


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL 8314  Accredited to ISO 15189:2012	<b>Spire Healthcare Limited</b>	
	Issue No: 003 Issue date: 17 September 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: Lesley.bloom@spirehealthcare.com
Testing performed at the above address plus sites below (POCT)		

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

Location details	Activity	Location code
Spire Bushey Pathology	Laboratory testing	SB
Spire Harpenden Laboratory	Specimen reception	N/A
Spire Thames Valley Laboratory	Specimen Reception	N/A
Spire Hospitals	Sampling for subsequent laboratory Covid-19 molecular testing	See appendix below
	Sampling and subsequent Covid-19 rapid antigen point of care testing	See appendix below



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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 Count Platelet Count Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Corpuscular haemoglobin concentration Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Reticulocyte count (Pentra DX Nexus only)	Horiba Pentra 80 and Horiba DX Nexus using impedance, cytochemistry and absorbance, SOP Pentra Analysers: SPS-HM-SOP0100	SB
Plasma	Coagulation screen PT APTT	ACL TOP 500 using turbidimetry and optical density and SPS-HM-SOP1400	SB



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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	SB
Blood	Erythrocyte Sedimentation Rate (ESR)	ESR Streck Auto-plus measurement of the sedimentation rate of erythrocytes SOP ESR SPS-HM-SOP0600	SB
Blood	D-dimer Troponin T	Roche H232 analyser using photometry and SOP Point of Care Testing SPS-GP-SOP1700	SB
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	SB



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum, plasma</p>	<p><u>Biochemistry examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Quantification of the following:</p> <p>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</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Roche Cobas 6000 (c501) using ISE, photometry. SOP Roche Cobas SPS-BC-SOP0100</p>	<p>SB</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purposes of clinical diagnosis (cont'd)</u>	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	SB
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 (cont'd)</u>	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	SB
Urine, CSF Serum, plasma	Total protein Calculated parameters: eGFR Adjusted calcium Globulin LDL cholesterol		
Serum	Detection and quantitation of the following abnormal proteins: IgG, IgA, IgM, kappa and Lambda	Electrophoresis and immunofixation using Interlab G26 and SOP Serum Electrophoresis SPS-BC-SOP0300	



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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	SB
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	SB
Rectal swabs and faeces	Carbapenemase-Producing Enterobacteriaceae screening, isolation and characterisation		SB
Low vaginal and rectal swabs	Group B Streptococcus screening, isolation and characterisation	Manual methods using SPS-MI-SOP0200	SB
Faeces	Isolation and characterisation of enteric pathogens	Manual culture methods SPS-MI-SOP0300	SB
Faeces	Detection of Cryptosporidia	Modified of Ziehl Neelsen stain and light microscopy, SPS-MI-SOP0800	SB
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	SB



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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	SB
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	SB
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	SB
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	SB
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	SB





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<p>HUMAN BODY TISSUES (cont'd)</p> <p>Bacterial isolates obtained from agar culture methods</p>	<p><u>Microbiology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Antimicrobial susceptibility testing and resistance mechanisms</p> <p>Identification of bacteria</p>	<p>In-house documented methods based on related PHE UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant</p> <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> <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>	<p>SB</p> <p>SB</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	SB



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab	Sampling with subsequent: <ol style="list-style-type: none"> <li>a) testing at a laboratory accredited to ISO 15189:2012 or ISO 17025:2017 and who is listed on the DHSC approved list for the testing performed for general population testing of SARS-CoV-2 virus RNA using molecular methods</li> <li>b) In-house detection of SARS-CoV-2 nucleocapsid antigen (see below)</li> <li>c) Point of care testing for Detection of SARS-Cov-2 antigen (see below)</li> </ol>	In house method based on PHE Guidance for COVID-19 Sampling for testing purposes	See appendix 1



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Combined Nasopharyngeal and oropharyngeal (Nose and Throat) Swab in viral transport medium	Virology examination procedures for the purposes of clinical diagnosis	Documented in house methods including DHSC requirements for private providers of Covid-19 testing, to include: <ul style="list-style-type: none"> <li>• General Population Testing</li> </ul>	SB
Combined Nasopharyngeal and Oropharyngeal (Nose & Throat) Swab	Detection of SARS-CoV-2 nucleocapsid antigen	VITROS Immunodiagnostics Products SARS-CoV-2 Antigen test on the VITROS XT 7600 system SPS-BC-SOP1000	SB
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab	Provision of Point of Care testing in accordance with ISO 22870: 2016 related to the following:	In house documented methods incorporating manufacturers' instructions where relevant	See appendix 1
Formalin fixed tissues	Detection of SARS-Cov-2 antigen	Siemens Clinitest SARS-CoV-2 rapid antigen test (LFT)	See appendix 1
	<u>Histopathology examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manual as relevant	
	Preparation and examination to identify or exclude morphological and cytological abnormalities	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	SB
		Tissue processing: Automated method using Leica ASP3005 Tissue Processor and SOP SPS-HT-SOP-0300	SB



