

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9308

Accredited to
ISO 15189:2012

University Hospitals of Derby and Burton NHS Foundation Trust operating as Derbyshire Pathology

Issue No: 007 Issue date: 08 February 2021

Royal Derby Hospital
Uttoxeter Road
Derby
Derbyshire
DE22 3NE

Contact: Mariska Faint-Uffen
Tel: +44 (0) 1332 789316
Website: www.derbyhospitals.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Department of Pathology Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE		A
Local contact Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316		
Address Fertility Unit, Level 1 Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE		B
Local contact Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316		
Address Combined Day Unit Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE		C
Local contact Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316		



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Site activities performed away from the locations listed above:

Location details	Activity
Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE	Local Contact: Mariska Faint-Uffen 01332 789316 Phlebotomy
London Road Community Hospital London Road Derby Derbyshire DE1 2QY	Local Contact Mariska Faint-Uffen 01332 789316 Phlebotomy
Blood Bank satellite issue fridge - Fridge room, level 5 Royal Derby Hospital DE22 3NE	Local Contact: Mariska Faint-Uffen 01332 789316 Blood Issue Fridge No testing occurs on this site, blood storage only
Blood satellite issue fridge - General theatre, level 2 , Royal Derby Hospital DE22 3NE	Local Contact: Mariska Faint-Uffen 01332 789316 Blood Issue Fridge No testing occurs on this site, blood storage only
	Local Contact: Mariska Faint-Uffen 01332 789316 Blood Issue Fridge No testing occurs on this site, blood storage only
Blood satellite fridge - Gynae theatre , M&G, level 2 Royal Derby Hospital DE22 3NE	Local Contact: Mariska Faint-Uffen 01332 789316 Blood Issue Fridge No testing occurs on this site, blood storage only
Blood satellite fridge - Combined Day unit, level1 , Royal Derby Hospital DE22 3NE	Local Contact: Mariska Faint-Uffen 01332 789316 Blood Issue Fridge No testing occurs on this site, blood storage only
Mortuary, Level 0, Royal Derby Hospital DE22 3NE	Local Contact: Mariska Faint-Uffen 01332 789316 Body storage facilities



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
HUMAN BODY FLUIDS	<u>Andrology examination activities for the purpose of clinical diagnosis:</u>	All techniques carried out manually according to WHO (2010) guidelines	B
Seminal fluid	Fertility assessment: Volume pH Motility Concentration	FERTSOP48	
	Fertility assessment: morphology	FERTSOP48	
	Post vasectomy testing: Sperm presence/absence	FERTSOP11	
	<u>Biochemistry examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant:	A
		AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide	
Serum/Plasma	AlphaFetoProtein (AFP)	Roche Cobas e601 Module using Immunoassay:	
Serum/Plasma	Anti-Mullerian Hormone		
Serum/Plasma	CA12-5		
Serum/Plasma	CA15-3		
Serum/Plasma	CA19-9		
Serum/Plasma	CEA		
Serum/Plasma	C-Peptide		



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
HUMAN BODY FLUIDS (cont'd)	Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide Roche Cobas e601 Module using Immunoassay: Roche Cobas c501 Module using photometry	A
Serum/Plasma	Free PSA		
Serum/Plasma	Total HCG		
Serum/Plasma	Insulin		
Serum/Plasma	Thyroglobulin		
Serum/Plasma	Thyroglobulin antibodies		
Serum/Plasma	Alpha-1-acid glycoprotein (AGP)		
Serum/Plasma	Alpha-1-antitrypsin		
Serum/Plasma	Amikacin		
Plasma	Ammonia		
Serum/Plasma	Angiotensin Converting Enzyme (ACE)	Tinity Biotech kit, AUTOCHSOP229	
Serum/Plasma	Carbamazepine		
Serum/Plasma	Complement C3		
Serum/Plasma	Complement C4		



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HUMAN BODY FLUIDS (cont'd)	Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide	A
Serum/Plasma	Ethanol		
Serum/Plasma	Haptoglobin		
Serum/Plasma	IgA		
Serum/Plasma	Lactate dehydrogenase		
Serum/Plasma	Methotrexate	Siemens Heathineers kit, AUTOCHSOP87	
Serum/Plasma	Phenobarbitone		
Serum/Plasma	Phenytoin		
Serum/Plasma	Rheumatoid factor		
Serum/Plasma	Teicoplanin	Thermo Scientific Quantitative Micoparticle system (QMS), AUTOCHSOP249	
Serum/Plasma	Theophylline		
Serum/Plasma	Tobramycin		
Serum/Plasma	Valproate		



