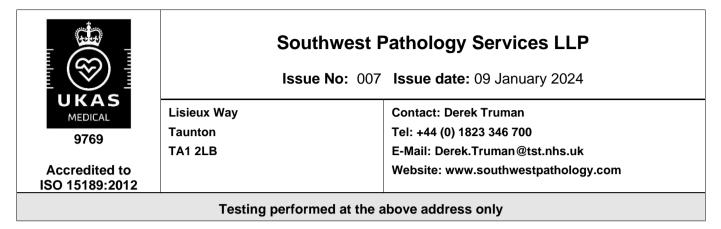
Schedule of Accreditation

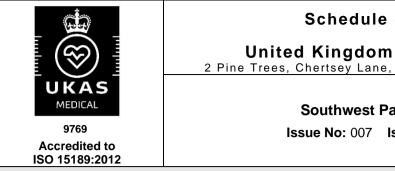
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United Kingdom Accreditation Service

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



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



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Southwest Pathology Services LLP

Issue No: 007 Issue date: 09 January 2024

Testing performed at main address only

	DETAIL OF ACCREDI	TATION	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Biochemistry examination activities for the purpose of clinical diagnosis	In-house documented methods incorporating manufacturers' instructions as required	
Serum, Heparin, Plasma	Quantification of:	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
	Albumin	SOPBVS72, BCG colourimetric method	М, Ү, Н
	Albumin	SOPBVS171, BCP colourimetric method	Н
	Alkaline Phosphatase (ALP)	SOPBVS74, Colourimetric	M, Y, H
	Alpha-1-Antitrypsin	SOPBVS87, Immunoturbidimetric	н
	Alanine Aminotransferase (ALT)	SOPBVS52, Colourimetric	М, Ү, Н
	Angiotensin Converting Enzyme (ACE)	SOPBVS116, Colourimetric	Н
	Asparate Aminotransferase (AST)	SOPBVS76, Colourimetric	М, Ү, Н
	Bicarbonate	SOPBVS56, Colourimetric	M, Y, H
	Bile Acids	SOPBVS28, Enzymatic/ Colourimetric	М
	Complement 3 (C3)	SOPBVS95, Immunoturbidimetric	н
	Complement 4 (C4)	SOPBVS96, Immunoturbidimetric	н
	Carbamazepine	SOPBVS57, Immunoturbidimetric	M, Y, H
	Cholesterol	SOPBVS78, Enzymatic/ Colourimetric	M, Y, H
	Creatine Kinase (CK)	SOPBVS79, Enzymatic/ Colourimetric	M, Y, H
	C-Reactive Protein (CRP)	SOPBVS80, Immunoturbidimetric	М, Ү, Н

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	Testing performed at main a	ddress only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
Serum, Heparin, Plasma (cont'd)	Quantification of: (cont'd)	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
	Digoxin	SOPBVS98, Immunoturbidimetric	М, Ү, Н
	Direct Bilirubin (Conjugated Bilirubin)	SOPBVS58, Colourimetric	М, Ү, Н
	Gentamicin	SOPBVS110, Cedia Immunoassay	М, Ү, Н
	Gamma Glutamyltransferase (GGT)	SOPBVS103, Colourimetric	М, Ү, Н
	High Density Lipoprotein (HDL)	SOPBVS59, Immunological/ Colourimetric	М, Ү, Н
	IgA	SOPBVS100, Immunoturbidimetric	н
	lgG	SOPBVS101, Immunoturbidimetric	н
	IgM	SOPBVS102, Immunoturbidimetric	н
	Iron	SOPBVS60, Colourimetric	М, Ү, Н
	Methotrexate	SOPBVS113, Enzyme Immunoassay	М
	Paracetamol (Acetaminophen)	SOPBVS39, Enzymatic/ Colourimetric	М, Ү
	Phenobarbitone	SOPBVS65, Cedia Immunoassay	М, Ү, Н
	Phenytoin	SOPBVS62, Cedia Immunoassay	М, Ү, Н
	Rheumatoid Factor	SOPBVS115, Immunoturbidimetric	н
	Salicylate	SOPBVS27, Enzymatic/ Colourimetric	М, Ү
	Theophylline	SOPBVS107, Cedia Immunoassay	M, Y

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
Serum, Heparin, Plasma (cont'd)	Quantification of: (cont'd)	Beckman Coulter AU5800 (H), AU700 (M) and AU480 (Y) using procedure and measurement principle as stated:	
	Tobramycin	SOPBVS129, Cedia Immunoassay	М
	Total Bilirubin	SOPBVS77, Colourimetric	М, Ү, Н
	Total Protein	SOPBVS63, Colourimetric	М, Ү, Н
	Transferrin	SOPBVS119, Immunoturbidimetric	н
	Triglyceride	SOPBVS118, Enzymatic/ Colourimetric	М, Ү, Н
	Vancomycin	SOPBVS111, Immunoturbidimetric	M, Y
Serum, Heparin, Plasma,	Amylase	SOPBVS53, Colourimetric	М, Ү, Н
Urine	Calcium	SOPBVS54, Colourimetric	М, Ү, Н
	Chloride	SOPBVS105, ISE	М, Ү, Н
	Creatinine	SOPBVS55, Colourimetric	М, Ү, Н
	Magnesium	SOPBVS82, Colourimetric	М, Ү, Н
	Phosphate	SOPBVS109, Colourimetric	М, Ү, Н
	Potassium and Sodium	SOPBVS105, ISE	М, Ү, Н
	Urea	SOPBVS104, Enzymatic/ Colourimetric	М, Ү, Н
	Uric Acid	SOPBVS106, Enzymatic/ Colourimetric	М, Ү, Н

