


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9769</p> <p>Accredited to ISO 15189:2012</p>	<p>Southwest Pathology Services LLP</p> <p>Issue No: 011 Issue date: 02 January 2025</p>	
	<p>Lisieux Way Taunton TA1 2LB</p>	<p>Contact: Derek Truman Tel: +44 (0) 1823 346 700 E-Mail: Derek.Truman@tst.nhs.uk Website: www.southwestpathology.com</p>
<p>Testing performed at the above address only</p>		

Location details		Activity	Location code
<p>Address ESL Laboratory Musgrove Park Hospital Taunton TA1 5DA</p>	<p>Local Contact Dr Andrzej Karmolinski Dr Katy Marden Dr Lisa Lowry Dr Sadie Thomas</p>	<p>Histology Microbiology on-call service Blood Sciences including Transfusion</p>	M
<p>Address Yeovil District Hospital Higher Kingston Yeovil BA21 4AT</p>	<p>Local Contact Dr Edwin Cooper</p>	<p>Histology Blood Sciences including Transfusion</p>	Y
<p>Address Hub Laboratory Southwest Pathology Services Lisieux Way Taunton TA1 2LB</p>	<p>Local Contact Dr Andrzej Karmolinski Dr Katy Marden Dr Lisa Lowry Dr Sadie Thomas</p>	<p>Non-Gynae Cytology Microbiology Blood Sciences (including Immunology) Andrology</p>	H



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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
Serum, Heparin, Plasma	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of:	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
	Albumin	SOPBVS72, BCG colourimetric method	M, Y, H
	Albumin	SOPBVS171, BCP colourimetric method	H
	Alkaline Phosphatase (ALP)	SOPBVS74, Colourimetric	M, Y, H
	Alpha-1-Antitrypsin	SOPBVS87, Immunoturbidimetric	H
	Alanine Aminotransferase (ALT)	SOPBVS52, Colourimetric	M, Y, H
	Angiotensin Converting Enzyme (ACE)	SOPBVS116, Colourimetric	H
	Asparate Aminotransferase (AST)	SOPBVS76, Colourimetric	M, Y, H
	Bicarbonate	SOPBVS56, Colourimetric	M, Y, H
	Bile Acids	SOPBVS28, Enzymatic/ Colourimetric	M
	Complement 3 (C3)	SOPBVS95, Immunoturbidimetric	H
	Complement 4 (C4)	SOPBVS96, Immunoturbidimetric	H
	Carbamazepine	SOPBVS57, Immunoturbidimetric	M, Y, H
Cholesterol	SOPBVS78, Enzymatic/ Colourimetric	M, Y, H	
Creatine Kinase (CK)	SOPBVS79, Enzymatic/ Colourimetric	M, Y, H	



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Serum, Heparin, Plasma (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of: (cont'd)	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
	C-Reactive Protein (CRP)	SOPBVS80, Immunoturbidimetric	M, Y, H
	Digoxin	SOPBVS98, Immunoturbidimetric	M, Y, H
	Direct Bilirubin (Conjugated Bilirubin)	SOPBVS58, Colourimetric	M, Y, H
	Gentamicin	SOPBVS110, Cedia Immunoassay	M, Y, H
	Gamma Glutamyltransferase (GGT)	SOPBVS103, Colourimetric	M, Y, H
	High Density Lipoprotein (HDL)	SOPBVS59, Immunological/ Colourimetric	M, Y, H
	IgA	SOPBVS100, Immunoturbidimetric	H
	IgG	SOPBVS101, Immunoturbidimetric	H
	IgM	SOPBVS102, Immunoturbidimetric	H
	Iron	SOPBVS60, Colourimetric	M, Y, H
	Methotrexate	SOPBVS113, Enzyme Immunoassay	M
	Serum/Plasma	Paracetamol (Acetaminophen)	SOPBVS39, Enzymatic
Phenobarbitone		SOPBVS65, Cedia Immunoassay	M, Y, H
Phenytoin		SOPBVS62, Cedia Immunoassay	M, Y, H
Rheumatoid Factor		SOPBVS115, Immunoturbidimetric	H
Serum/Plasma	Salicylate	SOPBVS27, Enzymatic	M, Y
	Theophylline	SOPBVS107, Cedia Immunoassay	M, Y



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Serum, Heparin, Plasma (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of: (cont'd)	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
Serum/Plasma	Tobramycin	SOPBVS129, Enzymatics	M, Y
	Total Bilirubin	SOPBVS77, Colourimetric	M, Y, H
	Total Protein	SOPBVS63, Colourimetric	M, Y, H
	Transferrin	SOPBVS119, Immunoturbidimetric	H
	Triglyceride	SOPBVS118, Enzymatic/ Colourimetric	M, Y, H
Serum/Plasma	Vancomycin	SOPBVS111, Enzymatic	M, Y
Serum, Heparin, Plasma, Urine	Amylase	SOPBVS53, Colourimetric	M, Y, H
	Calcium	SOPBVS54, Colourimetric	M, Y, H
	Chloride	SOPBVS105, ISE	M, Y, H
	Creatinine	SOPBVS55, Colourimetric	M, Y, H
	Magnesium	SOPBVS82, Colourimetric	M, Y, H
	Phosphate	SOPBVS109, Colourimetric	M, Y, H
	Potassium and Sodium	SOPBVS105, ISE	M, Y, H
	Urea	SOPBVS104, Enzymatic/ Colourimetric	M, Y, H
	Uric Acid	SOPBVS106, Enzymatic/ Colourimetric	M, Y, H