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HUMAN BODY FLUIDS (con't'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In house documented procedures based on standard methods and incorporating Roche cobas 8000 manufacturers' instructions as relevant: AUTOCHSOP192 Use of Roche Cobas 8000 Analysers AUTOCHSOP259 Roche Cobas MPA 8100 User Guide COBAS Line 1 ¹ COBAS Line 2 ² COBAS Line 3 ³	A
Serum, Plasma, Urine	Sodium, Potassium, Chloride	Roche Cobas c702 Module using Indirect ISE Line 1, 2, 3	
Serum, plasma	Albumin	Roche Cobas c702 Module using photometry Line 1, 2, 3	
Urine	Albumin	Line 2, 3	
Serum, plasma	ALP ALT Aspartate Aminotransferase	Line 1, 2, 3	
Serum, plasma	Amylase		
Serum, plasma	Bicarbonate		
Serum, plasma	Bilirubin total Bilirubin conjugated		
Serum, plasma, urine	Calcium		
Serum, plasma	Creatinine Kinase C-Reactive Protein		



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HUMAN BODY FLUIDS CONTD	Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide	A
Urine	Creatinine (enzymatic)		
CSF	Creatinine (Jaffe)		
Serum, plasma, urine	Glucose and total protein		
Serum, plasma	Glucose		
	Gentamicin		
	Gamma-GT		
	HDL Cholesterol		
	IgA	Line 2, 3	
	IgG		
	IgM		
Serum, plasma	Iron	Line 1, 2, 3	
Plasma	Lactate		
Serum, plasma	Magnesium		
	Paracetamol	Cambridge Life Sciences kit, AUTOCHSOP196	
Serum, plasma, urine	Phosphate		
Serum, plasma	Salicylate		
	Total cholesterol		



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HUMAN BODY FLUIDS CONTD	Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide	A
Serum, plasma, urine	Total protein		
	Transferrin	Line 2, 3	
	Triglyceride	Line 1, 2, 3	
	Urea		
	Urate		
Serum, plasma	Vancomycin	Roche Cobas c502 module using photometry	
Plasma	Ammonia	Line 1	
Serum, plasma	Bile acid	DIALAB kit, AUTOCHSOP159	
	Ethanol		
	Lactate dehydrogenase		
	Lithium	Roche Cobas e801 Module using Immunoassay	
	Cortisol	Line 1, 2, 3	
	Digoxin		
	Oestradiol	Line 2, 3	
	Ferritin		



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HUMAN BODY FLUIDS CONTD	<p>Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u></p> <p>Follicle stimulating hormone</p> <p>Free T3</p> <p>Free T4</p> <p>Free beta HCG</p> <p>Luteinising hormone</p> <p>NT Pro BNP</p> <p>Prolactin</p> <p>Macroprolactin</p> <p>Progesterone</p> <p>Parathyroid hormone</p> <p>Folate</p> <p>Sex hormone binding globulin</p> <p>Testosterone</p> <p>Total PSA</p> <p>Troponin T</p> <p>Thyroid stimulating hormone</p>	<p>In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant:</p> <p>AUTOCHSOP232 Use of Roche Cobas 6000 analysers</p> <p>AUTOCHSOP259 Roche Cobas MPA 8100 user guide</p> <p>Line 1, 2, 3</p> <p>Line 2, 3</p> <p>AUTOCHSOP101</p> <p>Line 1, 2, 3</p> <p>Line 2, 3</p> <p>Line 1, 2, 3</p>	A



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HUMAN BODY FLUIDS CONTD	Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide	A
	Vitamin B12	Line 2, 3	
	Vitamin D	Line 3	
		Chromosystems HPLC-ECD: SPCHEMSOP46 - HPLC	A
Urine	Metadrenaline, Normetadrenaline and 3-methoxytyramine	SPCHEMSOP3	
Urine	5-Hydroxy indole acetic acid (5HIAA)	SPCHEMSOP1	
		Chromosystems HPLC-UV: SPCHEMSOP46 - HPLC	
Blood	Vitamin B1	SPCHEMSOP37	



