Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8314

Accredited to ISO 15189:2022

Spire Healthcare Limited

Issue No: 022 **Issue date:** 21 August 2026

Spire Centennial Park
512 Centennial Avenue
Elstree
WD6 3SU
United Kingdom

Contact: Fiona McLeman
Tel: +44 (0) 77 2073 6827
E-Mail: spirepathologyaccreditation@spirehealthcare.com
Website: https://www.spirehealthcare.com/pathology/

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
Spire Centennial Park 512 Centennial Avenue Elsetree WD6 3SU	**Local contact** Name: Lesley Bloom	Haematology Biochemistry Microbiology	A1
Spire Dunedin 6 Bath Road Reading RG1 6NS	**Local contact** Name: Lesley Bloom	Haematology	A2
Spire Southampton Chalybeate Close Southampton SO16 6UY	**Local contact** Name: Rosie Burns	Haematology Biochemistry Blood Transfusion Microbiology	B1
Spire Portsmouth Bartons Road Havant PO9 5NP	**Local contact** Name: Rosie Burns	Haematology	B2
Spire Leeds Jackson Avenue Leeds West Yorkshire LS8 1NT	**Local contact** Name: Caroline Smith	Haematology Biochemistry Blood Transfusion	C1
Spire Washington Picktree Lane Rickleton Washington NE38 9JZ	**Local contact** Name: Caroline Smith	Haematology	C2

Laboratory locations (cont'd):

Location details		Activity	Location code
Spire Hull & East Riding Lowfield Road Anlaby Hull HU10 7AZ	**Local contact** Name: Caroline Smith	Haematology	C3
Spire Histology Centre Parkway 1 Princess Road Manchester M14 7LU	**Local contact** Name: Anthony Gledhill	Cellular Pathology	D1
Spire Manchester 170 Barlow Moor Road Didsbury Manchester M20 2AF	**Local contact** Name: Anthony Gledhill	Haematology Biochemistry Blood Transfusion Microbiology	E1
Spire Parkway 1 Damson Parkway Solihull Birmingham B91 2PP	**Local contact** Name: Peter Manning	Haematology Biochemistry Blood Transfusion	F1
Spire Little Aston Little Aston Hall Drive Sutton Coldfield B74 3UP	**Local contact** Name: Peter Manning	Haematology	F2
Spire Nottingham Tollerton Lane Tollerton Nottingham NG12 4GA	**Local contact** Name: Priscilla Patel	Haematology Biochemistry Blood Transfusion Microbiology	G1
Spire Leicester Gartree Road Oadby Leicester LE2 2FF	**Local contact** Name: Priscilla Patel	Haematology	G2
Spire Murrayfield 122 Corstorphine Road Edinburgh EH12 6UD	**Local contact** Name: Symon Lockhart	Haematology Biochemistry Blood Transfusion Microbiology	H1

Laboratory locations (cont'd):

Location details		Activity	Location code
Spire Hartswood Eagle Way Brentwood CM13 3LE	**Local contact** Name: Kirolos Gabiows	Haematology Biochemistry Blood Transfusion	I1
Spire St Anthonys 801 London Road North Cheam SM3 9DW	**Local contact** Name: Elke Stevenson	Haematology Biochemistry Blood Transfusion Microbiology	J1
Spire Montefiore 2 Montefiore Road Brighton and Hove Hove BN3 1RD	**Local contact** Name: Elke Stevenson	Haematology Biochemistry	J2
Spire Bristol The Glen Redland Hill Durdham Road Bristol BS6 6UT	**Local contact** Name: Rachel Ward	Haematology Biochemistry Blood Transfusion	K1

Site activities performed away from the locations listed above:

Location details	Activity
Spire Alexandra	Blood Fridge with electronic issue
Spire Bushey	Blood Fridge
Spire Cardiff	Blood Fridge with electronic issue Specimen Reception
Spire Elland	Blood Fridge with electronic issue
Spire Methley Park	Blood Fridge with electronic issue
Spire Cheshire	Blood Fridge with electronic issue
The Pines Hospital	Blood Fridge
Spire Wirral	Blood Fridge with electronic issue
Spire Regency	Blood Fridge with electronic issue
Spire Shawfair	Blood Fridge