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Urine	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of: (cont'd)	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
	Methadone	SOPBVS93, Cedia Immunoassay	M
	Opiates	SOPBVS94, Cedia Immunoassay	M
	Urine Albumin (Microalbumin)	SOPBVS117, Immunoturbidimetric	H
	Amphetamine/Ecstasy	SOPBVS88, Cedia Immunoassay	M
	Barbiturate	SOPBVS89, Cedia Immunoassay	M
	Benzodiazepine	SOPBVS90, Cedia Immunoassay	M
	Cannabinoids (THC)	SOPBVS91, Cedia Immunoassay	M
Urine, CSF	Cocaine Metabolite (Benzoyllecgonine)	SOPBVS92, Cedia Immunoassay	M
Urine, CSF	Urine, CSF Protein	SOPBVS123, Colourimetric	M, Y, H
Serum	Lithium	SOPBVS112, Colourimetric	M, Y, H
Serum, Heparin, Plasma, EDTA	Lactate Dehydrogenase (LDH)	SOPBVS61, Colourimetric	M, Y, H
Serum, Heparin, Plasma, Fluoride/ Oxalate Plasma, Urine	Alcohol	SOPBVS73, Enzymatic/ Colourimetric	M, Y, H
Serum, Heparin, Plasma, Fluoride/ Oxalate Plasma, Urine, CSF	Glucose	SOPBVS81, Enzymatic/ Colourimetric	M, Y, H



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	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of: (cont'd)	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
Heparin, Plasma,	Ammonia	SOPBVS75, Enzymatic/ Colourimetric	M, Y
Fluoride, Plasma, CSF	Lactate	SOPBVS121, Enzymatic/ Colourimetric	M, Y
Serum (trace metal tube), Heparin plasma (paediatric tube)	Zinc	SOPBVS70, Colourimetric	M
Faeces	Faecal Calprotectin	PETIA methodology	H
Faeces	Faecal Electrolytes	SOPBSB51, ISE	M, Y
Faeces	Faecal Elastase	SOPBSB50 using Sysmex DS2, Elisa test	H
Serum, Plasma, Urine	Osmolality	SOPBSB6 using Advanced Instruments micro-osmometer, Freezing point depression	M, Y
CSF	Xanthochromia	SOPBSB4 using Thermo Evolution 201 Spectrophotometer	M, Y
Sweat	Sweat Chloride Analysis	SOPBSB45 using Elitech Chlorochek 3400	H
Serum/Plasma	Immunoglobulin E (IgE)	Turbidimetric SOP BVS189	H



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Serum, Heparin, Plasma	<u>Endocrinology, Immunoassay examination activities for the purpose of clinical diagnosis</u>	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of:	Beckman Coulter Dxl, Immunoenzymatic Chemiluminescent analysis using procedure:	
	Alpha FetoProtein (AFP)	SOPBVS2	H
	CA 125	SOPBVS4	H
	CA 153	SOPBVS25	H
	CA199	SOPBVS5	H
	Carcinoembryonic Antigen (CEA)	SOPBVS6	H
	Cortisol	SOPBVS7	M, H
	Ferritin	SOPBVS13	M, H
	Folate	SOPBVS9	H
	Follicle Stimulating Hormone (FSH)	SOPBVS12	H
	Free T3	SOPBVS10	M, Y, H
	Free T4	SOPBVS11	M, Y, H
	Human Chorionic Gonadotrophin (Hcg)	SOPBVS14	M, Y, H
	IgE	SOPBVS15	H
	Luteinising Hormone (LH)	SOPBVS16	H
	Oestradiol	SOPBVS17	M, Y, H
Parathormone (PTH)	SOP BVS21	M, H	
Prolactin	SOPBVS18	H	



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Serum, Heparin, Plasma (cont'd)	<u>Endocrinology, Immunoassay examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Quantification of: (cont'd)	Beckman Coulter Dxl, Immunoenzymatic Chemiluminescent analysis using procedure:	
Serum/Plasma	Prostate Specific Antigen (PSA)	SOPBVS20	H
	Sex Hormone Binding Globulin (SHBG)	Chemiluminescent	H
	Testosterone	SOPBVS22	H
Serum, Heparin, Plasma	Thyroperoxidase Antibody (TPO)	SOPBVS1	H
	Thyroid Stimulating Hormone (TSH)	SOPBVS23 using Beckman	M, Y, H
Serum, Heparin, Plasma	Vitamin B12	SOPBVS3	H
	Vitamin D (25-OH Vitamin D)	SOPBVS38	H
	Cortisol	SOPBVS7	M, H
	Ferritin	SOPBVS13	M, H
	Free T3	SOPBVS10	M, Y, H
	Free T4	SOPBVS11	M, Y, H
	Human Chorionic Gonadotrophin (Hcg)	SOPBVS14	M, Y, H
	Oestradiol	SOPBVS17	M, Y, H
	Parathormone (PTH)	SOP BVS21	M, H
	Progesterone	SOPBVS19	M, Y, H



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Serum, Heparin, Plasma	<u>Endocrinology, Immunoassay examination activities for the purpose of clinical diagnosis</u> (cont'd) Thyroid Stimulating Hormone (TSH)	In-house documented methods incorporating manufacturers' instructions as required Beckman Coulter Access2 Immunoenzymatic Chemiluminescent analysis using procedure: SOPBVS23	M, Y, H
Serum/Plasma	Troponin I (High sensitive)	Chemiluminescent SOPBVS24	M, Y, H
Plasma	N-terminal pro B-type Natriuretic peptide (NT Pro BNP)	SOPBVS26 using Roche Cobas e411, Immunoenzymatic Chemiluminescent	H
Serum, Heparin, Plasma	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> AKI Risk Flag Cholesterol/HDL Ratio Adjusted Calcium eGFR LDL Cholesterol Non-HDL Cholesterol	Calculated tests using LabCentre System and procedure SOP RLR1	M, Y, H
Urine	Osmolar Gap		M, Y
	Transferrin Saturation		H
	24 Hour Urine Calcium/Creatinine Ratio		M, Y
	24 Hour Urine Calcium		M, Y
	24 Hour Urine Potassium		M, Y
	24 Hour Urine Magnesium		M, Y
	24 Hour Urine Sodium		M, Y
	24 Hour Urine Phosphate		M, Y
	24 Hour Urine Uric Acid		M, Y
	24 Hour Urine Urea		M, Y
24 Hour Urine Creatinine		M, Y, H	
24 Hour Urine Protein		M, Y	



