


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL <b>8314</b>  Accredited to ISO 15189:2012	<b>Spire Healthcare Limited</b>	
	Issue No: 004 Issue date: 15 November 2021	
	<b>Spire Bushey Pathology</b> 512 Centennial Avenue Elstree WD6 3FG United Kingdom	<b>Contact: Lesley Bloom</b> Tel: +44 (0) 208 238 6831 Fax: +44 (0) 208 238 6835 E-Mail: <a href="mailto:Lesley.bloom@spirehealthcare.com">Lesley.bloom@spirehealthcare.com</a>
Testing performed at the above address only		

### Site activities performed away from the locations listed above:

Location details	Activity	Location code
Spire Harpenden Laboratory	Specimen reception	N/A
Spire Thames Valley Laboratory	Specimen Reception	N/A



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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>Haematology examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant
Blood	Full Blood Count Haemoglobin White Blood Cell Count Red Blood Count Platelet Count Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Corpuscular haemoglobin concentration Red cell distribution width-SD* Red cell distribution width-CV Mean Platelet Volume Platelet Distribution Width Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Reticulocyte count* Large immature cells* Atypical lymphocytes* Immature lymphocytes* Immature granulocytes* Nucleated red blood cells*	Horiba Yumizen H2500, SPS-HM-SOP1500 and Yumizen H550, SPS-HM-SOP1700 using impedance, cytochemistry and absorbance,  *H2500 only
Plasma	Coagulation screen PT APTT	ACL TOP 500 using turbidimetry and optical density and SPS-HM-SOP1400



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Blood	Sickle cell solubility to detect sickle cell haemoglobin	Microgen solubility test kit and SOP Sickle Cell Screening SPS-HM-SOP0800
Blood	Erythrocyte Sedimentation Rate (ESR)	ESR using Seditainer manual method for measurement of the sedimentation rate of erythrocytes SOP ESR SPS-HM-SOP0600
Blood	D-dimer Troponin T	Roche H232 analyser using photometry and SOP Point of Care Testing SPS-GP-SOP1700
Blood	Blood film assessment for detection of abnormal cell type, morphology, numbers and white cell differential	Staining using May Grunwald/Geimsa and SOP Blood Films SPS-HM-SOP0500



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Serum, plasma	Quantification of the following:  Urea Creatinine (enzymatic) Sodium Potassium Chloride GGT Total Protein Cholesterol Triglycerides HDL Phosphate Albumin ALP ALT Amylase AST Total bilirubin and direct bilirubin Calcium CK Glucose CRP LDH Bicarbonate Creatinine Kinase MB Lactate dehydrogenase Iron Unsaturated Iron Binding Capacity Magnesium Uric Acid Gentamicin HbA1c AFP	Roche Cobas 6000 (c501) using ISE, photometry. SOP Roche Cobas SPS-BC-SOP0100



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Serum, plasma (cont'd)	Quantification of the following: (cont'd)	Roche Cobas 6000 (e601) using competitive or sandwich techniques. SOP Roche Cobas SPS-BC-SOP0100
Serum	Ca125 CA 15.3 CA 19.9 CEA Cortisol Oestradiol Ferritin Folate PSA/Free PSA FSH LH FT3 FT4 TSH Insulin Progesterone PTH SHBG Testosterone Prolactin HCG Vitamin B12 ProBNP II Vitamin D (total) IgG, IgG, IgM	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Urine	Urea Creatinine Sodium Potassium Chloride Phosphate Amylase Calcium Glucose Magnesium Uric acid	Roche Cobas 6000 (c501) using ISE, photometry and SOP Roche Cobas SPS-BC-SOP0100  Work instruction: Processing of Urine Samples on the Cobas 6000 SPS-BC-CP-WI0101
Urine, CSF Serum, plasma	Total protein Calculated parameters: eGFR Adjusted calcium Globulin LDL cholesterol	
Serum	Detection and quantitation of the following abnormal proteins fractions: alpha1, alpha 2, beta1, beta 2, gamma  Immunofixation to type paraproteins kappa and Lambda	Electrophoresis and immunofixation using Hydrasys Scan 2 and Assist Module and SPS-BC-SOP1100