Site activities performed away from the locations listed above (cont'd):

Location details	Activity
Spire Harpenden	Specimen reception
Spire Gatwick Park	Blood Fridge with electronic issue Specimen Reception
Spire Thames Valley	Specimen Reception
Spire Yale	Blood Fridge with electronic issue
Spire Hull	Blood Fridge with electronic issue
Spire London East	Blood Fridge with electronic issue
Spire Cambridge Lea	Blood Fridge with electronic issue Specimen Reception
Spire Liverpool	Blood Fridge with electronic issue
Manchester Private Hospital	Blood Fridge with electronic issue

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS	Haematology examinations for the purposes of clinical diagnosis	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	Horiba Yumizen H2500, using impedance, cytochemistry and absorbance with SPS-HM-SOP1500. *A1 Only	A1, E1
	Mean Cell Volume Mean Cell Haemoglobin Mean Corpuscular haemoglobin concentration Red cell distribution width-CV Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Reticulocyte count*	Horiba Yumizen H1500 Analyser using impedance, cytochemistry and absorbance with SPS-HM-SOP1500	B1, C1, F1, G1, I1, J1, K1
EDTA Whole Blood	Full Blood Count Haemoglobin White Blood Cell Count Red Blood Cell Count Platelet Count Haematocrit Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Red cell distribution width (RDW-CV)	Horiba Yumizen H550 using impedance, cytochemistry and absorbance, SPS-HM-SOP1700	A1, A2, , B1, B2, C1, C2, C3, E1, F1, F2, G1, G2, H1, I1, J1, J2, K1
Citrated Plasma Serum/Heparinised plasma	Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) International Normalised Ratio(INR) Activated Partial Thromboplastin Ratio (APTR) Fibrinogen	Stago STA Compact Max with specific reference to SOP SPS-HM-SOP1200	B1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Citrated Plasma	Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) International Normalised Ratio (INR)	Stago Satellite Max analyser, SPS-HM-SOP1900	A1, C1, E1, F1, G1, H1, I1, J1, K1
	Fibrinogen		E1, G1, J1
	D-Dimer		A1, I1, J1
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Manual ESR Westergren vacuette method using SPS-HM-SOP0600	A1, B1, C1, E1, F1, G1, H1, I1, J2, K1
		Vital Diagnostics Mix rate X20 analyser using SPS-HM-SOP0600	J1
EDTA Whole Blood	Blood film assessment for detection of abnormal cell type, morphology, and white cell differential	Staining using May Grunwald/Geimsa and SOP Blood Films SPS-HM-SOP0500	A1
		Haematek 3000 slide stainer using SOP SPS-HM-SOP0500	J1
		Manual staining using Clin-Tech Speedy Diff kit and stain with SPS-HM-SOP0500	B1, C1, F1, G1, H1, I1, J2, K1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis:	Documented in-house Methods and Manufacturer's instructions	
Whole blood EDTA & plasma	ABO/Rh/Kell groups	Automated method using Grifols Eflexis Analyser using DG Gel technology and SPS-BT-SOP0400	B1, C1, E1, F1, G1, H1, I1, J1, K1
Whole blood EDTA & plasma	ABO/Rh/Kell groups	Manual method using Grifols Gel Cards and SPS-BT-SOP0200	B1, C1, E1, F1, G1, H1, I1, J1, K1
Whole blood EDTA & plasma	Antibody identification for the following antibodies: D, C, E, c, e Cw, K, k, Kpa, Jsa, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua, Cob, Xga	Manual method using Grifols Gel Cards and SPS-BT-SOP0200	B1, H1, I1, J1, K1
Whole blood EDTA & plasma	Determination of phenotypes: (Rh), C, c, E, e & K (Kell)	Manual method using Grifols Gel Cards and SPS-BT-SOP0200	J1
Whole blood EDTA & plasma	Antibody screen for the following antibodies: D, C, E, c, e Cw, K, k, Kpa, Jsa, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua, Cob, Xga	Automated method using Grifols eFlexis Analyser using DG Gel technology and SPS-BT-SOP0400	B1, C1, E1, F1, G1, H1, I1, J1, K1
		Manual method using Grifols Gel Cards and SPS-BT-SOP0200	B1, C1, E1, F1, G1, H1, I1, J1, K1
Whole blood EDTA & plasma	Serological cross matching	Manual method using Grifols Gel Cards and SPS-BT-SOP0200	B1, C1, E1, F1, G1, H1, I1, K1, J1
Whole blood EDTA & plasma	Direct antiglobulin test	Manual method using Grifols Gel Cards and SPS-BT-SOP0200	B1, J1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant	
Serum, plasma	Quantification of the following: Urea Creatinine Sodium Potassium GGT Total Protein Cholesterol Triglycerides HDL Phosphates Albumin ALP ALT Amylase AST Total Bilirubin Calcium CK Glucose CRP LDH Magnesium Uric Acid Calculated Parameters: eGFR Adjusted calcium Globulin Non-HDL Cholesterol AKI Low Density Lipoprotein Cholesterol (LDL)	Roche Cobas C311 using SPS-BC-SOP0100	J2