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	Testing performed at main a	ddress only			
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code		
	Biochemistry examination activities for the purpose of clinical diagnosis (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:			
Urine	Methadone	SOPBVS93, Cedia Immunoassay	М		
	Opiates	SOPBVS94, Cedia Immunoassay	М		
	Urine Albumin (Microalbumin)	SOPBVS117, Immunoturbidimetric	н		
	Amphetamine/Ecstasy	SOPBVS88, Cedia Immunoassay	М		
	Barbiturate	SOPBVS89, Cedia Immunoassay	М		
	Benzodiazepine	SOPBVS90, Cedia Immunoassay	М		
	Cannabinoids (THC)	SOPBVS91, Cedia Immunoassay	М		
	Cocaine Metabolite (Benzoylecgonine)	SOPBVS92, Cedia Immunoassay	М		
Urine, CSF	Urine, CSF Protein	SOPBVS123, Colourimetric	М, Ү, Н		

SOPBVS112, Colourimetric

SOPBVS61, Colourimetric

SOPBVS73, Enzymatic/

SOPBVS81, Enzymatic/

Colourimetric

Colourimetric

Serum

Serum, Heparin, Plasma, EDTA Lithium

(LDH)

Alcohol

Glucose

Lactate Dehydrogenase

Serum, Heparin, Plasma, Fluoride/ Oxalate Plasma, Urine

Serum, Heparin, Plasma, Fluoride/ Oxalate Plasma, Urine, CSF M, Y, H

M, Y, H

M, Y, H

M, Y, H

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Biochemistry examination activities for the purpose of clinical diagnosis (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
Fluoride, Plasma, CSF	Lactate	SOPBVS121, Enzymatic/ Colourimetric
Serum (trace metal tube), Heparin plasma (paediatric tube)	Zinc	SOPBVS70, Colourimetric
Faeces	Faecal Electrolytes	SOPBSB51, ISE
Faeces	Faecal Elastase	SOPBSB50 using Sysmex DS2, Elisa test
Serum, Plasma, Urine	Osmolality	SOPBSB6 using Advanced Instruments micro-osmometer, Freezing point depression
CSF	Xanthochromia	SOPBSB4 using Thermo Evolution 201 Spectrophotometer
Sweat	Sweat Chloride Analysis	SOPBSB45 using Elitech Chlorochek 3400

Μ, Υ

M, Y

Μ

M, Y

Μ, Υ

Μ, Υ

Н

Н

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Accredited to			
	Testing performed at main a	ddress only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Endocrinology, Immunoassay examination activities for the purpose of clinical diagnosis	In-house documented methods incorporating manufacturers' instructions as required	
Serum, Heparin, Plasma	Quantification of:	Beckman Coulter Dxl,	

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

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	Testing performed at main a	ddress only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Endocrinology, Immunoassay examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
Serum, Heparin, Plasma (cont'd)	Quantification of: (cont'd)	Beckman Coulter Dxl, Immunoenzymatic Chemiluminescent analysis using procedure:	
	Prostate Specific Antigen (PSA)	SOPBVS20	н

	(PSA)		
	Testosterone	SOPBVS22	н
	Thyroperoxidase Antibody (TPO)	SOPBVS1	н
Serum, Heparin, Plasma	Thyroid Stimulating Hormone (TSH)	SOPBVS23 using Beckman	М, Ү, Н
	Vitamin B12	SOPBVS3	н
	Vitamin D (25-OH Vitamin D)	SOPBVS38	н
Serum, Heparin, Plasma		Beckman Coulter Access2 Immunoenzymatic Chemiluminescent analysis using procedure:	
	Cortisol	SOPBVS7	М, Н
	Ferritin	SOPBVS13	М, Н
	Free T3	SOPBVS10	М, Ү, Н
	Free T4	SOPBVS11	М, Ү, Н
	Human Chorionic Gonadotrophin (Hcg)	SOPBVS14	М, Ү, Н
	Oestradiol	SOPBVS17	М, Ү, Н
	Parathormone (PTH)	SOP BVS21	М, Н
	Progesterone	SOPBVS19	M, Y, H

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	Testing performed at main a	ddress only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Endocrinology, Immunoassay	In-house documented methods	