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HUMAN BODY FLUIDS (CONT'D):	Biochemistry <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Faeces	Faecal Elastase	ScheBo Biotech/ Dynex DS2 ELISA: POCSOP22 IMMSOP48 Sebia: SPCHEMSOP11 - SEBIA HYDRASYS SPCHEMSOP23 - USE OF SEBIA PHORESIS SOFTWARE SPCHEMSOP24 - USE OF SEBIA CAPILLARYS 2	
Serum/ Plasma	Protein Electrophoresis: monoclonal protein	SPCHEMSOP13	
Serum/ Plasma	Immunofixation: monoclonal protein typing	SPCHEMSOP14	
Serum/Plasma	Alkaline Phosphatase Isoenzymes	SPCHEMSOP16	
Serum	Alpha 1 antitrypsin phenotyping	SPCHEMSOP54 Binding Site: Optilite Immunoassay SPCHEMSOP31	
Serum/Plasma	Free Kappa and Lambda Light Chains	SPCHEMSOP30	
Serum/Plasma	Beta-2-microglobulin	SPCHEMSOP29	



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HUMAN BODY TISSUES AND FLUIDS (CONT'D)	Biochemistry <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Serum/Plasma	Free Kappa and Lambda Light Chains	Binding Site: Optilite Immunoassay SPCHEMSOP31	
Serum/Plasma	Beta-2-microglobulin	SPCHEMSOP30	
Sweat	Chloride	SPCHEMSOP29	
Sweat	Conductivity	Wescor/Sherwood 926S Titrimetric POCSOP31 PATHEXT19 - Guidelines for the Performance of the Sweat Test for the Investigation of CF in the UK POCSOP1 - WESCOR SWEAT TEST-COLLECTION OF SAMPLES POCSOP3 - WESCOR SWEATCHEK 3120 CONDUCTIVITY METER	
Serum/Plasma	IgA anti-tTg antibody IgG anti-tTg antibody	Wescor Macroduct® Sweat Collection System, conductivity measurement POCSOP3	
		ThermoPhadia ImmunoCap 250: Immunoassay SPCHEMSOP35 – TGA PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER CHIAUTH8-Authorisation guidelines for coeliac serology SPCHEMSOP52-Use of the Phadia 250 for measuring IgG Tissue Transglutaminase antibodies	



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HUMAN BODY TISSUES AND FLUIDS (CONT'D)	Biochemistry <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Serum/Plasma	IgA anti-tTg antibody IgG anti-tTg antibody	ThermoPhadia ImmunoCap 250: Immunoassay SPCHEMSOP35 – TGA PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER CHIAUTH8-Authorisation guidelines for coeliac serology SPCHEMSOP52-Use of the Phadia 250 for measuring IgG Tissue Transglutaminase antibodies	
Serum and Urine	Osmolality	Advanced Instruments 3320 Osmometry - Freezing point depression AUTOCHSOP97 AUTOCHSOP242 - Chemistry Calculators PATHEXT1125 - Osmometer 3320 User Guide & Service Manual	
CSF	CSF Xanthochromia	UVIKON/Northstar Photometric SPCHEMSOP9 SPCHEMSOP26 - Spectrophotometer	



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HUMAN BODY TISSUES AND FLUIDS (CONT'D)	Biochemistry <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: ABSciex API4000 Tandem Mass spectrometer LCMSMS SPCHEMSOP32 – API4000	A
Serum/Plasma	Steroids: androstenedione	SPCHEMSOP42	
Serum/Plasma	Steroids: testosterone	SPCHEMSOP42	
Blood	Carboxy-haemoglobin	Werfen Gem5000 Blood gas analyser, spectrophotometric analysis POCSOP7 POCUG1 ABSciex API4000 Tandem Mass spectrometer LCMSMS SPCHEMSOP32 – API4000	
Serum/Plasma	Steroids: 17 OH - progesterone	SPCHEMSOP42	
Blood	Cyclosporin, Sirolimus, Tacrolimus	SPCHEMSOP28	