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HUMAN BODY TISSUES	<u>Microbiology examinations for the purpose of clinical diagnosis</u>	In-house documented methods based on related PHE UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant
Swabs from Ear, Eye, Nose, Throat, Mouth, Skin, wounds, genitals. Exudates, pus, corneal scrapes, IUCD, tips, indwelling cannulae and catheters	Microscopic examination and isolation and characterisation of micro-organisms of clinical significance including bacterial vaginosis	Manual culture methods SPS-MI-SOP0200  Gram stain slide examination for detection of microorganisms and bacterial vaginosis as appropriate using light microscopy SPS-MI-SOP0200 SPS-MI-SOP0800 SPS-MI-SOP0500
Tissue and bone		SPS-MI-SOP0500
Fluid		SPS-MI-SOP0500
Nasal and groin swabs and swabs / specimens from other body sites	MRSA/ MSSA screening, isolation and characterisation	Chromogenic agar and routine culture methods SPS-MI-SOP0200
Rectal swabs and faeces	Carbapenemase-Producing Enterobacteriaceae screening, isolation and characterisation	
Low vaginal and rectal swabs	Group B Streptococcus screening, isolation and characterisation	Manual methods using SPS-MI-SOP0200
Faeces	Isolation and characterisation of enteric pathogens	Manual culture methods SPS-MI-SOP0300
Faeces	Detection of Cryptosporidia	Modified of Ziehl Neelsen stain and light microscopy, SPS-MI-SOP0800
Faeces	Detection of C.difficile GDH and C.difficile toxin A & B	Alere Techlab C diff Quik Chek Complete. Rapid membrane enzyme immunoassay. SPS-MI-SOP0300



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HUMAN BODY TISSUES cont'd	<u>Microbiology examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods based on related PHE UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant
Urine	Cell enumeration of white blood cells, red blood cells, casts, epithelial cells and culture, isolation and characterisation of micro-organisms of clinical significance	Manual culture methods SPS-MI-SOP0400 Manual light microscopy Immune Systems Fastread 102 counting chambers. SPS-MI-SOP0400
CSF, body fluids, blood	Culture, isolation and characterisation of micro-organisms of clinical significance	Manual culture methods SPS-MI-SOP0500 BD BACTEC FX40 for automated blood culture and sterile fluid enrichment SPS-MI-SOP0500
Fluid and CSF	Cell enumeration of red and white blood cells	Manual cell count using light microscopy. Immune Systems Fastread 102 counting chambers SPS-MI-SOP0500
Sputum, Bronchio-alveolar lavage (BAL), sinus aspirates, antral washouts	Culture, isolation and characterisation of micro-organisms of clinical significance	Manual culture methods SPS-MI-SOP0600
Various specimens such as blood, fluids, pus, tissue. Bacterial isolates from culture methods	Detection of Gram positive and Gram-negative bacteria	Manual staining using crystal violet, Gram's Iodine and Carbol Fuchsin SPS-MI-SOP0800



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HUMAN BODY TISSUES (cont'd)	<u>Microbiology examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods based on related PHE UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant
Bacterial isolates obtained from agar culture methods	Antimicrobial susceptibility testing and resistance mechanisms	<p>Biomerieux Vitek 2 Compact for automated antimicrobial susceptibility testing SPS-MI-SOP0800</p> <p>Manual antibiotic disc diffusion susceptibility testing using Oxoid antibiotic discs and Liofilchem gradient MIC strips using SPS-MI-SOP0800</p> <p>Following the EUCAST method and clinical breakpoints.</p> <p>Oxoid PBP2 latex test using SPS-MI-SOP0800</p> <p>Mastdiscs ID and SPS-MI-SOP0800</p>
	Identification of bacteria	<p>Biomerieux Vitek 2 Compact using SPS-MI-SOP-0800</p> <p>Manual methods using SPS-MI-SOP0800 Catalase test, chemical reaction</p> <p>Oxidase test, chemical reaction</p> <p>Tube coagulase agglutination</p> <p>DNase agar Methyl Green agar</p> <p>Urease test, chemical reaction</p>



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HUMAN BODY TISSUES (cont'd)	<u>Microbiology examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods based on related PHE UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant
Bacterial isolates obtained from agar culture methods (cont'd)	Identification of bacteria (cont'd)	Manual methods using SPS-MI-SOP0800 Bile aesculin, chemical reaction  Beta lactamase using nitrocefin disc  X&V discs, growth enhancement  Optochin, growth inhibitor  Enteric serology, slide agglutination  Staph latex agglutination, Pro-lab Staph kit  Strep grouping using Prolex Strep grouping kit  E coli O157 using Prolex E. coli O157 latex kit
Formalin fixed tissues	<u>Histopathology examinations for the purposes of clinical diagnosis</u>  Preparation and examination to identify or exclude morphological and cytological abnormalities	In-house documented procedures based on equipment manual as relevant  Macroscopic and microscopic examination using in-house procedures in conjunction with manufacturer's instructions where relevant for the following methods  Macroanalysis and dissection using SOP SPS-HT-SOP-0200  Tissue processing: Automated method using Leica ASP3005 Tissue Processor and SOP SPS-HT-SOP-0300



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HUMAN BODY TISSUES (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Formalin fixed tissues (cont'd)	Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using in-house procedures in conjunction with manufacturer's instructions where relevant for the following methods  Paraffin was tissue embedding Manual method using SOP SPS-HT-SOP-0400  Microtomy using SOP SPS-HT-SOP0500
Formalin fixed paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Haematoxylin and Eosin staining using Leica ST4040 stainer and SOP SPS-HT-SOP-600
Stained slides from tissue above	Examination to identify or exclude morphological abnormalities	Microscopic examination and reporting using in-house procedures and SOP SPS-HT-SOP0800
END		