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
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: Alanine Transaminase (ALT) Albumin Alkaline Phosphatase (ALP) Anti-Mullerian Hormone (AMH)[1] Amylase Bilirubin (Total) Calcium Cholesterol Creatinine Creatinine Kinase C-Reactive Protein Ferritin Follicle Stimulating Hormone (FSH)* Free triiodothyronine 3 (FT3)* Free triiodothyronine 4 (FT4) Gamma-Glutamyl Transpeptidase (GGT) Glucose High-density Lipoproteins Iron* Lactate Dehydrogenase (LDH) Luteinising Hormone (LH)* Magnesium Oestradiol* Phosphate Potassium Prolactin* Sodium Total Protein (TP) Triglycerides Thyroid-stimulating Hormone (TSH) Urea Uric Acid Unsaturated Iron Binding Capacity (UIBC)*	Roche Cobas Pure c303/e402 colorimetric, enzymatic, immunoturbidimetry SPS-BC-SOP1200	A1, B1, C1, E1, F1, G1, H1, I1, J1, K1 *A1 only [1] E1 only
	Bicarbonate		A1, K1
Whole blood	Haemoglobin HbA1c		A1, E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Quantification of the following:	Roche Cobas Pure c303/e402 colorimetric, enzymatic, immunoturbidimetry SPS-BC-SOP1200	E1
Faeces	Calprotectin Elastase		
Serum, plasma	Acetaminophen (paracetamol) Salicylate Valproate		E1
	Chloride		A1, B1, E1
	Calculated parameters: Non-HDL Cholesterol AKI Staging FPSA Ratio Fibrosis-4		B1, C1, F1, , H1, I1, J1, K1
	Aspartate Aminotransferase (AST)		A1, C1, E1, H1, K1, J1
	Vitamin B12 CA-125 CEA Folate TPSA FPSA		B1, C1, F1, H1, I1, J1, K1
	Lithium		E1
Serum, plasma	Quantification of the following: IgA IgG IgM	Roche Cobas Pure c303/e402 colorimetric, enzymatic, immunoturbidimetry immunoassay competitive and sandwich principles and SPS-BC-SOP1200	A1
Serum, plasma	Quantification of the following: Parathyroid Hormone (PTH)	Roche Cobas Pure c303 e402 colorimetric, enzymatic, immunoturbidimetry SPS-BC-SOP1200	B1, C1, F1, I1, J1, K1
	Troponin		I1, J1, K1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum, plasma	Quantification of the following: Calculated parameters: Adjusted calcium Low density lipoprotein Globulin eGFR		A1, B1, C1, F1, G1, H1, I1, J1, K1
Serum, plasma	Quantification of the following: Angiotensin Converting Enzyme (ACE)* Alanine Transaminase (ALT) Albumin Alkaline Phosphatase (ALP) Alpha-fetoprotein (AFP) Amylase Anti-Mullerian Hormone (AMH)[1] Apoliprotein (APO A)[1] Apoliprotein (APO B)[1] Aspartate Aminotransferase (AST) Bicarbonate Bilirubin (Total) Direct Bilirubin* Calcium Cancer Antigen 125 (CA-125) Cancer Antigen 15-3 (CA 15-3) Cancer Antigen 19-9 (CA 19-9) Carcinoembryonic antigen (CEA) Cholesterol Chloride Cortisol Creatinine Creatinine Kinase C-Reactive Protein Ferritin Folate Follicle Stimulating Hormone (FSH) Free Prostate specific antigen (FPSA)	Roche Cobas Pro ISE/C503/E801 using colorimetric, enzymatic, ISE and immunoturbidimetry, immunoassay competitive and sandwich principles and SPS-BC-SOP1500	A1, E1 *A1 only [1] E1 only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