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Urine (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Calculated tests using LabCentre System and procedure SOP RLR1	H M, Y M, Y, H M, Y, H M, Y, H M, Y, H M, Y, H M, Y
	Urine Microalbumin/Creatinine Ratio		
	Urine Calcium/Creatinine Ratio		
	Urine Protein/Creatinine Ratio		
Urine, Serum	24 Hr Creatinine Clearance		
Urine, Serum	4 Hr Creatinine Clearance		
Serum	Anion Gap Kappa/Lambda Light Chain Ratio		
CSF	Xanthochromasia Interpretive Comment		
Serum, Plasma	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	In-house documented methods incorporating manufacturers' instructions as required	
	Detection of:	BioPlex 2200 System Multiplex Flow Immunoassay using procedures IMD4, IMS16 and:	
	IgA TTG	IMS17	H
	IgG ANA (dsDNA and ENA)	IMS18	H
	IgG Cardiolipin & IgM Cardiolipin	IMS19	H
	IgG CCP	IMS21	H
Serum	IgG MPO, PR3 and GBM	IMS20	H



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Serum	<u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Detection of: (cont'd)	QUANTA-Lyser 2, NOVA View indirect immunofluorescent assay using procedures IMD9, IMD3, IMS22, IMS23, IMS24 and:	
	IgG ANCA	IMS6	H
	IgG AIP	IMS7	
	IgG ANA	IMS8	H
Serum, Urine	IgA & IgG Endomysial	IMS9	H
	Paraprotein quantitation	BSB7, Sebia Capillarys 2 Flex-piercing, capillary electrophoresis	H
Serum	Free light chains	Binding Site Optilite, BVS166 Immunoturbidimetric method	H
CSF, Bone Marrow, Pleural Fluid EDTA Whole Blood	Leucocyte Immunophenotyping	NAVIOS Flow Cytometry using procedure, HSB34, and: HSB31	H
EDTA Whole Blood	CD4 Enumeration (with absolute count beads)	HSB37	H
Citrate Plasma	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	ACL TOP 350 and 550 HSB54	
	PT/INR	HSB55, Coagulation Method	M, Y, H
	APTT	HSB56, Coagulation Method	M, Y, H
	D-Dimers	HSB58, Immunoassay	M, Y, H
	Fibrinogen	HSB57, Coagulation Method	M, Y, H



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Citrate Plasma (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
		ACL TOP 350 and 550 HSB54	
	Thrombin time	HSB69, Coagulation Method	M, H
	LMWH Heparin assay	HSB75 Chromogenic	M
	FVIII	HSB65, Chromogenic	M, H
	Lupus Anticoagulant	HSB66 Coagulation Method	H
	Thrombophilia Screen: Protein C Protein S ATIII APCR	HSB67 Chromogenic Immunoassay Chromogenic Coagulation Method	H
	Inhibitor (Bethesda assay)	HSB63, Coagulation Method	H
	Intrinsic factor assays (FVIII, FIX, FXI, FXII)	HSB61, Coagulation Method	M, H
	Extrinsic factor assay (FII, FV, FVII, FX)	HSB64, Coagulation Method	H
	vWF Activity	HSB62, Immunoturbidimetric	H
	vWF Antigen	HSB62,, Immunoassay	H
	Correction tests	HSB68, Coagulation Method	M, H
	Rivaroxaban assay	HSB75, Chromogenic	M
Apixaban	HSB75, Chromogenic	M	



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EDTA Blood	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd) Full Blood Count: RBC WBC Platelets Haemoglobin MCV HCT MCH MCHC RDW %HYPO Reticulocyte count Neutrophils Lymphocytes Monocytes Eosinophils Basophils	In-house documented methods incorporating manufacturers' instructions as required Sysmex XN10 HSB81 HSB82 HSB83 HSB84	M, Y, H
EDTA Blood	Erythrocyte Sedimentation Rate (ESR)	Alifax analyser HSB8 SOP	M, Y
	Detection & speciation of malaria parasites <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	HSB10 SOP Commercial CareUS RDT Malaria Kit	M, Y, H
	Manual Method <i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium ovale</i> <i>Plasmodium vivax</i> <i>Plasmodium knowlesi</i>	Fields Staining (Thick films), Giemsa Staining (Thin films)	
	G6PD Screen	HSB2 SOP, BinaxNow G6PD	M



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EDTA Blood/Bone Marrow	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Viscosity	HSB16 SOP, capillary tube	M
Blood	Detection of normal and abnormal morphologies	Light microscopy analysis of slide following manual staining (Wright and Perls) using procedure HSB9 SOP	M
Blood	Blood film assessment for detection of abnormal cell types, morphology and numbers	Sysmex SP50 Automated Blood Film maker HSB80	M, Y, H
CSF, Ascitic Fluid	Morphological assessment of cell types present in serous fluids	Light microscopy analysis of cytopins produced using the Thermo Fisher Cytospin 4 and procedures HSB13	M
EDTA Blood	Sickle cell solubility	Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia (SCT) screening programme as defined in the July 2018 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements.'	
EDTA Blood	Sickle cell solubility	COS19 SOP, Manual solubility test	M, Y, H
EDTA Whole Blood	Haemoglobin A1c	Tosoh G8 Cation Exchange HPLC and procedures:	
	Haemoglobinopathy Screen to determine HbA2 and HbF levels and the presence of abnormal haemoglobins	SOPHSB20 SOPHSB18	H H



