

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8891 Accredited to ISO 15189:2012</p>	Spire Healthcare Ltd Issue No: 007 Issue date: 15 November 2021	
	3 Dorset Rise London EC4Y 8EN United Kingdom	Contact: Claire Grinnell Tel: +44 (0)161 447 6777 E-Mail: claire.grinnell@spirehealthcare.com Website: www.spirehealthcare.com
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Spire Manchester (Blood Sciences, Microbiology) 170 Barlow Moor Road, Didsbury, Manchester, M20 2AF	Local contact Alison Benson Diagnostic testing: Haematology, Blood Transfusion, Biochemistry, Microbiology	A
Address Spire Histology Centre Parkway 1 Princess Road Manchester M14 7LU	Local contact Alison Benson Diagnostic testing: Histopathology Non-gynae cytology	B

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Spire Manchester Lab	Blood issue fridge	
Spire Cheshire	Blood issue fridge	C
Abbey Pines	Blood issue 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>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 Cell Count Platelet Count Mean platelet volume Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Cell Haemoglobin Concentration Red cell distribution width-CV and SD Platelet Distribution Width Plateletcrit Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Large immature cells Atypical lymphocytes Immature lymphocytes Immature granulocytes Nucleated red blood cells	Horiba Yumizen H2500 using impedance, cytochemistry and absorbance, SPS-HM-SOP1500	A
Plasma	Coagulation screen PT APTT INR	IL Elite Pro analyser using viscosity based detection and SPS-HM-SOP0400	A
Blood	Estimation of Erythrocyte Sedimentation Rate	Manual Westergren Sedatiner method using SPS-HM-SOP0600	A
Blood	Detection of sickle cell	S test kit and SPS-HM-SOP0400	A
Serum, plasma	Detection of infectious mononucleosis heterophile antibody	Monocol card latex agglutination kit and SPS-HM-SOP1100	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry and Serology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum, plasma	Quantification of the following: Urea Creatinine (Jaffe) Sodium Potassium GGT Total protein Cholesterol Triglycerides HDL Phosphates Albumin ALP ALT Amylase AST Total bilirubin Calcium CK Glucose CRP Iron Iron binding capacity unsaturated Apolipoprotein A Apolipoprotein B Lipoprotein Triglycerides Magnesium Uric Acid Salicylate Paracetamol AMH Valproate	Roche Cobas C501 using colorimetric, enzymatic, immunoturbidometry and SPS-BC-SOP0100	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry and Serology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	A
Serum, plasma	Quantification the following: Lithium Bicarbonate LDH Calculated parameters: eGFR Globulin Adjusted Calcium LCL cholesterol ratio Troponin T Oestradiol FSH LH Progesterone Prolactin Vitamin B12 Folate Ferritin CA-19 CA15-3 CEA CA-125 Total PSA TSH	Roche Cobas C601 using electrochemiluminescence immunoassay and SPS-BC-SOP0100	
Faeces	Qualitative detection of the following: HIV Hep B surface antigen Hep C antibody Hep B antibody Hep A Syphilis antibody Rubella IgG Detection of occult blood	HM-JACKarc faecal immunochemical testing (FIT) using SPS-BC-SOP0900	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry and Serology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Faeces	Qualitative detection of the following: Calprotectin Elastase	Trituris 4 ELISA analyser and SPS-VL-SOP0100 Buhlmann kit Bioserve kit	A
Serum, plasma	TB Quantiferon Parvovirus B19 IgG Parvovirus B19 IgM	Qiagen kit Grifols kit Grifols kit	
HUMAN BODY FLUIDS (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum, plasma	Qualitative detection of the following: EBV VCA IgG EBV VCA IgM EBV EBNA CMV IgG CMV IgM Herpes IgG Herpes IgG Toxoplasma IgG Toxoplasma IgM Mycoplasma IgG Mycoplasma IgM Measles IgG Measles IgM Mumps IgM VZV IgG VZV IgM Rubella IgM Helicobacter pylori IgA Coxsackie A Coxsackie B	Chorus ELISA analyser and SPS-VL-SOP0200	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Blood and plasma	Blood group detecting ABO Antibody screen and identification detecting: Rh-D, C, c, e, cw Kell, K, k, kpa, kpd JK-a, JK-b Lewis, LEa, LEb P1 M, N, F, f Lutheran a, b XGa	Automated method using Grifols Eflexis analysr and manual method using Grifols gel cards and SPS-BT-SOP0200	A
Blood and plasma	Serological Crossmatching	Manual method using Grifols gel cards and SPS-BT-SOP0200. Electronic and remote issue using SPS-BT-WI0409	A A, C
HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis</u>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant.	A
Swabs, tissue, fluids, faeces, tips, urine	Isolation and characterisation of microorganisms of clinical significance.	Manual inoculation and media culture SPS-MI-SOP0200 SPS-MI-SOP0400 SPS-MI-SOP0500 SPS-MI-SOP0300	A
Faeces	Detection of Clostridium difficile GDH antigen and toxins A & B Detection of Helicobacter pylori antigen	Prolab Proflow lateral flow immunoassay SPS-MI-SOP0300	A
Sputum, Bronchial wash and sinus washouts	Culture, isolation and characterisation of microorganisms of clinical significance	Manual culture methods SPS-MI-SOP0600	