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 (cont'd): Free triiodothyronine 3 (FT3)* Free triiodothyronine 4 (FT4) Gamma-Glutamyl Transpeptidase (GGT) Gentamicin* Glucose HCG-Beta* High-density Lipoproteins Insulin* Iron Lactate Dehydrogenase (LDH) Lipoprotein (a))[1] Luteinising Hormone (LH) Magnesium Oestradiol Phosphate Parathyroid Hormone (PTH) Potassium ProBNP* Prolactin Progesterone* Sex hormone binding globulin (SHBG)* Sodium Testosterone* Thyroid-stimulating Hormone (TSH) Total PSA Total Protein (TP) Triglycerides Troponin T Urea Uric Acid Unsaturated Iron Binding Capacity (UIBC)* Vitamin B12	Roche Cobas Pro ISE/C503/E801 using colorimetric, enzymatic, ISE and immunoturbidimetry, immunoassay competitive and sandwich principles and SPS-BC-SOP1500	A1, E1 *A1 only [1] E1 only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
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	
Whole Blood	Quantification of the following (cont'd):	Roche Cobas Pro ISE/C503/E801 using colorimetric, enzymatic, ISE and immunoturbidimetry, immunoassay competitive and sandwich principles and SPS-BC-SOP1500	A1, E1 *A1 only [1] E1 only
	Haemoglobin A1c		
Serum, plasma	<u>Calculated parameters:</u> Corrected/adjusted calcium Low density lipoprotein Cholesterol Globulin eGFR FPSA ratio AKI Staging Non-HDL cholesterol Fibrosis-4 Free Androgen Index* Free/Total PSA ratio* Total Iron Binding Capacity (TIBC)* Free calculated Testosterone* Transferrin Saturation *		
	Lithium[1]		E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Urine	Quantification of the following (cont'd): Urine Amylase Urine Calcium Urine Chloride Urine Creatinine Urine Glucose Urine Magnesium Urine Phosphate Urine Potassium Urine Sodium Urine Uric acid Urine Total protein Urine Urea Calculated parameters Urine Protein / Creatinine Ratio Urine Calcium / Creatinine Ratio Urine Calcium / Creatinine Clearance Ratio Urine 24 hour Creatinine Clearance	Roche Cobas Pro ISE/C503/E801 using colorimetric, enzymatic, ISE and immunoturbidimetry, immunoassay competitive and sandwich principles and SPS-BC-SOP1500	A1
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	A1
Faeces	Faecal Immunochemical Testing (FIT) for symptomatic testing	HM-JACKarc faecal immunochemical testing (FIT) using SPS-BC-SOP0900	E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS (cont'd)	Serology examinations for the purposes of clinical diagnosis Qualitative detection of the following:	In-house documented procedures based on equipment manuals as relevant	
Heparinised Blood	TB Quantiferon	Diasorin Liaison XL using direct, sandwich chemiluminescence immunoassay (CLIA) with SPS-VL-SOP0400	E1
Serum	Herpes simplex virus (HSV) 1 and 2 IgG	Diasorin Liaison XL using direct, sandwich chemiluminescence immunoassay (CLIA) with SPS-VL-SOP0400	E1
Serum	Qualitative detection of the following: Cytomegalovirus (CMV) IgG Cytomegalovirus (CMV) IgM Epstein-Barr Virus (EBV) viral capsid antigen (VCA) IgG Epstein Barr Virus (EBV) viral capsid antigen (VCA) IgM Epstein-Barr Virus Nuclear Antigen (EBNA) Toxoplasma IgG Toxoplamsa IgM Varicella Zoster IgG Measles IgG Mumps IgG	VIDAS Analyser and SOP SPS-VL-SOP0300	E1
Serum, plasma	Qualitative detection of the following: Hepatitis B Surface Antigen Hepatitis B Core Antibody Hepatitis B Antibody Hepatitis C Antibody Hepatitis A IgM HIV Rubella IgG Syphilis IgG IgM	Roche Cobas Pure c303 e402 colorimetric, enzymatic, immunoturbidimetry with SPS-BC-SOP1200	E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES	Microbiology examinations for the purpose of clinical diagnosis	In-house documented methods based on related UKHSA Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant	