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D)</p> <p>Serum/Plasma & Urine</p>	<p>Biochemistry <u>examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Calculated Tests: eGFR Adjusted Calcium AKI Standard urine test reporting per 24hrs AST: ALT ratio Albumin excretion ratio Calcium excretion index Calcium creatinine ratio Low density lipoprotein Creatinine clearance Free androgen index Globulin Kappa/Lambda Ratio Macroprolactin % recovery Macroprolactin – monomeric Non-HDL Cholesterol Normalised Carbamazepine Normalised Phenytoin Transferrin saturation Urine protein: creatinine</p>	<p>In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:</p> <p>CHIAUTH44</p>	<p>A</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens	<p><u>Histopathology</u> <u>examination activities for the purpose of clinical diagnosis:</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Macroscopic and Microscopic examination supported by:</p> <p><u>Tissue Dissection</u>- HISDSOPs 1-68 <u>HISDSOP1-10, 12-21, 23-39,41-42, 44-47, 49, 51-55, 58, 62-65, 67-69, 71-73, HGENSOP58 - 59</u> <u>Decalcification</u> – HISRSOP20</p>	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples.		<p>Macroscopic and Microscopic examination supported by:</p> <p><u>Tissue Processing</u> Leica- ASP300, ASP6025 Thermo- ES, ET HISDSOP23, HISRSOP50, HISRSOP43 <u>HISDSOP40, HISDSOP56</u></p>	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples.		<p>Specimen X-Ray Daax BioVision Path Vision Faxitron HISROP21</p> <p><u>Embedding</u> Thermo Histostar HRLSOP1 CPMANHIST 08</p> <p><u>Microtomy</u> Leica RM2235 Leica RM2255 Thermo-cryotome AS 620E Nikon E400 HRLSOP4, HRLSOP5, HRLSOP7</p>	



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HUMAN BODY FLUIDS (CONT'D):	<p><u>Histopathology</u> <u>examination activities for the purpose of clinical diagnosis:</u></p>	<p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: All stains are undertaken manually; however some stains are performed on an automated special stains platform (Benchmark Special stains): HSSSOP43, HSSSOP45. Automated stains are highlighted below.</p>	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples.	Routine staining for identification of basophilic and eosinophilic structures	<p><u>Frozen section</u> H+E staining- HSSSOP13</p> <p><u>Routine FFPE Automated H & E Staining</u> using the Leica ST5010 Stainer – SOP HRLSOP9 Haematoxylin & Eosin Stain – SOP HRLSOP9 and HRLSOP12</p>	
	Acid Mucins	Alcian Blue Method (pH2.5) for Acid Mucin – SOP HSSSOP1	
	Glycogen, Neutral & Acid Mucins	Alcian Blue Periodic Acid Sciffs diastase – SOP HSSSOP46 Diastase Periodic Acid Schiffs- HSSSOP6 (Automated).	
	Amyloid	Congo Red – SOP HSSSOP5	
	Elastic Fibres, Collagen and muscle, connective tissue	Elastin Van Gieson - HSSSOP7 HVG - HSSSOP15	
	Microrganisums and parasites: Campylobacter	Giemsa - HSSSOP9	
Gram	Gram - HSSSOP10		



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HUMAN BODY FLUIDS (CONT'D):	<u>Histopathology</u> <u>examination activities for the purpose of clinical diagnosis:</u>	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: All stains are undertaken manually; however some stains are performed on an automated special stains platform (Benchmark Special stains): HSSSOP43, HSSSOP45. Automated stains are highlighted below.	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples	Pnumocystis /Fungi	Grocott - HSSSOP12 (Automated).	
	Leprosy	Wade Fite - HSSSOP33	
	TB	Ziehl Neelsen - HSSSOP35	
	Collagen/fibrin	MSB - HSSSOP19	
	Melanin and argentaffin granules	Masson Fontana- HSSSOP16	
	Ferric Iron	Perls - HSSSOP24 (Automated).	
	Reticulin fibres	Retic - HSSSOP27 (Automated).	
	Mast cells	Toluidine Blue - HSSSOP31	
	Fibrin and muscle	Masson Trichrome - HSSSOP17 (Automated).	
	Neutral fats	Oil Red O - HSSSOP20	
	Hepatitis B surface antigen	Shikata's Orcein - HSSSOP29	
FFPE tissue on slides and tissue curls	Detection of EGFR mutations	RT-PCR on Cobas z480, HMOLSOP1 and HMOLSOP2	



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Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples	Fibrin and muscle	Masson Trichrome - HSSSOP17 (Automated).	
	Neutral fats	Oil Red O - HSSSOP20	
	Hepatitis B surface antigen	Shikata's Orcein - HSSSOP29	
FFPE tissue on slides and tissue curls	Detection of EGFR mutations	RT-PCR on Cobas z480, HMOLSOP1 and HMOLSOP2	