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

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ISO 15189:2012	Testing performed at main a	address only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Dischemistry exemination	Coloulated tests using LabContro	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Calculated tests using LabCentre System and procedure SOP RLR1	
Urine (conťd)	Urine Microalbumin/Creatinine Ratio		н
	Urine Calcium/Creatinine Ratio		М, Ү
	Urine Protein/Creatinine Ratio		М, Ү, Н
Urine, Serum	24 Hr Creatinine Clearance		М, Ү, Н
Urine, Serum	4 Hr Creatinine Clearance		М, Ү, Н
Serum	Anion Gap Kappa/Lambda Light Chain Ratio		М, Ү, Н Н
CSF	Xanthochromasia Interpretive Comment		М, Ү
	Immunology examination activities for the purpose of clinical diagnosis	In-house documented methods incorporating manufacturers' instructions as required	
	Detection of:	BioPlex 2200 System Multiplex Flow Immunoassay using procedures IMD4, IMS16 and:	
Serum, Plasma	IgA TTG	IMS17	н
	IgG ANA (dsDNA and ENA)	IMS18	н
	IgG Cardiolipin & IgM Cardiolipin	IMS19	н
	IgG CCP	IMS21	н
Serum	IgG MPO, PR3 and GBM	IMS20	н

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Immunology examination activities for the purpose of clinical diagnosis (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:	
Serum	IgG ANCA	IMS6	н
	IgG AIP	IMS7	
	IgG ANA	IMS8	н
	IgA & IgG Endomysial	IMS9	н
Serum, Urine	Paraprotein quantitation	BSB7, Sebia Capillarys 2 Flex- piercing, capillary electrophoresis	н
Serum	Free light chains	Binding Site Optilite, BVS166 Immunoturbidimetric method	н
		NAVIOS Flow Cytometry using procedure, HSB34, and:	
CSF, Bone Marrow, Pleural Fluid EDTA Whole Blood	Leucocyte Immunophenotyping	HSB31	Н
EDTA Whole Blood	CD4 Enumeration (with absolute count beads)	HSB37	н
	Haematology examination activities for the purpose of clinical diagnosis	ACL TOP 350 and 550 HSB54	
Citrate Plasma	PT/INR	HSB55, Coagulation Method	M, Y, H
	APTT	HSB56, Coagulation Method	М, Ү, Н

D-Dimers

Fibrinogen

-

M, Y, H

M, Y, H

HSB58, Immunoassay

HSB57, Coagulation Method

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	Haematology examination	In-house documented methods	

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

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130 13103.2012	Testing performed at main a	ddress only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
EDTA Blood	Haematology examination activities for the purpose of clinical diagnosis (cont'd) Full Blood Count: WBC, RBC, PLT Haemoglobin MCV Neutrophils, Lymphocytes, Monocytes, Eosinophils, LUC Basophils HCT MCH MCHC RDW % HYPO Retic	Advia 2120 by flow cell and colorimetric methods using procedures HSB4, HSB5, HSB6 and HSB7)	М, Ү, Н
EDTA Blood	Erythrocyte Sedimentation Rate (ESR) 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>	Alifax analyser HSB8 SOP HSB10 SOP Commercial Apacor CareStart Malaria Kit	М,Ү,Н М, Ү, Н

Manual Method

G6PD Screen

Viscosity

Plasmodium falciparum Plasmodium malariae Plasmodium ovale Plasmodium vivax Plasmodium knowlesi Fields Staining (Thick films), Giemsa Staining (Thin films)

HSB2 SOP, BinaxNow G6PD

HSB16 SOP, capillary tube

Μ

Μ

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology examination activities for the purpose of	In-house documented methods incorporating manufacturers'	

clinical diagnosis (cont'd)

Detection of normal and

abnormal morphologies

Morphological assessment of

cell types present in serous

Sickle cell solubility

Haemoglobin A1c

Haemoglobinopathy Screen

fluids

instructions as required

SOP

Light microscopy analysis of slide

following manual staining (Wright and Perls) using procedure HSB9

Light microscopy analysis of

procedures HSB13

Thalassaemia Screening Programme: laboratory QA evidence requirements.'

and procedures:

SOPHSB20

SOPHSB18

cytospins produced using the Thermo Fisher Cytospin 4 and

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

COS19 SOP, Manual solubility test

Tosoh G8 Cation Exchange HPLC

Μ

Μ

M, Y, H

Н

Н

to determine HbA2 and HbF levels and the presence of abnormal haemoglobins

EDTA Blood/Bone Marrow

CSF, Ascitic Fluid

EDTA Blood

EDTA Whole Blood

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	Testing performed at main a	ddress only	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Microbiology examination activities for the purpose of clinical diagnosis	In-house documented methods incorporating manufacturers' instructions as required	
	Isolation and characterisation of micro-organisms of clinical significance	Kiestra Total Laboratory Automation microscopy, manual gram stain, and manual culture using procedure MGB21 and	
Superficial Wound Swabs		MGB3 Examination of superficial wound swabs	Н, М
Deep Seated Wound Swabs Pus, Drain fluid, Bile, Aspirates, Tissues, Bone, Prosthetic Joints		MGB14 Examination of Pus, Pus swabs from deep seated infections SOP MME4 Microbiology stains	Н, М
Body fluids from normally sterile sites		MGB8 – Examination of Body fluids from normally sterile sites MME4 - Microbiology stains MME7 – Performing Cell Counts using counting chambers	Н, М
Continuous ambulatory peritoneal dialysis fluid (CAPD)		MGB9 Examination of Continuous ambulatory peritoneal dialysis fluid MME4 Microbiology stains	Н, М
CSF and Shunts		MGB7 Examination of CSF and CSF shunts MME4 Microbiology stains MME7 Performing cell counts using counting chambers	Н, М
Genital Swabs/Fluids		MGB18 Bacteriological Examination of GU specimens MME4 Microbiology stains	Н, М
Eye Swabs, Canalicular Pus, Corneal Scrapes and Intraocular Fluids		MGB6 Eye swabs, canalicular pus, corneal scrapes and intraocular fluids MME4 Microbiology stains	Н, М
ENT Swabs including - Ear,		MGB4 Examination of ear, nose,	Н, М