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	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In-house documented methods incorporating manufacturers' instructions as required	
Superficial Wound Swabs	Isolation and characterisation of micro-organisms of clinical significance	Kiestra Total Laboratory Automation microscopy, manual gram stain, and manual culture using procedure MGB21 and MGB3 Examination of superficial wound swabs	H, M
Deep Seated Wound Swabs Pus, Drain fluid, Bile, Aspirates, Tissues, Bone, Prosthetic Joints		MGB11 & MGB14 Examination of Pus, Pus swabs from deep seated infections SOP MME4 Microbiology stains	H, M
Body fluids from normally sterile sites (excluding Blood Cultures)		MGB8 – Examination of Body fluids from normally sterile sites MME4 - Microbiology stains MME7 – Performing Cell Counts using counting chambers	H, M
Continuous ambulatory peritoneal dialysis fluid (CAPD)		MGB9 Examination of Continuous ambulatory peritoneal dialysis fluid MME4 Microbiology stains	H, M
CSF and Shunts		MGB7 Examination of CSF and CSF shunts MME4 Microbiology stains MME7 Performing cell counts using counting chambers	H, M
Genital Swabs/Fluids		MGB18 Bacteriological Examination of GU specimens MME4 Microbiology stains	H, M
Eye Swabs, Canalicular Pus, Corneal Scrapes and Intraocular Fluids		MGB6 Eye swabs, canalicular pus, corneal scrapes and intraocular fluids MME4 Microbiology stains	H, M
ENT Swabs including - Ear, Nose, Throat, Mouth, Pernal Swabs		MGB4 Examination of ear, nose, mouth, throat and pernasal swabs	H, M



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High Vaginal Swab (HVS)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd) Enrichment and culture for Group B streptococci	In-house documented methods incorporating manufacturers' instructions as required MGB38	H
Sputum, Bronchial washing and associated respiratory samples, Anstral washouts	Isolation and characterisation of micro-organisms of clinical significance (cont'd)	Kiestra Total Laboratory Automation microscopy, manual gram stain, and manual culture using procedure MGB21 and MGB15 Examination of Sputum and associated specimens MME4 Microbiology stains	H
Urine		the automated microscopy using Beckman IQ200 Analyser Laminar Flow using procedure MGB26 and	H
Urine	Isolation and characterisation of micro-organisms of clinical significance	Manual microscopy and culture using procedure MGB16 Examination of Urine Specimens.	H, M
Faeces	Detection and identification of the following: Ova, cysts and parasites	Concentration microscopy for faecal ova, cysts and parasites.MGB13B3 Examination of Faecal samples for Parasites	H
Perianal swab	Enterobius vermicularis ova	Detection of ova using light microscopy MGB13 Examination of Enteric samples	H
Blood, Bone Marrow and Transfusion Packs	Isolation of microorganisms of clinical significance	BacTec FX blood culture system, automated monitoring of culture bottles. Agar plate culture of positive culture bottles using Kiestra Total Laboratory Automation MGB10 Examination of Blood Cultures, bone marrow and transfusion packs	H, M, Y



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Swabs, Fluids, Respiratory Samples and Tissues Bacterial cultures isolated in-house from all samples listed above	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	MRSA & MSSA Screening Isolation of microorganisms of clinical significance	Agar plate culture using Kiestra Total Laboratory Automation MGB22 MRSA & MSSA screening	H, M
	Antimicrobial susceptibility testing of clinically significant bacteria	EUCAST Disc Diffusion MME22 antimicrobial susceptibility testing	H
		Minimum Inhibitory Concentration (MIC) Testing Strip / agar plate culture MME22 Antimicrobial susceptibility testing	H
		BD Phoenix AP System and Phoenix M50 panel incubation device, automated ID / AST System MGB20 Phoenix ID and AST Analyser	H
Fungal isolates from samples listed above	Antifungal Susceptibility testing	ESBL and AmpC confirmation by combination disc testing using procedure MME24	H
Bacterial cultures isolated in-house from all samples listed above		Sensitite YeastOne, manual MIC microplate method MME17 Antifungal susceptibility testing	H
	Automated Identification of microorganisms of clinical significance from culture	Bruker Maldi-ToF automated ID System MGB28 Using the Maldi-ToF	H
	Manual Identification of microorganisms of clinical significance from culture	Biochemical tests - Oxidase test, Catalase test, Gram stain MGB25 Bacterial Identification MME4 - Microbiology stains	H
	Identification of Staphylococcal isolates	Tube Coagulase test, Prolex Staph Xtra latex MGB25 Bacterial Identification	H



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Bacterial cultures isolated in-house from all samples listed above (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Antigen identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Strep grouping kit MGB25 Bacterial Identification	H
	Antigen identification of Salmonella Polyvalent 'O' (PSO) and 'H' (PSH), plus single factor 'O' and 'H' antisera. Detection of Shigella and Vibrio using specific antisera	Agglutination using Salmonella, Shigella and Vibrio agglutination sera. MGB25 Bacterial Identification	H
Bacterial cultures isolated in-house from Faeces, Rectal samples	Confirmatory identification of Neisseria gonorrhoeae	Gram stain, oxidase test, catalase test MGB25 Bacterial Identification. MME4 Microbiology stains	H
	Carbapenemase Producing Organism (CPO) screen	Selective plate agar culture SOP MGB32 Carbapenemase screening	H
	Confirmation of E. coli 0157	E. coli 0157 latex MME8 0157 Prolab Latex Agglutination	H
Vaginal Smears	Diagnosis of Bacterial vaginosis	Gram stain and microscopy in accordance with Hays Criteria. MGB18 Bacteriological Examination of GU Specimens MME4 Microbiology stains	H