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<p>HUMAN BODY FLUIDS (CONT'D):</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Normal/neoplastic tissue of epithelial origin</p> <p>Non-neoplastic, neoplastic liver disease, tumours of the testis and ovary such as yolk sac tumour</p> <p>ALK-positive anaplastic large cell lymphoma</p> <p>Androgen Receptor – member of the superfamily of ligand responsive transcription regulators.</p> <p>Desmoid tumors, colorectal cancer and colon adenoma.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment:</p> <p>Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>AE1/AE3*- Reacts with the 65-67, 64, 59, 58, 56.5, 56, 54, 52, 50, 48 and 40 kDa cytokeratins.</p> <p>AFP- Alpha-1-fetoprotein (AFP)*</p> <p>ALK1**</p> <p>AR^</p> <p>B-CATENIN*</p>	<p>A</p>



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D):</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynaec samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Follicular lymphomas and diffuse lymphoproliferative diseases.</p> <p>Diffuse large B-cell lymphomas, follicular lymphomas and Burkitt lymphomas/ leukaemia</p> <p>Adenocarcinoma V malignant mesothelioma and BBC v SCC of Skin</p> <p>Germ cell tumours, choriocarcinoma, granulosa cell tumour, hydatiform mole and seminoma</p> <p>Serous ovarian carcinoma and mesothelioma</p> <p>Gastrointestinal and pancreatic cancers</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment:</p> <p>Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>BCL2*</p> <p>BCL6*</p> <p>BEREP4**</p> <p>B-HCG*</p> <p>CA125*</p> <p>CA19.9*</p>	<p>A</p>



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D):</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Basal epithelial cells</p> <p>Cytokeratins</p> <p>Protien of the paired box (PAX) family of transcription factors</p> <p><u>PD-L1 testing in NSCLC</u></p> <p>Malignant germ cell tumours</p> <p>Mismatch repair gene marker</p> <p>Progesterone receptor levels in breast cancer tissue</p> <p>Tumours of prostatic origin prostate adenocarcinoma.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>P63**</p> <p>PanCK**</p> <p>PAX8^</p> <p>PD-L1 (SP263) ^</p> <p>PLAP**</p> <p>PMS2^</p> <p>Progesterone Receptor^</p> <p>Prostate Specific Antigen (PSA) & Racemase (AMACAR)**</p>	A



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D):</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynaec samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Renal cell carcinoma vs. non-renal cell tumours</p> <p>Malignant melanoma, chondroblastoma, schwannoma</p> <p>Smooth muscle cells, myofibroblasts, and myoepithelial cells and their tumours</p> <p>For identification of myoepithelial cells and smooth muscle neoplasm.</p> <p>Melanoma Marker</p> <p>Neuroendocrine neoplasms and tumours with neuroendocrine differentiation.</p> <p>Non Small cell lung cancer (NSCLC)</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>Renal Cell Carcinoma**</p> <p>S100**</p> <p>SMA**</p> <p>SMM-HC**</p> <p>SOX10 * **</p> <p>Synaptophysin **</p> <p>ROS1^</p>	<p>A</p>



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D):</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Precursor B- and T-cell lymphoblastic lymphoma/ leukemia, and for identification of thymoma.</p> <p>Differentiation of mesothelioma from adenocarcinoma: Identification of vascular tumours</p> <p>Tumours of thyroid origin</p> <p>Primary vs. metastatic tumours in the lung and thyroid</p> <p>Cells of mesenchymal origin in normal and neoplastic tissues</p> <p>Wilms's tumour, malignant mesotheliomas</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>TdT**</p> <p>Thrombomodulin**</p> <p>Thyroglobulin**</p> <p>TTF1**</p> <p>Vimentin**</p> <p>WT1**</p>	<p>A</p>



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D):</p> <p>Liquid Based Cytology (LBC) suspension of cervical/vaginal cells</p>	<p><u>Cytopathology examination activities for the purpose of clinical diagnosis:</u></p> <p>Preparation and screening for detection or exclusion of pathological abnormalities</p>	<p>Sample preparation using the Hologic Thinprep Liquid Based Cytology method in conjunction with manufacturer's instructions using:</p> <p>Gynaecological cytology - Hologic T5000 Processor Papanicolaou Staining and coverslipping using: Sakura Tissue-Tek Prisma Stainer and Film coverslipper Screening by light microscopy (qualitative analysis). CSRSOP46, CSRSOP49, CSRSOP50, CSRSOP51, and CCSOP9</p>	A
<p>Samples collected from the cervix and stored in Liquid Based Cytology Collection Fluid</p>	<p>Detection of high-risk HPV mRNA</p>	<p>HOLOGIC –TOMCAT pre-analytics instrument, CSRSOP53 and HOLOGIC – PANTHER Molecular analyser: SOP CCSOP33 HPV Hologic Panther – Aptima HPV Assay.</p>	A