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant.	A
Blood	Culture, isolation and characterisation of micro-organisms of clinical significance	Manual culture methods SPS-MI-SOP0500 BD BACTEC FX40 for automated blood culture SPS-MI-SOP0500	
Hair, nail, skin scrape	Culture, isolation and characterisation of fungi and yeasts of clinical significance	Manual culture methods and manual microscopy using Calcofluor white stain and light microscopy, SPS-MI-SOP0700	
Male urethral swabs and urine. Female vaginal swabs and urine	Detection of Chlamydia trichomatis and Neisseria gonorrhoea	BD Probetec amplified DNA assay and SPS-MI-SOP0200	
Rectal swab and bacterial isolate	Carbapenemase resistance gene detection	Cepheid GeneXpert PCR using SPS-MI-SOP0900	A
Urine and genital swabs	Detection of Chlamydia trachomatis and Neisseria gonorrhoeae		
Swabs, Tissue, Fluids	Differentiation of different organism types: gram positive/negative/variable, branching organisms, yeasts.	Gram Staining and light microscopy SPS-MI-SOP0800	A
Faeces	Detection of Cryptosporidium oocysts	Manual staining using auramine and fluorescent microscopy SPS-MI-SOP0800	A
Faeces, urine, fluids	Detection of ova cysts and parasites	Manual concentration method using Parasep and SPS-MI-SOP0300	A
Synovial fluid	Detection of uric acid and pyrophosphate crystals	Manual method using bi-refringent polarising microscopy and SPS-MI-SOP0800	A
Urine, fluids	Enumeration of white and red blood cells	Manual method using inverted microscopy Kova slide and SPS-MI-SOP0800 and 0400	A



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant.	
Sellotape slide	Detection of ova of Enterobius vermicularis	Light microscopy and lactophenol blue stain SPS-MI-SOP0700	A
Bacterial/fungi/yeasts culture isolates produced by the laboratory	Antibiotic susceptibility testing of microorganisms of clinical significance	Disc diffusion & EUCAST methodology/criteria. Gradient MIC determination by E-test & EUCAST criteria Automated MIC by broth dilution using Vitek 2 & EUCAST criteria SPS-MI-SOP0800	A
Bacterial/fungi/yeasts culture isolates produced by the laboratory	Identification of bacteria/fungi/yeasts	Manual methods using SPS-MI-SOP0800 Oxidase, chemical reaction Catalase, chemical reaction β -lactamase enzyme detection using Remel Nitrocephin X&V factor growth enhancement DNase using Oxoid Methyl Green plates	A
Bacterial/fungi/yeasts culture isolates produced by the laboratory	Identification of bacteria/fungi/yeasts	Manual methods using SPS-MI-SOP0800 Optochin growth inhibitor using Oxoid discs Urease production using Oxoid urea slopes Strep latex grouping kit (Prolab) agglutination E.coli O157 latex agglutination Prolab Prolex kit	A