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Aspirates, Fluids, Sputum, Tissue, Urine	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd) Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	In-house documented methods incorporating manufacturers' instructions as required Direct microscopy for Acid Fast Bacilli (AFB) using LJ slope culture and manual inoculation MGIT Mycobacteria liquid culture system, automated monitoring of culture bottles MGB12 Examination of specimens for Acid Fast bacilli MME4 Microbiology stains	H
Skin, Hair, Nail, Mucous membranes, Subcutaneous biopsies, Sinus samples, Clear adhesive tape strips	Isolation & identification of fungal pathogens including: Filamentous moulds Yeasts	Microscopic examination of fungal hyphae using KOH preparation Calcofluor stain. Agar plate culture. MGB22 Investigation of mycology MGB24 Mycology Identification	H
Faeces	Clostridioides difficile GDH antigen screening	R Biopharm ELISA kit performed on DS2 platform VSB18 MGB1	H
Faeces	Clostridioides Toxin A/B	R Biopharm RidaQuick Toxin A/B lateral flow test MGB1	H
Faeces	Identification of Cryptosporidium and Giardia	Launch kit performed on DS2 platform (ELISA) VSB18 MGB13	H
Serum	Semi-quantitative non-treponemal flocculation test	RPR card LSB35	H
Faeces	Molecular detection of the following: Detection of Clostridium difficile toxin	Use of the Cepheid GeneXpert, RT PCR MPS4 and procedures: MGB1 Detection of Clostridium difficile and its toxins in faeces	H
MRSA nasal swabs, Blood cultures	Detection of MRSA	MGB2 MRSA/MSSA screening MGB10 Blood cultures, bone marrow and transfusion packs	H, M



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Bacterial cultures isolated in-house	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd) Carbapenemase detection	In-house documented methods incorporating manufacturers' instructions as required Carba-R assay MPS4 MPS15	H, M
Genital swabs and urine	Detection of Mycoplasma genitalium	SpeeDx ResistancePlus MG flexible kit MPS4 LSB43	H
Respiratory fluids, Sputum	Detection of MTB	MGB12 Examination of specimens for Acid Fast bacilli	H
Faeces	Detection of Helicobacter pylori Antigen	– Investigation of H. pylori. SOP VSB18 - DS2 analyser using Launch HPA ELISA kit (HpSA)	H
Serum/EDTA Plasma	<u>Virology examination activities for the purpose of clinical diagnosis</u> HCV RNA quantification	In-house documented methods incorporating manufacturers' instructions as required Use of the Cepheid GeneXpert, RT PCR MPS4 and procedures: MPS11 Hepatitis C Viral Load and Positive monitoring	H
Faeces, Vomit	Detection of Norovirus	MPS8 Investigation of viral gastroenteritis and diarrhoea by PCR	H
Whole Blood	Factor II and Factor V Mutation genotyping	MPS10 - Factor II and Factor V genotyping	H
Respiratory Fluids	Multiplex PCR testing for SARS-CoV, RSV, FluA and FluB	MPS4 GeneXpert MPS13 Viral Respiratory PCR	M, H, Y
Serum	Hepatitis B viral load		M, H
Faeces	Detection of Rotavirus / Adenovirus	Lateral flow Biorapid (EIA) card test SOP MGB13 – Examination of Enteric samples	H



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Urine	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u> Urinary antigen detection of Legionella pneumophila and Streptococcus pneumoniae	In-house documented methods incorporating manufacturers' instructions as required Lateral flow – BINAX NOW card test. SOP VSB 9 – Urinary antigen tests	H
CSF	Viral PCR detection in CSF	Launch Fast Track Diagnostics Viral Meningitis panel MP7 PCR detection of viruses from CSF Hologic Panther system MPS3 Panther system for use with Hologic assays:	H
Genital, Oral or Skin	Detection of Herpes Simplex virus	MPS1 NAATs testing for sexually transmitted infections	H
EDTA Plasma	HIV RNA quantification	Aptima HIV Viral Load TMA NAATs assay. MPS12 HIV Viral Load Testing	H
Genital Swab, Urine (GenProbe only)	Detection of Neisseria Gonorrhoeae and Chlamydia	Aptima Combo 2 NAAT + Aptima GC confirmation NAAT + Aptima CT confirmation NAAT MPS1 NAATs testing for sexually transmitted infections	H
Genital swabs and urine	Detection of Trichomonas vaginalis	Aptima Trichomonas PCR assay MPS3 LSB39	H
Serum, EDTA Plasma	Monospot (Paul Bunnell) Test	Manual Test, Latex agglutination VSB13 EBV serology	H
Nasopharyngeal Aspirate/ Swab	Respiratory Syncytial Virus	Binax Now, Lateral Flow antigen test VSB10 - Investigation of RSV in respiratory samples	H