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<p>HUMAN BODY TISSUES AND FLUIDS (CONT'D):</p> <p>Bile duct brushings Cerebrospinal fluid Cyst fluid (various sites) Fine Needle Aspirates Gastric brushings Hydrocele fluid Oesophageal brushings Pancreatic duct brushings Respiratory Cytology: Bronchial brushings Bronchial washings Endobronchial Ultrasound-guided/Transbronchial Needle Aspiration (EBUS) Sputum Serous fluids Synovial fluid Urine Cytology: Uretric washings Urethral washings Urine</p> <p>Slides prepared in house as above</p>	<p><u>Cytopathology examination activities for the purpose of clinical diagnosis:</u></p> <p>Preparation and screening for detection or exclusion of pathological abnormalities</p> <p>Morphological assessment and interpretation/ diagnosis</p>	<p>Non-gynaecological (diagnostic) cytology - Sample preparation following in-house method ThermoShandon Cytospin 4 Hettich Centrifuge Cell blocks, clots and tissue microbiopsies Papanicolaou, May Grunwald-Giemsa and Haematoxylin and Eosin Staining using: ThermoFisher Scientific StainMate Immunocytochemical and Special Stains are performed in the Histology. Coverslipping using: Sakura Film coverslipper</p> <p>CNGCSOP4, CNGCSOP6,CNGSCSOP8, CNGCSOP13 and CNGCSOP15</p> <p>Microscopy: CPGENSOP2 CCSOP7</p>	A



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HUMAN BODY TISSUES AND FLUIDS (CONT'D):	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Blood	Glucose-6-Phosphate Dehydrogenase Screen (G6PD)	Trinity Biotech semi-quantitative fluorescent blood spot test SPHAEMSOP26	
EDTA Whole Blood	Full blood counts and automated differential: Haemoglobin (Hb) Total white cell count (WBC) Red cell count (RBC) Platelet count MCV MCH MCHC Nucleated red blood cells (NRBC) Neutrophils Lymphocytes Monocytes Eosinophils Reticulocytes HCT Basophils	Sysmex XN9000 Fluorescence flow cytometry, electrical impedance, SLS-haemoglobin method, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameters AUTOHASOP40 - XN-Series: Processing FBC and Retic Samples	
EDTA Whole Blood	Full blood counts and automated differential: Haemoglobin (Hb) HCT Total white cell count (WBC) Red cell count (RBC) Platelet count MCV MCH MCHC Neutrophils Lymphocytes Monocytes Eosinophils Basophils	Sysmex XN550 Fluorescence flow cytometry, electrical impedance, SLS-haemoglobin method, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameters AUTOHASOP70 – XN550: Processing FBC Samples	C



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HUMAN BODY TISSUES AND FLUIDS (CONT'D):	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
		In house documented procedures based on standard methods and incorporating Sysmex CS5100 and Sysmex CS2500 manufacturers' instructions as relevant:	A
Plasma	APTT	COAGSOP5	
Plasma	Fibrinogen	COAGSOP7	
Plasma	Prothrombin & International normalised ratio (INR)	In house documented procedures based on standard methods and incorporating Sysmex CS5100 manufacturers' instructions as relevant: COAGSOP4	A
Plasma	D-Dimers	Immunoassay: COAGSOP6	
Plasma	Manual Clotting Tests PT & APTT	In house documented manual procedures based on visual end point tilt tube method: Clifton Water Bath COAGSOP36	
Blood	Factor VIII inhibitor	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: Sysmex CS2500 Photometric Bethesda Method – COAGSOP37	



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HUMAN BODY TISSUES AND FLUIDS (CONT'D):	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Plasma	Factor assays Factor II Factor V Factor VII Factor VIII Factor IX Factor X Factor XI Factor XII	Sysmex CS2500 Photometric COAGSOP10 COAGSOP15	
Plasma	Lupus screen	COAGSOP14	
Plasma	Thrombin time	COAGSOP18	
Plasma	Protein S	COAGSOP13	
Plasma	VWF activity	COAGSOP16	
Plasma	VWF antigen	COAGSOP17	
Plasma	Antithrombin	COAGSOP11	
Plasma	Activated protein C Resistance (APC-R)	COAGSOP8	
Plasma	Anti-Xa activity, Rivaroxaban and Apixaban	COAGSOP39	
Plasma	Protein C	COAGSOP12	
Blood	Detection of: Prothrombin 20210A	Hain GenoXtract and Fluorocycler PCR, COAGSOP21	
	Factor V Leiden	Hain GenoXtract and Fluorocycler PCR, COAGSOP21	