Nose, Throat, Mouth, Pernasal Swabs

mouth, throat and pernasal swabs

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	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	
Sputum, Bronchial washing and associated respiratory samples, Anstral washouts		MGB15 Examination of Sputum and associated specimens MME4 Microbiology stains	н
Urine		the automated microscopy using Beckman IQ200 Analyser Laminar Flow using procedure MGB26 and MGB16 Examination of Urine Specimens	н
Urine	Isolation and characterisation of micro-organisms of clinical significance	Manual microscopy and culture using procedure MGB16 Examination of Urine Specimens.	Н, М
Faeces	Detection of GDH	Techlab C Diff Chek 60 kit on Dynex DS2 analyser enzyme Immunoassay (EIA) MGB1 Detection of Clostridium difficile and its toxins in faeces VSB18 DS2 analyser	н
	Detection of GDH and Toxins A & B	Techlab Lateral flow C. difficile Quik Chek (EIA) card test	н

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	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	

	clinical diagnosis (cont'd)	instructions as required	
	Detection and identification of the following:		
Faeces	Ova, cysts and parasites	Techlab Cryptosporidium and Giardia kit on Dynex DS2 analyser enzyme Immunoassay (EIA) Direct and concentration microscopy for faecal ova, cysts and parasites. VSB18 DS2 analyser MGB13 Examination of Enteric samples	н
Faeces	Confirmatory test to distinguish Cryptosporidium and Giardia after EIA test as above	Techlab Cryptosporidium and Giardia Quick test – lateral flow device. MGB13 Examination of Enteric samples.	
Perianal swab	Enterobius vermicularis ova	Detection of ova using light microscopy MGB13 Examination of Enteric samples	Н
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 MGB10 Examination of Blood Cultures, bone marrow and transfusion packs	Н, М, Ү
		Kiestra Total Laboratory Automation, chromogenic agar plate culture MGB21 Kiestra TLA and	

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	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required		
MRSA & MSSA Screening Swabs, Fluids, Respiratory Samples and Tissues	Isolation of microorganisms of clinical significance	MGB22 MRSA & MSSA screening	Н, М	
Bacterial cultures isolated in- house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	EUCAST Disc Diffusion MME22 antimicrobial susceptibility testing	н	
		Minimum Inhibitory Concentration (MIC) Testing Strip / agar plate culture MME22 Antimicrobial susceptibility testing	Н	
		BD Phoenix System, automated ID / AST System MGB20 Phoenix ID and AST Analyser	н	
		ESBL and AmpC confirmation by combination disc testing using procedure MME24	н	
Fungal isolates from samples listed above	Antifungal Susceptibility testing	Sensitite YeastOne, manual MIC microplate method MME17 Antifungal susceptibility testing	Η	

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Bacterial cultures isolated in- house from all samples listed	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) Automated Identification of microorganisms of clinical	In-house documented methods incorporating manufacturers' instructions as required Bruker Maldi-Tof automated ID System	н
above	significance from culture Manual Identification of microorganisms of clinical significance from culture	MGB28 Using the Maldi-Tof Biochemical tests - Oxidase test, Catalase test, MGB25 Bacterial Identification MME4 - Microbiology stains	н
	Identification of Staphylococcal isolates	Tube Coagulase test, Prolex Staph Xtra latex MGB25 Bacterial Identification	н
	Serological 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	н
	Detection of Salmonella Polyvalent 'O' (PSO) and 'H' (PSH), plus single factor 'O' and 'H' antisera	Agglutination using Salmonella, Shigella and Vibrio agglutination sera. MGB25 Bacterial Identification	н

Detection of Shigella and Vibrio using specific antisera

Confirmatory identification of

Neisseria gonorrhoeae

Bacterial differentiationGram stain and microscopy
MME4 Microbiological
StainsMulti-resistant Gram Negative
Bacilli (GNB) ScreenSelective plate agar culture
SOP MGB32 Carbapenamase
screening

Gram stain, oxidase test, catalase

MGB25 Bacterial Identification. MME4 Microbiology stains

test and Gonocheck II tube

hydrolysis assay.