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Serum	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy (IDPS) screening programme, as defined in the as defined in the July 2018 IDPS screening programme: laboratory QA evidence requirements (assays marked *)	
	Quantification of:	Beckman DXi, Chemiluminescence Immunoassay VSB20 Antenatal infection screening VBS30 Beckman Coulter Dxl and	
	HIV 1/2 Antigen/Antibody*	VSB7 Serological investigation of HIV	H
	Rubella IgG Antibody screen Rubella IgM Antibody	VSB12 Rubella serology	H
	CMV (Cytomegalovirus) IgG Antibody, CMV IgM Antibody	VSB11 CMV serology	H
	HBsAg Screen* Anti-HBs Hepatitis B core antibody	VSB8 Investigation of Hepatitis B	H
	HEPA A (Total Antibody)	VSB3 Investigation of Hepatitis A	H
	Hepatitis A IgM Antibody	VSB11 Investigation of Hepatitis A	H
	Hepatitis C Antibody*	VSB2 Investigation of Hepatitis C	H
Treponema Pallidum Total Antibody*	Beckman AU5800 Immunoturbidimetric assay and manual immunocard VSB39 Method SOP Syphilis TPLA VSB41 Method SOP Syphilis Determine	H	



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Serum	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u> HIV confirmation (HIV 1/2 Ag/Ab assay)*	In-house documented methods incorporating manufacturers' instructions as required Manual immunocard VSB7 Serological investigation of HIV	H, M
Serum	Detection of: HBsAg confirmation test HIV 1/2 Ag/Ab assay (confirmation from Beckman Dxl results)	Biomerieux, Vidas, Immunoassay (ELFA) VSB21 Vidas analyser and VSB8 Investigation of Hepatitis B VSB7 HIV serology	H H
	B.burgdorferi IgG Antibody B.burgdorferi IgM Antibody	VSB6 Investigation of Lyme Disease	H
	CMV IgG Antibody, CMV IgM Antibody	VSB11 CMV Serology	H
	EBV Serology (VCA IgM, VCA IgG, EBNA IgG)	VSB13 EBV serology SOP	H
	Hepatitis B core antibody	VSB8 Investigation of Hepatitis B	H
	Hepatitis C Antibody	VSB2 Investigation of Hepatitis C	H
	Toxoplasma IgG and IgM Detection of:	VBS5 Toxoplasma IgM and IgG NovaTek Novalisa, DS2, ELISA VSB18 DS2 analyser	H
Serum	Measels virus IgG	VSB14 Measles virus serology	H
	Parvovirus Serology IgM Parvovirus Serology IgG	VSB15 Parvovirus serology	H
	Varicella Zoster (VZ) virus IgG	VSB16 Varicella Zoster virus serology Roche Cobas e411	H
Serum	Detection of HIV 1/2 antigen and antibody	BVS68 Chemiluminescence immunoassay	H



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	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented methods incorporating manufacturers' instructions as required	
Serum	Treponema Pallidum IgM/IgG screen*	BVS68 Chemiluminescence immunoassay	H
Serum	HBsAg	BVS68 LSB42 Chemiluminescence immunoassay	H
Respiratory Fluids Nose, throat and Nasopharyngeal swabs	Extended Respiratory PCR (Winterplex panel)	Bosphore SARS CoV-2/Respiratory Pathogens (Winterplex) panel from Launch LSB1 LSB13 LSB26	H
CSF	SARS-CoV-2 RSV A&B Influenza A&B Enterovirus Metapneumovirus Adenovirus Human Parainfluenza 1, 2, 3, 4 Rhinovirus		
	Viral Meningitis	Bosphore Viral Meningitis PCR panel using Kingfisher extraction and QS5 PCR LSB1 LSB13 MPS7	H
Genital swabs	Detection of Treponema pallidum	Bosphore Treponema pallidum PCR assay using Kingfisher extraction and QS5 PCR LSB1 LSB13 LSB41	H
Genital swabs, urine, Virocult, near and Aptima lysis buffer	Urethritis STD Multiplex assay	Bosphore STD Urethritis Mini Bundle assay using Kingfisher extraction and QS5 PCR LSB1 LSB13 LSB40	H



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HUMAN TISSUE	<u>Histopathology examination activities for the purpose of clinical diagnosis</u>	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues		Macroanalysis and dissection Manual method using: PDR4 BMS dissection and MLA duties PDR16 Specimen Dissection YDH PDR50 Pathologist Specimen Dissection Decalcification Manual method using: PGM10: Decalcification Tissue Processing Automated method using: Leica Peloris, Leica ASP300, Leica ASP300S and PGM20 Tissue processing HistoCore Peloris III	M, Y
Formalin fixed tissues		Embedding Manual method using: Tissue-Tek 5 embedder and PME3 Embedding Microtomy Manual method using: PME2 Microtomy and Leica 2235 Leica 2245, Shandon HM340E HistoCore Biocut	M Y Y M
Fresh tissue Frozen tissue	Intra-operative diagnosis	Rapid frozen section Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using: PSM34 Manual H&E and Bright cryostat OFT5000	M, Y



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic & eosinophilic tissue structures	Routine Haematoxylin & Eosin (H&E) staining and coverslipping Automated method using: Prisma stainer and film coverslipper PSM1 H&E staining Manual method using PSM34 H&E staining	M, Y
FFPE tissue	Detection of the following:	Special staining Manual methods using:	
	Alcian Blue/Pas with diastase Digestion Acid Mucins	PSM30 Alcian Blue	M, Y
	Acid and sulphated mucins	PSM6 Alcian Blue	M, Y
	Amyloid	PSM31 Congo Red	M, Y
	Bile Pigments	PSM32 Fouchet	M, Y
	Differentiating between hematopoietic cells	PSM9 Giemsa	M, Y
	Helicobacter pylori	PSM10 Modified Giemsa	M, Y
	Gram positive and gram negative organisms	PSM11 Gram	M, Y
	Basement membranes	PSM33 Jones Methenamine Silver	M, Y
	Fungal organisms	PSM12 Grocott Hexamine-silver	M, Y
	Fibrin	PSM13 Martius Soluble Blue (MSB)	M, Y
	5HT in melanin and lipofuscins	PSM14 Masson-Fontana	M, Y
	Collagen and smooth muscle	PSM15 Masson Trichrome	M, Y