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<p>HUMAN BODY FLUIDS (cont'd)</p>	<p><u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of carbapenemase producing Enterobacteriaceae</p>	<p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant.</p> <p>Staph latex agglutination Prolab Prolex kit</p> <p>Enteric Serology-Enteric slide agglutinations</p> <p>Vitek 2 Compact identification</p> <p>Oxoid PBP2 latex kit</p> <p>MASTDISCS Combi</p>	



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HUMAN TISSUES AND FLUIDS Formalin fixed tissues	<u>Histopathology examinations for the purposes of clinical diagnosis</u> Preparation and examination to identify or exclude morphological abnormalities	In-house documented procedures based on equipment manuals as relevant Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant). Macroanalysis and dissection using SOP SPS-HT-SOP-0200 Tissue processing: Automated method using Leica ASP300S and Peloris processors and SOP SPS-HT-SOP-0300 Embedding Manual method using SOP SPS-HT-SOP-0400 Microtomy Manual method using SOP SPS-HT-0500	B
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures Detection of the following: Liberated aldehydes Acid and sulphated mucins Glycoproteins	Routine Haematoxylin & Eosin (H&E) staining: Automated method using Leica Auto-stainer XL and coverslipper CV5030 SPS-HT-SOP0600 Special stains: Manual methods using SOP SPS-HT-SOP0600 and the following stains Periodic Acid Schiff's (+/- diastase) Alcian Blue PAS Alcian Blue	



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p>	<p><u>Histopathology examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of the following:</p> <p>Helicobacter pylori</p> <p>Acid fast bacilli</p> <p>Haemosiderin</p> <p>Fungal Hyphae</p> <p>Hep B</p> <p>Reticulin Fibres</p> <p>Elastic fibres and collagen</p> <p>Blood and Elastic Tissue</p> <p>Amyloid</p> <p>Collagen and smooth muscle</p> <p>Fibrin</p> <p>Gram positive and Gram-negative organisms</p> <p>Mast cell granules</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Special stains: Manual methods using SOP SPS-HT-SOP0600 and the following stains</p> <p>Modified Giemsa</p> <p>Ziehl Neelsen</p> <p>Perls Prussian Blue</p> <p>Grocott</p> <p>Orcein</p> <p>Retic</p> <p>Elastic Van Gieson</p> <p>HVG</p> <p>Congo Red</p> <p>Mason Trichrome</p> <p>MSB</p> <p>Gram</p> <p>Toluidine Blue</p>	<p>B</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	B
FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700.	
	Smooth muscle	Actin*	
	Pan-keratin	AE1/AE3*^	
	Fibromatosis in Breast/ Abdomen	Beta-Catenin*	
	Mantle zone B lymphocytes & interfollicular T lymphocytes	Bcl-2*^	
	Large B-cell lymphomas	Bcl-6*	
	Cell membranes and glycoproteins	BerEP4*^	
	Breast Carcinomas	BRST-2/GCDFP-15	
	Ovarian Carcinomas	CA125*^	
	Medullary Carcinoma of Thyroid	Calcitonin*	
	Oesophagus, Smooth Muscle from bowel and Uterus.	Caldesmon*^	
	Oesophagus, Smooth Muscle from bowel and Uterus.	Calponin*	
	Mesothelioma, Normal Appendix	Calretinin*^	
	Melanoma marker	SOX-10^	
	<u>Marker of Her 2 amplification in breast tumour</u>	Her-2*^	



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FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700.	
	Thymus	CD1a*	
	T Lymphocytes	CD3*^	
	Liver and tonsil. T lymphocytes	CD4*^	
	Germinal centre T lymphocytes; B lymphocyte subset	CD5*^	
	T cell Lymphoma	CD8*^	
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10*^	
	Hodgkins Lymphoma	CD15*^	
	B lymphocytes	CD20*	
	Follicular Dendritic cell matrix in tonsil.	CD21*^	
	Lymphoma/ Leukaemia's for small cell B cell lymphoma	CD23*^	