Н

Н

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	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
Destavial sultures is closed in	Confirmation of E call 0457		

<u>clinical diagnosis</u> (cont'd)	instructions as required	
Confirmation of E. coli 0157	E. coli 0157 latex MME8 0157 Prolab Latex Agglutination	Н
Diagnosis of Bacterial vaginosis	Gram stain and microscopy in accordance with Hays Criteria. MGB18 Bacteriological Examination of GU Specimens MME4 Microbiology stains	н
Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Direct microscopy for Acid Fast Bacilli (AFB) MGIT Mycobacteria liquid culture system, automated monitoring of culture bottles Solid slope culture, manual inoculation. MGB12 Examination of specimens for Acid Fast bacilli MME4 Microbiology stains	Н
Isolation & identification of fungal pathogens including: Filamentous moulds Yeasts	Microscopic examination of fungal hyphae using KOH preparation Calcofluor statin. Agar plate culture. MGB22 Investigation of mycology	Н
Yeast Isolate identification	Bruker Maldi-Tof automated ID System MME1 Maldi-Tof analyser MGB24 Mycology Identification	Н
	Confirmation of E. coli 0157 Diagnosis of Bacterial vaginosis Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.) Isolation & identification of fungal pathogens including: Filamentous moulds Yeasts	Confirmation of E. coli 0157E. coli 0157LatexMME8 0157 Prolab LatexAgglutinationAgglutinationDiagnosis of Bacterial vaginosisGram stain and microscopy in accordance with Hays Criteria. MGB18 Bacteriological Examination of GU Specimens MME4 Microbiology stainsIsolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)Direct microscopy for Acid Fast Bacilli (AFB) MGIT Mycobacteria liquid culture system, automated monitoring of culture bottles Solid slope culture, manual inoculation. MGB12 Examination of specimens for Acid Fast bacilli MME4 Microbiology stainsIsolation & identification of fungal pathogens including: Filamentous moulds YeastsMicroscopic examination of fungal hyphae using KOH preparation Calcofluor statin. Agar plate culture. MGB22 Investigation of mycologyYeast Isolate identificationBruker Maldi-Tof automated ID System MIME1 Maldi-Tof analyser

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	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
		Use of the Cepheid GeneXpert, RT PCR MPS4 and procedures:	
Faeces	Detection of Clostridium difficile toxin	MGB1 Detection of Clostridium difficile and its toxins in faeces	н
MRSA nasal swabs, Blood cultures	Detection of MRSA	MGB2 MRSA/MSSA screening MGB10 Blood cultures, bone marrow and transfusion packs	Н, М
Respiratory fluids, Sputum	Detection of TB	MGB12 Examination of specimens for Acid Fast bacilli	н
Faeces	Detection of Helicobacter pylori Antigen	 Investigation of H. pylori. SOP VSB18 - DS2 analyser 	н
	Virology examination activities for the purpose of clinical diagnosis	Use of the Cepheid GeneXpert, RT PCR MPS4 and procedures:	
CSF	Detection of Enterovirus	MPS7 PCR detection of viruses from CSF	н
Serum/EDTA Plasma	HCV RNA quantification	MPS11 Hepatitis C Viral Load and Positive monitoring	н
Respiratory Fluids, Nose, Throat and Nasopharyngael Swabs	Detection of Influenza A & B + RSV	MPS13 Respiratory virus detection by PCR	н
Faeces, Vomit	Detection of Norovirus	MPS8 Investigation of viral gastroenteritis and diarrhoea by PCR	н
Whole Blood	Factor II and Factor V Mutation genotyping	MPS10 - Factor II and Factor V genotyping	н
Faeces	Detection of Rotavirus / Adenovirus	Lateral flow Biorapid (EIA) card test SOP MGB13 – Examination of Enteric samples	н

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>Virology examination activities</u> for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
Urine	Urinary antigen detection of Legionella pneumophila and Streptocouus pneumoniae	Lateral flow – BINAX NOW card test. SOP VSB 9 – Urinary antigen tests	Н
		EuroClone DuplicaPrep and Cepheid Smartcycler RT PCR. MPS6 DuplicaPrep MPS5 SmartCycler and	
CSF	Viral PCR detection in CSF	Launch Fast Track Diagnostics Viral Meningitis panel MP7 PCR detection of viruses from CSF	н
		Hologic Gen-Probe Panther system MPS3 Panther system for use with Hologic assays:	
Genital, Oral or Skin	Detection of Herpes Simplex virus	MPS1 NAATs testing for sexually transmitted infections	н
EDTA Plasma	HIV RNA quantification	Aptima HIV Viral Load TMA NAATs assay. MPS12 HIV Viral Load Testing	н
Genital Swab, Urine (GenProbe only)	Detection of Neisseria Gonorrhoeae and Chlamydia	Aptima Combo 2 NAAT + Aptima GC confirmation NAAT MPS1 NAATs testing for sexually transmitted infections	н
Serum, EDTA Plasma	Monospot (Paul Bunnell) Test	Manual Test, Latex agglutination VSB13 EBV serology	Н
Nasopharyngeal Aspirate/ Swab	Respiratory Syncytial Virus	Binax Now, Lateral Flow antigen test VSB10 - Investigation of RSV in respiratory samples	Н

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	Virology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
		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 DxI and	
Serum	HIV 1/2 Antigen/Antibody*	VSB7 Serological investigation of HIV	н
	Rubella IgG Antibody screen Rubella IgM Antibody	VSB12 Rubella serology	н
	CMV (Cytomegalovirus) IgG Antibody, CMV IgM Antibody	VSB11 CMV serology	н
	HBsAg Screen Anti-HBs Hepatitis B core antibody	VSB8 Investigation of Hepatitis B	н
	HEPA A (Total Antibody)	VSB3 Investigation of Hepatitis A	н
	Hepatitis A IgM Antibody	VSB11 Investigation of Hepatitis A	н
	Hepatitis C Antibody*	VSB2 Investigation of Hepatitis C	н
	Treponema Pallidum IgM/IgG screen*	Beckman AU5800, Immunoturbidimetric assay VSB19 Syphilis (Treponema pallidum) serology VSB20 Antenatal infection screening VBS36 AU5800	н