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Special staining Manual methods using:	
	Elastic fibres & collagen	PSM17 Miller's Elastic Van Gieson	M, Y
	Hepatitis B surface antigen	PSM18 Shikata's Orcein	M, Y
	Liberated aldehydes	PSM30 Periodic acid Schiff/diastase +/- Digestion	M, Y
	Haemosiderin	PSM20 Perls' Prussian Blue	M, Y
	Reticulin fibres	PSM21 Reticulin, Gordon and Sweet's modification	M, Y
	Mast cell granules	PSM27 Toluidine Blue Metachromatic	M, Y
	Collagen and fibrosis	PSM25 Haematoxylin Van Gieson (HVG)	M, Y
	Acid Fast Bacilli	PSM29 Ziehl-Neelson	M, Y



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	Detection of the following:	Immunohistochemistry Automated methods using: PIC1 using Leica Bond III staining machines	
	Anaplastic lymphoma kinase (Human p80 protein)	Alk1	M
	Mantle zone B lymphocytes & interfollicular T lymphocytes and other rare tumour types	Bcl2	M, Y
	Germinal centre B lymphocytes	Bcl6	M, Y
	Cell membrane glycoproteins expressed on healthy epithelia and in various carcinomas	Ber-EP4	M, Y
	B cells, plasma cells	BOB-1	M
	Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma	34βE12	M, Y
	Cancer antigen 125	CA125	Y
	Lymphoma panel	C-Myc	M, Y
	Smooth muscle cells	Calponin	M
	Calcium binding protein structurally related to S100 and inhibin	Calretinin	M, Y
Epithelial	CAM 5.2	M, Y	
Colonic transcription factor	CDX2	M, Y	



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	T lymphocytes; helper/inducer T lymphocytes	CD3	M, Y
	T cell marker	CD4	M
	T cell	CD5	M, Y
	T cell	CD7	M
	T cell	CD8	M
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10	M, Y
	Hodgkin's & Reed-Sternberg cells	CD15	M, Y
	B lymphocytes	CD20cy	M, Y
	Follicular dendritic cells	CD21	M
	Key molecule for B cell activation and growth	CD23	M, Y
	Activated T lymphocytes; NK cells	CD25	M
	Hodgkin's & Reed-Sternberg cells	CD30	M, Y
Endothelial cells; plasma cells; activated B & T lymphocytes	CD31	M, Y	
Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours	CD34	M, Y	
Multifunctional enzyme, identify plasma cells and plasmablastic differentiation	CD38	M, Y	



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	T lymphocytes; myeloid lineage cells	CD43	M
	T & B lymphocytes	CD45	M, Y
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56	M, Y
	Macrophages; monocytes; granulocytes	CD68	M, Y
	Normal & neoplastic B lymphocytes	CD79a	M, Y
	Stem cell factor receptor, proto-oncogene activated in GIST tumors	CD117	M, Y
	Heparan sulfate proteoglycan, syndecan-1 in the late stage of B cell differentiation	CD138	M, Y
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	CEA	M, Y
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin A	M, Y
	Squamous epithelium	CK5	M,
	Simple, glandular & transitional epithelia	CK7	M, Y
Epithelial	CK8/18	M, Y	
Epithelia	CK19	Y	



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	GI epithelia	CK20	M, Y
	Cytomegalovirus viral inclusions	CMV	M
	Mantle cell lymphoma	Cyclin D1	M, Y
	Smooth & striated muscle cells	Desmin	M, Y
	Interstitial cells of Cajal in GI tract, GIST	DOG-1	M
	Neural cell adhesion	E-Cadherin	M, Y
	Epstein Barr virus	EBER	M
	Epithelial membrane antigen (Glandular & ductal epithelia, perineurium; other cell types in various tumours)	EMA	M, Y
	Cellular estrogen receptor expression	ER	M, Y
	Dendritic cells.	Fascin	M
	Thyroid tumour subtyping	Galactin 3	M
	Primary breast cancer marker	GATA-3	M
	Metastatic Breast Cancer	GCDFFP-15	M
	Glial fibrillary acidic protein (Neural cells)	GFAP	M, Y
	Human Chorionic Gonadotropin (Trophoblastic elements, e.g. in germ cell tumours)	HCG	M, Y



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours)	HMB45	M, Y
	Sertoli cells (diffuse and strong), granulosa cells, prostate, brain, adrenal	Inhibin	M, Y
	Kappa Light Chain	Kappa	M
	Demonstrates proliferating cells	Ki-67	M, Y
	Macrophages	KP1	M
	Lambda Light chain	Lambda	M
	Breast cancer	Mammoglobin	M, Y
	Melan A (MART-1) differentiation antigen (Normal, activated & neoplastic melanocytes)	Melan A	M, Y
	MLH-1 mismatch repair protein	MLH1	M
	Cytokeratins 5, 6, 8, 17, 19 (All epithelia)	MNF116	M, Y
	Myeloperoxidase in Neutrophils, eosinophils, monocytes	MPO	M
MSH-2 mismatch repair protein	MSH2	M	



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HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	MSH6 mismatch repair protein in colorectal carcinomas	MSH6	M
	Multiple myeloma oncogene-1	MUM-1p	M, Y
	Enolase gamma subunit (neuronal & neuroendocrine cells)	NSE	M, Y
	Seminoma	Oct-02	M
	Pluripotent germ cell tumours	OCT 3/ 4	M, Y
	Pre-B cells	PAX-5	M
	Ovarian serous carcinoma, clear cell renal cell carcinoma, papillary thyroid carcinoma	PAX-8	M
	Placental Alkaline Phosphatase in germ cell tumours, particularly seminomas; also breast, lung, ovarian carcinomas	PLAP	M, Y
	Macrophages	PG-M1	M
	Pulmonary squamous cell carcinoma marker	P40	Y
	Cellular progesterone receptor expression	PR	M, Y
	PMS2 mismatch repair protein in colorectal carcinomas	PMS2	M
Prostate specific antigen	PSA	M, Y	
Prostate secretory and ductal epithelium	PSMA	M, Y	



