K, k, Kp(a),Kp(b), Fy(a), Fy(b), Jk(a), Jk(b), Le(a), Le(b), P1, M, N, S, s, Lu(a), Lu(b), V, JS(a), JS(b), Xg(a),  Phenotyping: Rh subgroups and Kell by Gel card (C, E, c, e, Kell) Lorne antisera with Diamed technique (Gel card) (S, s, M, Fy(a), Fy(b), JK(a), JK(b)	Documented In-house Methods for ABO & Rh D Urgent and Routine Manual Tube Grouping: SOP BB004, ABO, RhD & DAT for Newborns: SOP BB 009  IBG Gallileo Echo: SOP B Bank 69430 Antibody Panel: SOP BB010 Antigen Typing: SOP BB011
Whole Blood:EDTA	DAT / DAGT (gel card) (IgG, IgA, IgM, C3c, C3d)  Detection and Estimation of Feto Maternal Haemorrhage  Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma antibody.	Documented In-house Methods for Direct Antiglobulin Test: SOP BB 008  Documented In-house Methods for Kleihauer Staining Procedure for Foetal Leak: SOP BB 013  Documented In-house Methods for Crossmatching (XMatch): SOP BB 020 and Crossmatching for Massive Transfusion: SOP BB 015



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<p>HUMAN BODY FLUIDS: (cont'd)</p> <p>Swabs from various body sites, and various body specimens: Female genital tract swabs Fluids (joint, pleural, drain, peritoneal) Skin Sputum Tissue</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis:</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs):</p> <p><u>Manual</u> culture and microscopy.</p> <p>SOP: Investigation of abscesses and deep seated wound infections (Micro SOP 26) SOP: Investigation of genital tract and associated specimens (Micro SOP 33) SOP: Culture of specimens for Bordetella pertussis and Bordetella parapertussis (Mi095)SOP: Bronchoalveolar Lavage &amp; Associated Specimens, Investigation of (Micro SOP 5) SOP: Investigation of bacterial eye infections (Micro SOP 41)SOP: Investigation of Ear Swabs and Associated Specimens (Micro SOP 30) SOP: Investigation of Skin and Superficial Wound Swabs (Micro SOP 37)</p> <p>SOP: Throat swab processing (Micro SOP 58) SOP: Investigation of Nasal samples (Micro SOP 35) SOP: Investigation of fluids from normally sterile sites (Micro SOP 32) SOP: Investigation of Bile (Micro 1058) SOP: Investigation of bone and soft tissue associated with with osteomyelitis (Micro 1054) SOP: Investigation of prosthetic joint infection samples (Micro 1053) SOP: Investigation of superficial mouth samples (Micro SOP 39) SOP: Investigation of tissues and biopsies from deep seated sites and organs (Mi020)</p>
<p>Cellular and fluid material contained on swabs</p>	<p>Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)</p>	<p>Manual inoculation, incubation and interpretation of chromogenic culture media using SOP: Investigation of Specimens for Screening for MRSA (Mi070)</p>
<p>Blood</p>	<p>General isolation of micro-organisms of clinical significance</p>	<p><u>Automated</u> culture using Bact/Alert blood culture system: SOP: BactAlert 3D Automated Blood Culture System (Micro909)</p>



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CSF	General isolation and characterisation of micro-organisms of clinical significance	SOP: Cerebrospinal Fluid Investigation (Micro SOP 6)
Faeces	Culture and isolation of gastrointestinal pathogens	Culture to SOP: Investigation of Faeces Specimens for Bacterial Pathogens (Micro SOP 31)



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HUMAN BODY FLUIDS: (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs):
Faeces	Microscopy for ova, cysts and parasites (OCP).  Detection of Cryptosporidium oocysts	Unstained and iodine stained direct microscopic examination and/or Formal-ether faecal concentration and microscopic examination to SOP: Parasitology (Micro SOP 44)  Cold ZN incident light microscopy to SOP: Parasitology (Micro SOP 44) SOP: Investigation of Faeces Specimens for Bacterial Pathogens (Micro SOP 31)
Hair Skin Nail	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture and macroscopic and microscopic examination (stained and unstained) to SOP: Investigation of dermatological specimens for superficial mycoses (Micro SOP 29)
Cellular and fluid material contained on swabs Fluids Sputum Tissue Urine	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Microscopy (auramine phenol staining and incident-light fluorescence microscopy) to SOP: Investigation of Specimens for Mycobacterium Species (Micro SOP 38)
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Menarini Sedimax for Urine Microscopies SOP: Investigation of Urine (Micro SOP 16) SOP: Sedimax Urine Analyser (Micro SOP 51)
Faeces	Detection of DNA of Norovirus	SOP: Cepheid GeneXpert PCR (Micro 1008) SOP: Processing of specimens for Norovirus (Micro 1613)



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HUMAN BODY FLUIDS: (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	
Faeces	Clostridium difficile glutamate dehydrogenase (GDH). C. difficile toxins A & B	Documented In-house Methods and Manufacturer's instructions for Cepheid Xpert (PCR) to: Processing of Faeces for Clostridium difficile SOP
Urine	Detection of Legionella pneumophila serotype 1 antigen	Legionella and Streptococcus pneumoniae Antigen Testing (Micro 2685)
Bacterial cultures isolated in-house.	Bacteriological identification	SOP: Bruker MalDI-TOF of Mass Spectrometry (Micro SOP 7)
	Antimicrobial susceptibility testing of clinically significant bacteria	Manual (disc diffusion and E-Test) and automated using BioMerieux Vitek 2 (EUCAST) SOP: Vitek 2 (Micro SOP 60) SOP: Susceptibility Testing (Mi 010)
	Detection of bacterial vaginosis	Microscopy (gram stain) to SOP: Investigation of genital tract and associated specimens (Micro SOP 33)
	Detection of Trichomonas vaginalis	Microscopy (unstained or acridine orange) to SOP: Investigation of genital tract and associated specimens (Micro SOP 33)
END		