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code

	measurement	Equipment/Techniques used	Code
	<u>Virology examination activities</u> for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Confirmation of results from Beckman DxI and e411 assays:	Determine Immunocard, Manual Immunocard test:	
Serum (cont'd)	Treponema Pallidum Antibody*	VSB19 Syphilis (Treponema pallidum) serology	н
Serum	HIV (HIV 1/2 Ag/Ab assay)*	VSB7 Serological investigation of HIV	Н, М
	Detection of:	Biomerieux, Vidas, Immunoassay (ELFA) VSB21 Vidas analyser and	
Serum	HBsAg confirmation test	VSB8 Investigation of Hepatitis B	н
	HIV 1/2 Ag/Ab assay (confirmation of Beckman DxI results)	VSB7 HIV serology	н
	B.burgdorferi IgG Antibody B.burgdorferi IgM Antibody	VSB6 Investigation of Lyme Disease	н
	CMV IgG Antibody, CMV IgM Antibody	VSB11 CMV Serology	н
	EBV Serology (VCA IgM, VCA IgG, EBNA IgG)	VSB13 EBV serology SOP	н
	Hepatitis B core antibody	VSB8 Investigation of Hepatitis B	н
	Hepatitis C Antibody	VSB2 Investigation of Hepatitis C	н
	Toxoplasma IgG and IgM	VBS5 Toxoplasma IgM and IgG	н

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>Virology examination activities</u> for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
	Detection of:	NovaTek Novalisa, DS2, ELISA VSB18 DS2 analyser	
Serum (cont'd)	Helicobacter pylori IgG	VSB1 Investigation of H. pylori	Н
	Measels virus IgG	VSB14 Measles virus serology	н
	Parvovirus Serology IgM Parvovirus Serology IgG	VSB15 Parvovirus serology	Н
	Varicella Zoster (VZ) virus IgG	VSB16Varicella Zoster virus serology	Н
Serum	Detection of HIV 1/2 antigen and antibody	Roche Cobas e411 BVS68	н
		Chemiluminescence immunoassay	
Serum	Treponema Pallidum IgM/IgG screen	BVS68	н
	500011	Chemiluminescence immunoassay	
Serum from clotted blood sample	Detection of SARS-CoV-2 Antibody (including IgG)	VSB26	н
	Target: Nucleocapsid antigen antibodies	Elecsys Anti-SARS-CoV-2 electrochemiluminescent immunoassay (ECLIA)	
	Detection of:		
Serum	Mycoplasma pneumoniae IgM	Manual, Serodia Gelatin agglutination test SOP VSB4 – Investigation of Mycoplasma pneumoniae	Н
	Mycoplasma pneumoniae IgM (confirmation)	Manual, Meridian Lateral Flow immunoassay SOP VSB4 – Investigation of Mycoplasma pneumoniae	Н

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Matariala (Das durata tanta d	Type of test/Properties	Standard specifications/	Location	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>Virology examination activities</u> for the purpose of clinical diagnosis (cont'd)	In-house documented methods incorporating manufacturers' instructions as required	
		NHS testing (marked *) and Private testing incorporating DHSC requirements for private providers of Covid-19 testing, to include: • General Population Testing • (marked #)	
Nasopharyngeal, oropharyngeal swabs in VTM	Detection of SARS-CoV-2 RNA	# ThermoFisher MPV2 extraction kit.	н
	Targets: E gene, N gene and ORF1ab gene sequences	KingFisher Flex extraction platforms.	
		Bosphore 2019-nCoV assay using QS5 analysers	
		SOP: MPS20	
	Detection of SARS-CoV-2 RNA Targets: E gene and N2 gene sequences	* Xpert Xpress SARS-CoV-2 PCR assay with Cepheid GeneXpert PCR platform SOP: MPS33	Н
	Detection of SARS-CoV-2 RNA Targets: N gene (2 regions)	* VitaPCR™ SARS-CoV-2-Assay performed on the VitaPCR™ instrument SOP: MPS29	Н, Ү, М
	Detection of SARS-CoV-2 RNA Targets: ORF1ab 2 undifferentiated regions	* Aptima SARS CoV-2 TMA assay for Hologic Panther platform SOP: CVS2	Н

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measured/Range of measurement	Equipment/Techniques used	Code
Histopathology examination activities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	Macroanalysis and dissection Manual method using: PDR4 BMS dissection and MLA duties PDR16 Specimen Dissection YDH PDR50 Pathologist Specimen Dissection	М, Ү
	Decalcification Manual method using: PGM10: Decalcification	
	Tissue Processing Automated method using: Leica Peloris, Leica ASP300, Leica ASP300S and PGM20 Tissue processing	
	Embedding Manual method using: Tissue-Tek 5 embedder and PME3 Embedding	
	Microtomy Manual method using: PME2 Microtomy and Leica 2235 Leica 2245, Shandon HM340E	M Y Y
Intra-operative diagnosis	Rapid frozen section Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using: PSM34 Manual H&E and Bright cryostat OFT5000	М, Ү
	measurement <u>Histopathology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u>	measurementEquipment rechniques usedHistopathology examination activities for the purpose of clinical diagnosisMacroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)Macroanalysis and dissection Manual method using: PDR16 Specimen Dissection AMLA duties PDR16 Specimen Dissection YDH PDR50 Pathologist Specimen DissectionDecalcification Manual method using: Leica ASP300S and PGM20 Tissue processingEmbedding Manual method using: Leica ASP300S and PGM20 Tissue processingEmbedding Manual method using: Tissue-Tek 5 embedder and PME3 Embedding Manual method using: Tissue-Tek 5 embedder and PME3 EmbeddingIntra-operative diagnosisRapid frozen section Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using: PM34 Manual H&E and