Swabs from Ear, Eye, Nose, Throat, Mouth, Skin, wounds, faeces, genitals. Exudates, pus, corneal scrapes, IUCD, tips, indwelling cannulae and catheters	Microscopic examination and isolation and characterisation of micro-organisms of clinical significance	Manual culture methods SPS-MI-SOP0200	A1, E1
Urine	Quantification of white blood cells, red blood cells, casts and epithelial cells culture, isolation and characterisation of micro-organisms of clinical significance	Examination of urines using light microscopy and disposable counting chambers (Immune Systems Fastread 102) and culture SOP SPS-MI-SOP0400	A1,
Urine		Examination of urines using inverted microscopy, Microtitre trays and culture, isolation and characterisation of micro-organisms of clinical significance SOP SPS-MI-SOP0400	E1
Faeces	Isolation and characterisation of enteric pathogens	Examination of faeces using culture SPS-MI-SOP0300 - Investigation of samples for enteric pathogens and parasites (non-blood)	A1, E1
Faeces	Detection of Cryptosporidium oocysts	Examination of faeces using fluorescent microscopy SPS-MI-SOP0300 - Investigation of samples for enteric pathogens and parasites (non-blood) SPS-MI-SOP0300	E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods based on related UKHSA UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant	
	Detection of C.difficile GDH and C.difficile toxin A & B	Alere Techlab C diff Quik Chek Complete. Rapid membrane enzyme immunoassay	A1, E1
	Detection of *Helicobacter pylori* antigen	Prolab Proflow lateral flow immunoassay	E1
Faeces, urine, fluids	Detection of ova cysts and parasites	Manual concentration and light microscopy method using Parasep concentrations and SPS-MI-SOP0300	E1
Sellotape slide	Detection of ova of *Enterobius vermicularis*	Light microscopy SPS-MI-SOP0300	E1
Synovial Fluid	Detection of MSU and CPP crystals	Examination using birefringent polarised light microscopy SPS-MI-SOP0500	A1, E1
Tissue	Detection of MSU and CPP crystals	Examination using birefringent polarised light microscopy SPS-MI-SOP0500	A1
CSF, body fluids, tissue and bone	Quantification of white blood cells, red blood cells, culture, isolation and characterisation of micro-organisms of clinical significance	Examination of specimens from sterile sites using light and polarised microscopy and culture SPS-MI-SOP0500	A1, E1
Sterile fluids, tissue and tips			E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods based on related UKHSA UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant	
Blood, sterile fluids	Culture, isolation and detection of microorganisms	BD BACTEC FX40 for automated blood culture and sterile fluid enrichment SPS-MI-SOP1300	A1, E1
Blood	Detection of microbial growth (reporting of negative samples only)	BD BACTEC FX40 blood culture analyser and SPS-MI-SOP1300	B1, C1, G1, H1, J1
Sputum, Bronchio-alveolar lavage (BAL), sinus aspirates, antral washouts	Culture, isolation and characterisation of micro-organisms of clinical significance	Methods for investigation of respiratory samples using light microscopy and cultureSPS-MI-SOP0600	A1, E1
Bacterial isolates obtained from agar culture methods	Bacterial susceptibility testing	Beckman Coulter Microscan DxM1040 Walkaway for automated bacterial susceptibility testing SPS-MI-SOP1000	A1, E1
Isolates of bacteria, fungi and yeasts	Identification of Filamentous Fungi	Automated method using Bruker MALDI ToF Biotyper Sirius SPS-MI-SOP1100	E1