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FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700.	
	Hodgkin lymphoma and Anaplastic large cell lymphoma	CD30*	
	Neoplasms of vascular origin	CD31*^	
	Haemopoietic precursor cells; endothelial cells; fibroblasts	CD34*^	
	Lymphoid or myelomonocytic lineage identification.	CD43*	
	Hodgkin and T-cell lymphomas.	CD45(LCA)*	
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56*^	
	Macrophages	CD68*^	
	B lymphocytes	CD79a*^	
	Marker of GI origin for adenocarcinomas	CDX2*^	
	Normal and neoplastic plasma cells in plasmacytoid lymphomas.	CD138*	



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FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700.	
	Adenocarcinomas of Colon/Colon mucosa	CEA*^	
	Neuroendocrine conditions.	Chromogranin A*	
	Proliferating squamous epithelium	CK5/6*^	
	Simple, glandular & transitional epithelia	CK7*^	
	Adenocarcinomas and non-keratinising squamous carcinomas.	CK8/18*^	
	Tumours of epithelium origin.	CK14*^	
	Epithelia	CK19*^	
	GI epithelia	CK20*^	
	Basal cells in the prostate and myoepithelial cells.	CK34*^	
	Mantle cell lymphoma and breast carcinoma	Cyclin D1*^	
	Smooth and striated muscle cells	Desmin*^	



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue</p>	<p><u>Histopathology examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of the following:</p> <p>Adenocarcinoma or mesothelioma in Lung, G.I. tract and Ovary</p> <p>Epithelial membrane on glandular tissue.</p> <p>Breast carcinomas.</p> <p>Endothelial cells and neoplastic blood cells.</p> <p>Platelets, megakaryocyte and fibroblast.</p> <p>Adrenal cortical tumours and renal cell carcinomas.</p> <p>Light Chain and heavy chain identification</p> <p>Cell proliferation rate</p> <p>Light and heavy chain identification</p> <p>Detect melanoma quantitatively.</p> <p>Human melanoma black 45 antigen</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p><u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700.</p> <p>E-Cadherin*^</p> <p>EMA*^</p> <p>ER*^</p> <p>Factor VIII*</p> <p>Factor XIIIa*^</p> <p>Inhibin*^</p> <p>Kappa*</p> <p>Ki67*^</p> <p>Lambda*</p> <p>Melan A*^</p> <p>HMB45*^</p>	<p>B</p>



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FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700.	
	Colorectal carcinoma	MNF116*^	
	Detection of Racemase tumours	P504S/AMACR*	
	Ovarian Carcinomas	P16*^	
	Colon Andenocarcinomas	P53*^	
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells; abluminal cells	P63*^	
	Breast carcinomas	PR*^	
	Prostate specific antigen	PSA*^	
	Hyperplastic prostate or carcinoma of prostate	PSAP*^	
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres	S100*^	
	Smooth muscle	Smooth Muscle Myosin*	
	Pancreatic Islet cells	Synaptophysin*^	



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FFPE tissue	Detection of the following: Follicular carcinomas of the thyroid. Thyroid transcription factor-1 (Thyroid follicular & C cells) Vimentin intermediate filament Ovarian carcinomas and mesotheliomas	<u>Immunohistochemistry</u> Automated methods using the Roche Ventana Benchmark XT* and Ultra^ for the following antibodies: SPS-HT-SOP0700. Thyroglobulin* TTF1*^ Vimentin*^ WT1*^	
Urine, abdominal fluid, synovial fluid, FNA (breast and thyroid), serous fluid, cyst fluid	<u>Diagnostic Cytology</u> Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities	<u>Preparation/centrifugation</u> In-house procedures: SPS-HT-SOP0800 Non-Gynae Cytology in conjunction with manufacturer's instructions using Cytospin 3 Automated staining using Sakura DRS2000 stainer using Papanicolaou stain and SPS-HT-SOP0800	B
END			