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	Type of test/Properties		
Materials/Products tested	measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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	Μ, Υ
FFPE tissue	Detection of the following:	Special staining Manual methods using:	
	Alcian Blue/Pas with diastase Digestion Acid Mucins		М, Ү
	Acid and sulphated mucins	PSM6 Alcian Blue	M, Y
	Amyloid	PSM31Congo Red	M, Y
	Bile Pigments	PSM32 Fouchet	M, Y
	Differentiating between hematopoietic cells	PSM9 Giemsa	М, Ү
	Helicobacter pylori	PSM10 Modified Giemsa	M, Y
	Gram positive and gram negative organisms	PSM11 Gram	М, Ү
	Basement membranes	PSM33 Jones Methenamine Silver	M, Y
	Fungal organisms	PSM12 Grocott Hexamine-silver	M, Y
	Fibrin	PSM13 Martius Soluble Blue (MSB)	М, Ү
	5HT in melanin and lipofuscins	PSM14 Masson-Fontana	М, Ү
	Collagen and smooth muscle	PSM15 Masson Trichrome	М, Ү

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HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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	М, Ү
	Haemosiderin	PSM20 Perls' Prussian Blue	M, Y
	Reticulin fibres	PSM21 Reticulin, Gordon and Sweet's modification	М, Ү
	Mast cell granules	PSM27 Toluidine Blue Metachromatic	М, Ү
	Collagen and fibrosis	PSM25 Haematoxylin Van Gieson (HVG)	М, Ү
	Acid Fast Bacilli	PSM29 Ziehl-Neelson	М, Ү

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HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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 Bondmax III staining machines	
	Anaplastic lymphoma kinase (Human p80 protein)	Alk1	М
	Mantle zone B lymphocytes & interfollicular T lymphocytes and other rare tumour types	Bcl2	Μ, Υ
	Germinal centre B lymphocytes	Bcl6	Μ, Υ
	Cell membrane glycoproteins expressed on healthy epithelia and in various carcinomas	Ber-EP4	Μ, Υ
	B cells, plasma cells	BOB-1	М
	Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma	34βE12	М, Ү
	Cancer antigen 125	CA125	Y
	Lymphoma panel	С-Мус	М, Ү
	Smooth muscle cells	Calponin	М
	Calcium binding protein structurally related to S100 and inhibin	Calretinin	Μ, Υ
	Epithelial	CAM 5.2	М, Ү
	Colonic transcription factor	CDX2	М, Ү

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HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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	М, Ү
	T cell	CD5	M, Y
	T cell	CD7	М
	T cell	CD8	М
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10	М, Ү
	Hodgkin's & Reed-Sternberg cells	CD15	М, Ү
	B lymphocytes	CD20cy	M, Y
	Follicular dendritic cells	CD21	М
	Key molecule for B cell activation and growth	CD23	М, Ү
	Activated T lymphocytes; NK cells	CD25	М
	Hodgkin's & Reed-Sternberg cells	CD30	М, Ү
	Endothelial cells; plasma cells; activated B & T lymphocytes	CD31	М, Ү
	Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours	CD34	М, Ү
	Multifunctional enzyme, identify plasma cells and plasmablastic differentiation	CD38	Μ, Υ

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HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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	М
	T & B lymphocytes	CD45	М, Ү
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56	М, Ү
	Macrophages; monocytes; granulocytes	CD68	М, Ү
	Normal & neoplastic B lymphocytes	CD79a	М, Ү
	Stem cell factor receptor, proto-oncogene activated in GIST tumors	CD117	Μ, Υ
	Heparan sulfate proteoglycan, syndecan-1 in the late stage of B cell differentiation	CD138	Μ, Υ
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	CEA	Μ, Υ
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin A	Μ, Υ
	Squamous epithelium	CK5	M,
	Simple, glandular & transitional epithelia	CK7	М, Ү
	Epithelial	CK8/18	М, Ү
	Epithelia	СК19	Y

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HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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	М, Ү
	Cytomegalovirus viral inclusions	CMV	М
	Mantle cell lymphoma	Cyclin D1	М, Ү
	Smooth & striated muscle cells	Desmin	M, Y
	Interstitial cells of Cajal in GI tract, GIST	DOG-1	М
	Neural cell adhesion	E-Cadherin	М, Ү
	Epstein Barr virus	EBER	М
	Epithelial membrane antigen (Glandular & ductal epithelia, perineurium; other cell types in various tumours)	EMA	М, Ү
	Cellular estrogen receptor expression	ER	Μ, Υ
	Dendritic cells.	Fascin	М
	Thyroid tumour subtyping	Galactin 3	М
	Primary breast cancer marker	GATA-3	М
	Metastatic Breast Cancer	GCDFP-15	М
	Glial fibrillary acidic protein (Neural cells)	GFAP	М, Ү