	Identification of bacteria and yeasts	Automated method using Bruker MALDI ToF Biotyper Sirius SPS-MI-SOP1100	A1, E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods based on related UKHSA UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant	
Isolates of bacteria	Identification of bacteria	Staining, light microscopy and biochemical reactions SPS-MI-SOP0800 - Manual identification and susceptibility testing	
		Oxidase test, chemical reaction	A1, E1
		Urease test, chemical reaction	E1
		Beta lactamase using nitrocefin disc	A1, E1
		Catalase test, chemical reaction	E1
		Optochin, growth inhibitor	A1, E1
		Enteric serology, slide agglutination	A1, E1
		Staph latex agglutination, Pro-lab Staph kit	A1, E1
		Strep grouping using Prolab Strep grouping kit	A1, E1
		E coli O157 using Prolab E. coli O157 latex kit	A1, E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods based on related UKHSA UK Standards for Microbiology Investigations (SMI's), incorporating manufacturers' instructions where relevant	
Isolates of bacteria(cont'd)	Identification of bacteria (cont'd)	Staining, light microscopy and biochemical reactions SPS-MI-SOP0800 - Manual identification and susceptibility testing	
		Antimicrobial susceptibility testing and resistance mechanisms using manual antibiotic disc diffusion susceptibility testing using Oxoid antibiotic discs and Liofilchem gradient MIC strips	A1, E1
		Detection of Methicillin resistant staphylococcus aureus using Abbot Clearview PBP2a latex kit	A1, E1
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 and Safranin	A1, E1
skin, hair and nails	Identification of fungi of clinical significance	Light Microscopy and Lactofuchsin staining from manual culture methods for fungal growth following SOP, SPS-MI-SOP0700 - Investigation of Dermatological Specimens for Superficial Mycosis	E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES AND FLUIDS	Molecular examination procedures for the purposes of clinical diagnosis	Documented in house methods:	
Vaginal swab, endocervical swab, urine	Detection of: Trichomonas vaginalis Chlamydia trachomatis Neisseria gonorrhoeae	PCR method using BD-MAX SPS-MI-SOP1200	A1, E1
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat)	Detection of : SARS-CoV-2 (N1 and N2) Influenza A and Influenza B Human Respiratory Syncytial Virus A/B (RSV)	PCR molecular techniques using Cepheid GeneXpert SPS-MI-SOP0900	A1
Isolates of bacteria from rectal swabs and faeces	Detection of Carbapenemase Producing Organisms	PCR method using the BD Max SPS-MI-SOP1200	A1, E1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	Histopathology examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manual as relevant	
Formalin fixed tissues	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-SOP0200	D1
		Tissue processing: Automated method using Leica ASP300S and Peloris IITissue Processors and SOP SPS-HT-SOP0300	D1
		Paraffin wax tissue embedding Manual method using SOP SPS-HT-SOP0400	D1
		Microtomy Manual method using Histocore Biocut SOP SPS-HT-SOP0500	D1
Formalin fixed paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin and Eosin (H&E) staining using Sakura Tissue Tec Prisma stainers and coverslipper and SOP SPS-HT-SOP0600	D1
	Detection of the following:	Special Staining using in house manual methods following SOP SPS-HT-SOP0600	