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	p16INK4a oncoprotein (Normal, activated and neoplastic melanocytes)	p16	M, Y
	Neoplastic cells in epithelium	p53	M, Y
	Squamous epithelium	p63	M, Y
	Prostatic cancer	Racemase	M
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types	S100	M, Y
	Mantle cell lymphoma	Sox 11	M
	melanoma/breast carcinoma	Sox 10	M, Y
	Smooth muscle, myoepithelial and other contractile cells	SMActin	M, Y
	Smooth muscle	SMM	M, Y
	Neuroendocrine cells	Synaptophysin	M, Y
	Gastrin	Gastrin	M
	Programmed cell death protein 1	PD1	M
	Prostatic tumor suppressor gene	NKX3.1	M
Terminal Deoxynucleotidyl Transferase	Tdt	M	
Thyroid	Thyroglobulin	M	



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Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	Lung cancer	Thyroid Transcription Factor	M, Y
	Renal cell carcinoma	Vimentin	M, Y
	ovarian serous carcinoma and mesothelioma	WT1	M, Y
	CK HMW+p63+AMACR (RM)	PIN cocktail	M, Y
	Podoplanin antibody	D2-40	Y
	Helicobacter Pylori	H pylori	M
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: PDR50	M, Y
HUMAN TISSUE	<u>Diagnostic cytology examination activities for the purpose of clinical diagnosis</u>	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Body fluids: Cerebrospinal fluid (CSF) Urine General body fluids Brushings (Bronchial, gastric, oesophageal, duodenal etc.) Fine Needle Aspirations Respiratory Samples (Broncho alveolar lavage (BAL), Brushings, washings and sputum)		Preparation/centrifugation In-house procedures: CEQ9 using stainer/coverslipper CEQ1 using Microscope CEQ5 using Downflow unit CPR31 Body fluids CPR32 Urine CPR33 Bronchial samples and sputum CPR34 FNA CPR35 Joint fluids CPR36 CSF CPR38 Summary NG Prep CPR76 Immunology and Cell Block requests	H



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HUMAN TISSUE (cont'd)	<u>Diagnostic cytology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Papanicolaou and MGG staining Automated/manual using in-house procedures: CEQ4 using Cytospin 4, CEQ10 T2000 Tissue Processor	H
		Microscopy (qualitative analysis) In-house procedures: CPR35 CPR100	H
Blood	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below	
	Blood Grouping (ABO and RhD type)	TXS10, TXS11, TXS12, TXS27, TXS63 and TXS64 using Ortho Vision card/column agglutination and tube technique	M, Y
	Red Cell Antibody Screen	TXS10, TXS63 and TXS64 using Ortho Vision card/column agglutination	M, Y
	Rhesus and K phenotyping Rh – C, D, E, c, e, Kell - K	TXS5, TXS63 and TXS64 using Ortho Vision card/column agglutination	M, Y
	Phenotyping of red cell Antigens: Jka/Jkb, M/N, S/s and Fya/Fyb	TXS6, TXS63 and TXS64 using Ortho Vision card/column agglutination against Ortho Sera	M, Y
	Detection of Antibodies: Rhesus blood group Antibodies: anti-C, anti-c, anti-D, anti-E, anti-e	TXS10, TXS12, TXS15, TXS63 and TXS64 using Ortho Vision Card/column agglutination	M, Y



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Blood (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below	
	Detection of Antibodies: (cont'd) Kell system blood group antibodies: anti-K, anti-k, anti-Kpa Kidd blood group antibodies: anti-Jka, anti-Jkb MNS blood group antibodies: anti-M, anti-N, anti-S, anti-s Duffy blood group antibodies: anti-Fya, anti-Fyb Lewis blood group antibodies: anti-Lea, anti-Leb	TXS10, TXS12, TXS15, TXS63 and TXS64 using Ortho Vision Card/column agglutination	M, Y
	Direct Antiglobulin Test	TXS12, TXS26, TXS63 and TXS64 using Ortho Vision card/column agglutination	M, Y
	Monospecific Coombs Test (IgG, C3d/C3b)	TXS12, TXS45, TXS63 and TXS64 using Ortho Vision card/column agglutination	M, Y
	Serological cross match: Serological compatibility Testing between donor red cell Antigens and patient plasma antibody	TXS38, TXS63 and TXS64 using Ortho Vision card/column agglutination	M, Y
	Detection and Estimation of Foetal Maternal Haemorrhage through Quantification of foetal Hb in Maternal blood	TXS16 using Kleihauer test - acid elution followed by microscopy	M, Y
Antibody titration • Rhesus: anti-Cw, anti-C, anti-E, anti-e, • Kell system: anti-K, anti-k, anti-Kpa, • Kidd: anti-Jka, anti-Jkb, • Duffy: anti-Fya, anti-Fyb	TXS8 - Titration techniques by serial dilution of plasma using Ortho Vision card/column agglutination	M, Y	



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>		
Semen	<u>Post vasectomy:</u>	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP APV1	H
Semen	<u>Fertility testing:</u>	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedures SOPs ASB11, ASB12, ASB15, ASB20	H
	Sperm morphology excluding TZI scoring	Stained slides (DiffQuik) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	
	Sperm vitality	Stained slide (Eosin dye exclusion test) microscopy (Phase contrast)	
END			