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	Human Chorionic Gonadotropin (Trophoblastic elements, e.g. in germ cell tumours)	HCG	М, Ү
	Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours)	HMB45	М, Ү
	Sertoli cells (diffuse and strong), granulosa cells, prostate, brain, adrenal	Inhibin	M, Y
	Demonstrates proliferating cells	Ki-67	М, Ү
	Breast cancer	Mammoglobin	M, Y
	Melan A (MART-1) differentiation antigen (Normal, activated & neoplastic melanocytes)	Melan A	М, Ү
	MLH-1 mismatch repair protein	MLH1	М
	Cytokeratins 5, 6, 8, 17, 19 (All epithelia)	MNF116	М, Ү
	Myeloperoxidase in Neutrophils, eosinophils, monocytes	МРО	Μ
	MSH-2 mismatch repair protein	MSH2	Μ

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (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	М
	Multiple myeloma oncogene-1	MUM-1p	M, Y
	Enolase gamma subunit (neuronal & neuroendocrine cells)	NSE	М, Ү
	Seminoma	Oct-02	М
	Pluripotent germ cell tumours	OCT 3/ 4	M, Y
	Pre-B cells	PAX-5	М
	Ovarian serous carcinoma, clear cell renal cell carcinoma, papillary thyroid carcinoma	PAX-8	Μ
	Placental Alkaline Phosphatase in germ cell tumours, particularly seminomas; also breast, lung, ovarian carcinomas	PLAP	Μ, Υ
	Pulmonary squamous cell carcinoma marker	P40	Y
	Cellular progesterone receptor expression	PR	М, Ү
	PMS2 mismatch repair protein in colorectal carcinomas	PMS2	М
	Prostate specific antigen	PSA	M, Y
	Prostate secretory and ductal epithelium	PSMA	М, Ү
		PSMA	M, Y



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	p16INK4a oncoprotein (Normal, activated and neoplastic melanocytes)	p16	М, Ү
	Neoplastic cells in epithelium	р53	М, Ү
	Squamous epithelium	p63	М, Ү
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types	S100	М, Ү
	Smooth muscle, myoepithelial and other contractile cells	SMActin	М, Ү
	Gastrin	Gastrin	М
	Programmed cell death protein 1	PD1	М
	Prostatic tumor suppressor gene	NKX3.1	М
	Terminal Deoxynucleotidyl Transferase	Tdt	М
	CK HMW+p63+AMACR (RM)	PIN cocktail	M,Y
	Podoplanin antibody	D2-40	Y
	Helicobacter Pylori	H pylori	М
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: PDR50	Μ, Υ

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE (cont'd)	Diagnostic cytology examination activities for the purpose of clinical diagnosis	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	Н
		Papanicolaou and MGG staining Automated/manual using in-house procedures: CEQ4 using Cytospin 4, CEQ10 T2000 Tissue Processor	Н
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: CPR35 CPR100	Н

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code	
	Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below		
Blood	Blood Grouping (ABO and RhD type	TXS10, TXS11, TXS12, TXS27, TXS63 and TXS64 using Ortho Vision card/column agglutination and tube technique	М, Ү	
	Red Cell Antibody Screen	TXS10, TXS63 and TXS64 using Ortho Vision card/column agglutination	М, Ү	
	Rhesus and K phenotyping Rh – C, D, E, c, e, Kell - K	TXS5, TXS63 and TXS64 using Ortho Vision card/column agglutination	М, Ү	
	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	М, Ү	
	Detection of Antibodies: Rhesus blood group Antibodies: anti-C, anti-c, anti-D, anti-E, anti-e 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	М, Ү	
	Direct Antiglobulin Test	TXS12, TXS26, TXS63 and TXS64 using Ortho Vision card/column agglutination	М, Ү	
	Monospecific Coombs Test (IgG, C3d/C3b)	TXS12, TXS45, TXS63 and TXS64 using Ortho Vision card/column agglutination	Μ, Υ	

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MEDICAL 9769	Southwest Pathology Services LLP Issue No: 007 Issue date: 09 January 2024				
Accredited to	1330C NO. 007				
	ISO 15189:2012 Testing performed at main address only				
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code		
	Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below			
Blood (cont'd)	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	М, Ү		
	Detection and Estimation of Foetal Maternal Haemorrhage through Quantification of foetal Hb in Maternal blood	TXS16 using Kleihauer test - acid elution followed by microscopy	М, Ү		
	 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		

UKAS MEDICAL 9769 Accredited to ISO 15189:2012	United Kingdor 2 Pine Trees, Chertsey Land Southwest F	e of Accreditation issued by n Accreditation Service a, Staines-upon-Thames, TW18 3H Pathology Services LLP Issue date: 09 January 2024	
Testing performed at main address only			
Materials/Products tested	Type of test/Properties	Standard specifications/	Location

HUMAN BODY FLUIDS	Andrological examination activities for the purposes of		
	clinical diagnosis		
Semen	Post vasectomy:	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	Н
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	н
	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)	
I	END		