	Liberated aldehydes	Periodic Acid Schiff's (+/- diastase)	D1
	Acid and sulphated mucins	Alcian Blue	D1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
Formalin fixed paraffin embedded (FFPE) tissue	Detection of the following:	Special Staining using in house manual methods following SOP SPS-HT-SOP0600	D1
	Helicobacter pylori	Modified Giemsa	
	Acid fast bacilli	Ziehl Neelsen	
	Haemosiderin	Perls Prussian Blue	
	Fungal Hyphae	Grocott	
	Hep B	Orcein	
	Reticulin Fibres	Retic	
	Elastic fibres and collagen	Elastic Van Gieson	
	Blood and Elastic Tissue	HVG	
	Amyloid	Congo Red	
	Collagen and smooth muscle	Masson Trichrome	
	Fibrin	Martius Scarlet Blue (MSB)	
	Gram positive and Gram-negative organisms	Gram	
	Mast cell granules	Toluidine Blue	
	Collagen and fibrin	Haematoxylin Picro-Sirius Red (HPSR)	
	Melanin	Masson Fontana	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
Formalin fixed paraffin embedded (FFPE) tissue	Detection of the following:	Special Staining using Roche BenchMark Special stainer with SPS-HT-SOP0600	D1
	Acid mucins and neutral mucins	Alcian Blue/DPAS	
	Acid mucins and neutral mucins and glycogen	Alcian Blue PAS/PASD PAS/PASF/PASD	
	Fungal Hyphae	Grocott	
	Elastic fibres and collagen	Elastic Van Gieson	
	Collagen and smooth muscle	Masson Trichrome	
	Haemosiderin	Perls Prussian Blue	
	Reticulin Fibres	Retic	
	Acid Fast Bacilli	Ziehl Neelsen	
Stained slides from tissue above	Examination to identify or exclude morphological abnormalities	Microscopic examination and reporting using in-house procedures and SPS-IT-SOP0600E	D1
Digital images from slides prepared in-house	Morphological assessment and interpretation / diagnosis	Sysmex 3DHISTECH P1000 scanners with Tribun CaloPix Image management system interfaced with Roche Ventana Vantage using SPS-HT-SOP1100, SPS-HT-SOP1700, SPS-HT-SOP1800, SPS-HT-SOP1600	D1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue	Detection of the following:	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	Smooth muscle	Actin	
	Sebaceous gland marker	Adipophilin	
	Pan-cytokeratin	AE1/AE3, MNF-116	
	Germ cell tumours	AFP	
	Prognostic cancer marker	Androgen Receptor	
	Mantle zone B lymphocytes & interfollicular T lymphocytes	Bcl-2	
	Large B-cell lymphomas	Bcl-6	
	Cell membranes and glycoproteins	BerEP4	
	Fibromatosis in Breast/ Abdomen	Beta-Catenin	
	Colorectal cancer and Melanoma	BRAF v600e	
	Apocrine epithelium	GCDFP-15	
	Ovarian Carcinomas	CA125	
	Renal cancers	CAIX	
	Medullary Carcinoma of Thyroid	Calcitonin	
	Oesopahgus, Smooth Muscle from bowel and Uterus.	Caldesmon	
	Oesopahgus, Smooth Muscle from bowel and Uterus	Calponin	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	Mesothelial cell marker	Calretinin	
	Simple and glandular epithelium	CAM 5.2	
	Corticol thymocytes and Langerhann cells	CD1a	
	T cell lymphocytes	CD2	
	T cell Lymphocytes	CD3	
	T-cell lymphocytes	CD4	
	T-cell lymphocytes	CD5	
	Immature and mature T-cells	CD7	
	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	
	Differentiating gastrointestinal stroma tumours from Kaposi's sarcoma and tumours of smooth muscle origin	CD117	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	Hodgkin lymphoma and Anaplastic large cell lymphoma	CD30	
	Neoplasms of vascular origin	CD31	
	Haemopoietic precursor cells; endothelial cells; fibroblasts	CD34	