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HUMAN BODY FLUIDS (CONT'D):	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Blood	Erythrocyte Sedimentation Rate (ESR)	Starsted TL ESR analyser AUTOHASOP57 -Starsted TL: Processing ESR Samples	
Bone Marrow	Examination of bone marrow: in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Manual slide preparation and interpretation. AUTOHASOP15 - Processing Bone Marrow Requests AUTOHASOP16 – Procedure for staining of bone marrow slides SPHAEMSOP63 – Reporting bone marrow aspirates and trephines	
Blood	Blood Film: Detection of normal and abnormal morphologies and white blood cell differential	Manual slide preparation and interpretation. AUTOHASOP30 - Examination and Reporting Blood of Blood Films Automated Staining: Sysmex SP10 AUTOHASOP45 - SP-10: Processing Samples	
Blood	Pre-caterisation of cells	Sysmex DI-60 Digital Morphology Analyser for automated blood film morphology AUTOHASOP65, AUTOHASOP43.	
Blood	Glandular fever: heterophile antibodies to Epstein Barr Virus	Accusay mono Immunoassay AUTOHASOP10	
Blood	Haemoglobin A1C (HbA1C)	Bio-Rad D100 HPLC system SPHAEMACSOP16 SPHAEMACSOP17	



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HUMAN BODY FLUIDS (CONT'D):	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Blood	Haemo-globinopathy: Quantitation of HbA2, HbF, HbS Identification/ Quantitation of other Variant Hb	Biorad Variant II: SPHAEMHBESOP1 - Haemoglobinopathies Introduction SPHAEMHBESOP5 -Biorad Variant II run procedure	
Blood	CD4 count / Immune Monitoring CD3 % & Absolute CD3/4 % & Absolute CD3/8 % & Absolute CD19 % & Absolute	Beckman Coulter Navios: Flow cytometry SPHAEMSOP55 - Navios Processing of samples for CD4 counts	
Urine	Haemosiderin	Manual Colorimetric stain assay SPHAEMSOP27 AUTOHASOP17 – Iron Stain	
Plasma	Detection of Malarial antigens of: <i>P. falciparum</i> Pan-detection for <i>P. malariae</i> , <i>P. ovale</i> & <i>P. vivax</i>	CareStart™ Malaria HRP2/pLDH Combo Immunoassay AUTOHASOP34	
Blood	Sickle Solubility test	Microgen Bioproducts S-Test Turbidity SPHAEMSOP28	
Blood	Detection of Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae, Plasmodium knowlesi	Manual staining of thick and thin films using Fields stain AUTOHASOP9.	



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HUMAN BODY FLUIDS (CONT'D): Whole blood (EDTA)	<p><u>Blood Transfusion examination activities for the purpose of clinical diagnosis:</u></p> <p>Automated blood grouping by antigen detection:</p> <ul style="list-style-type: none"> • ABO blood groups • Rh blood group antigens: C,c,D,E,e • K (K1) blood group antigens <p>Automated antibody Identification for the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb,Fya,Fyb,Jka,Jkb, Lea,Leb,P1,M,N,S,s,Lu,Lub, Xga</p> <p>Direct Antiglobulin Test (DAT)</p>	<p>Documented in-house procedures based on manufacturer's instructions for BioRad analysers, IH1000:</p> <p>Automated antibody screening using 3 cells containing the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb,Fya,Fyb,Jka,Jkb, Lea,Leb,P1,M,N,S,s,Lu,Lub, Xga: BBSOP92 BBSOP97 BBSOP15 BBSOP6</p> <p>BBSOP4 Automated (IAT) identification of red cell antibodies.</p> <p>IH1000 automated or manually read Diamed ID Microtyping cards: Coombs direct antiglobulin test. BBSOP19</p>	A