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HUMAN BODY TISSUES (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis (cont'd)</u>	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	SB
		Paraffin was tissue embedding Manual method using SOP SPS-HT-SOP-0400	SB
		Microtomy using SOP SPS-HT-SOP0500	SB
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	SB
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	SB
END			



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Site	Sampling for referral, inhouse testing and POCT	Delivery Points for POCT			
		Bedroom	OPD/ Clinic Room	Porta Cabins	Additional Locations
Spire Southampton Impton Lane, Walderslade Chatham, Kent ME5 9PG	X	X			
Spire Bristol, Redland Hill Durdham Down, Bristol BS6 6UT	X	X		X	
Spire Bushey Heathbourne Road, Bushey, Hertfordshire WD23 1RD	X				
Spire Cambridge Lea 30 New Road, Impington Cambridge, CB24 9EL	X	X	X		
Spire Cardiff Croescadarn Road Pentwyn, Cardiff CF23 8XL	X	X	X		
Spire Cheshire Fir Tree Close, Stretton Warrington, Cheshire WA4 4LU	X	X	X	X	
Spire Clare Park Cron dall Lane, Farnham Surrey, GU10 5XX	X				
Spire Dunedin Bath Road, Reading RG1 6NS	X	X	X		
Spire Murrayfield Hospital 122 Corstorphine Road Edinburgh, EH12 6UD	X	X	X		Beechwood House
Spire Elland Elland Lane, Elland West Yorkshire, HX5 9EB	X	X	X	X	



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		Bedroom	OPD/ Clinic Room	Porta Cabins	Additional Locations
Spire Fylde Coast St Walburgas Road Blackpool, Lancashire FY3 8BP	X				
Spire Gatwick ark Cross Road, Horley Surrey, RH6 0BB	X	X		X	
Spire Harpenden Ambrose Lane, Harpenden Hertfordshire, AL5 4BP	X	X			ONC unit
Spire Hartswood Eagle Way, Brentwood Essex, CM13 3LE	X	X			
Spire Hull Lowfield Road, Anlaby East Yorkshire, HU10 7AZ	X	X			
Spire Leeds, Jackson Ave Roundhay, Leeds, LS8 1NT	X	X			
Spire Leicester Gartree Road, Oadby Leicester, LE2 2FF	X	X			
Spire Little Aston Little Aston Hall Drive Sutton Coldfield, B74 3UP	X	X			
Spire Liverpool 57 Greenbank Road Liverpool, L18 1HQ	X		X		
Spire London East Roding Lane South Redbridge, Essex IG4 5PZ	X	X	X	X	
Spire Manchester 170 Barlow Moor Road Didsbury Manchester M20 2AF	X				



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		Bedroom	OPD/ Clinic Room	Porta Cabins	Additional Locations
Spire Methley Park Methley Lane, Methley Leeds, LS26 9HG	X	X	X		
Spire Montifiore 2 Montefiore Road Hove, East Sussex BN3 1RD	X	x			
Spire Norwich Old Watton Road Colney, Norwich NR4 7TD	X	x			Pathology room OPD
Spire Nottingham Tollerton Lane Tollerton, Nottingham NG12 4GA	X	X			Pod on Willow Wood One unit Side room on ICU
Spire Parkway 1 Damson Parkway Solihull, Birmingham West Midlands, B91 2PP	X	X	X	X	
Spire Portsmouth Bartons Road, Havant PO9 5NP	X	X			
Spire Regency West Street, Macclesfield Cheshire, SK11 8DW	X	X			
Spire South Bank 139 Bath Road, Worcester WR5 3YB	X	X			
Spire Southampton Chalybeate Close Southampton, SO16 6UY	X	X	X		CCU
Spire St Anthony's 801 London Road Cheam, Sutton Surrey, SM3 9DW					





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		Bedroom	OPD/ Clinic Room	Porta Cabins	Additional Locations
Spire Sussex, The Ridge St Leonards On Sea East Sussex, TN37 7RE	X	X			
Spire Thames Valley Wexham Street, Wexham Bucks, SL3 6NH	X	X			
Spire Tunbridge Fordcombe Road Tunbridge Wells, Kent TN3 ORD	X	X			
Spire Washington Picktree Lane, Rickleton Washington, NE38 9JZ	X	X			
Spire Wellesley Eastern Avenue Southend-on-Sea, Essex SS2 4XH	X	X	X	X	
Spire Wirral Holmwood Drive Thingwall, Wirral Merseyside, CH61 1AU	X				
Spire Yale Wrexham Technology Park Croesnewydd Road Wrexham, LL13 7YP	X	X			