	Pan lymphocyte marker	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	
	Adenocarcinomas of Colon/Colon mucosa	CEA	
	Neuroendocrine conditions.	Chromogranin A	
	Proliferating squamous epithelium	CK5/6	
	Simple, glandular & transitional epithelia	CK7	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	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	
	Lymphatic endothelium	Podoplanin (D2-40)	
	Smooth and striated muscle cells	Desmin	
	Gastrointestinal stroma tumours (GIST)	DOG1	
	Adenocarcinoma or mesothelioma in Lung, G.I. tract and Ovary	E-Cadherin	
	Epithelial membrane on glandular tissue.	EMA	
	Breast carcinomas.	ER	
	Endothelial cells and neoplastic blood cells.	Factor VIII	
	Platelets, megakaryocyte and fibroblast.	Factor XIIIa	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	breast carcinomas and urothelial carcinomas	GATA3	
	Helicobacter pylori infection	H.PYLORI	
	Marker of Her 2 amplification in breast tumour	Her-2	
	Trophoblastic tumours in testis	HCG	
	Adrenal cortical tumours and renal cell carcinomas.	Inhibin	
	Light Chain and heavy chain identification	Kappa	
	Cell proliferation rate	Ki67	
	Light and heavy chain identification	Lambda	
	Melanin / melanoma marker	Melan A	
	Several cancer types for detection of mismatch repair proteins	MMR Panel: • MLH1 • MSH2 • MSH6 • PMS2	
	Human melanoma black 45 antigen	HMB45	
	Marker for Reed Sternberg cells and Lymphocyte marker for lymphoid malignancies	MUM-1	
	Adenocarcinoma marker for lung	Napsin	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	Detection of prostate intraepithelial neoplasia	P504S/AMACR	
	Detection of the presence of HPV in tissue	P16	
	Identification of lung adenocarcinoma and basal cell marker for prostate cancer	P40	
	Colon Adenocarcinoma	P53	
	Normal proliferating cells; squamous cell carcinoma, basal cells; abluminal cells	P63	
	B-Cells	PAX5	
	Thyroid carcinoma, RCC and ovarian non-mucinous carcinoma	PAX8	
	Germ cell tumours	PLAP	
	Breast carcinomas	PR	
	Melanoma marker	PRAME	
	Prostate marker	PSA	
	Hyperplastic prostate or carcinoma of prostate	PSAP	
	Renal cancer marker	RCC	
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres	S100	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUES (cont'd)	Histopathology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using the Roche Ventana Ultra for the following antibodies: SPS-HT-SOP0700.	D1
	Smooth muscle marker	Smooth muscle myosin	
	Skin melanoma	SOX10	
	Pancreatic Islet cells	Synaptophysin	
	Follicular carcinomas of the thyroid.	Thyroglobulin	
	Thyroid transcription factor-1 (Thyroid follicular & C cells)	TTF1	
	Vimentin intermediate filament	Vimentin	
	Ovarian carcinomas and mesotheliomas	WT1	
FFPE tissue	HER2 DDISH for breast tumours	Roche Ventana Ultra using Dual-colour dual-hapten in situ hybridization and DNA probe cocktail SPS-HT-SOP0700	D1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS	Diagnostic Cytology examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant	
Urine, abdominal fluid, synovial fluid, FNA (breast and thyroid), serous fluid, cyst fluid	Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities	In-house procedures: SPS-HT-SOP0800 Non-Gynae Cytology in conjunction with manufacturer's instructions using Hologic Thinprep Genesis	D1
		Automated staining using Sakura DRS2000 stainer using Papanicolaou stain and SPS-HT-SOP0800	D1
END			