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HUMAN BODY FLUIDS (CONT'D):	<p><u>Blood Transfusion examination activities for the purpose of clinical diagnosis:</u></p> <p>Red cell phenotyping:</p> <ul style="list-style-type: none"> • Biorad Diaclon Anti-M (monoclonal) • Lorne Anti-Fya (monoclonal) • Lorne Anti-Fyb (polyclonal) • Lorne Anti-Jka (polyclonal) • Lorne Anti-Jkb (monoclonal) • Lorne Anti-S (polyclonal) • Lorne Anti-s (monoclonal) 	<p>Documented in-house procedures based on manufacturer's instructions for BioRad analysers, IH1000:</p> <p>BBSOP56</p>	A
Whole blood (EDTA)	<p>Manual blood grouping by antigen detection:</p> <ul style="list-style-type: none"> • ABO blood groups • Rhesus blood group antigens: C,c,D,E,e <p>K (K1) blood group antigens</p>	<p>ABO/D Forward + Reverse Group, K and Rh Phenotype by Gel column agglutination and centrifugation.</p> <p>BBSOP14 BBSOP43 BBSOP6</p>	



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HUMAN BODY FLUIDS (CONT'D):	<p><u>Blood Transfusion examination activities for the purpose of clinical diagnosis:</u></p> <p>Manual antibody screening and identification using cells containing the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kp b,Fya,Fyb,Jka,Jkb,Lea,Le b,P1,M,N,S,s,Lua Lub, Xga</p> <p>Compatibility Testing: Serological Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma.</p> <p>Detection and Estimation of Foetal Maternal Haemorrhage</p> <p>Acid Elution & confirmation of FMH >2mL</p>	<p>Documented in-house procedures based on manufacturer's instructions for BioRad analysers, IH1000:</p> <p>BioRad -Gel column agglutination and centrifugation technology: BBSOP4</p> <p>Documented in-house procedures based on BioRad manufacturer's instructions for column technology and centrifugation. BBSOP18</p> <p>Clin-Tech Kleihauer Method BBSOP7</p> <p>Navios Flow Cytometer SPHAEMSOP19</p>	A



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HUMAN BODY FLUIDS (CONT'D):	<u>Immunology</u> <u>examination activities for the purpose of clinical diagnosis:</u>	In house documented procedures based on standard methods and incorporating Dynex DS2 immunoassay manufacturers' instructions as relevant	A
Serum/Plasma	Anti-Cardiolipin abs IgG	IMMSOP48	
	Anti-ds-DNA antibodies	IMMSOP34	
	Anti-ENA antibodies	IMMSOP35	
	Anti-Jo-1 antibodies	IMMSOP37	
	Anti-RNP antibodies	IMMSOP36	
	Anti-Sm antibodies	IMMSOP36	
	Anti-SS-A antibodies (Ro)	IMMSOP36	
	Anti-SS-B antibodies (La)	IMMSOP36	
	Glomerular basement membrane antibodies	IMMSOP36	
	Intrinsic factor antibody	IMMSOP33	
	Myeloperoxidase antibodies	IMMSOP38	
		IMMSOP39	



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HUMAN BODY FLUIDS (CONT'D):	Immunology <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating Dynex DS2 immunoassay manufacturers' instructions as relevant IMMSOP48	A
Serum/Plasma	Proteinase 3	IMMSOP40	
	SCL-70 antibody	IMMSOP36	
Serum/Plasma	Specific IgE testing: Almond Apple Aspergillus F Banana Bee venom Birch Brazil nut Cashew Cat Celery Cheddar Cheese Coconut Cod Crab Dog Egg Fish mix Food mix Hazel	In house documented procedures based on standard methods and incorporating ThermoPhadia ImmunoCap 250: PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER SPCHEMSOP18	



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HUMAN BODY FLUIDS (CONT'D):	<u>Immunology</u> <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions for ThermoPhadia ImmunoCap 250: PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER	A
Serum/Plasma	Specific IgE testing: Horse House Dust Mite Total IgE Kiwi Latex Milk (Cows) Mould mix Nut mix Peanut Pecan Penicillin g Penicillin v Pistachio Salmon Sesame Seed Shrimp Soya Strawberry Timothy Grass Tomato Tree mix Tuna Wheat Weed mix Walnut Wasp	SPCHEMSOP18	



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HUMAN BODY FLUIDS (CONT'D): Serum/Plasma	<p><u>Immunology</u> <u>examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Anti-cyclic citrullinated peptide antibodies</p> <p>Anti-nuclear antibodies (IgG)</p> <p>Anti-nuclear cytoplasmic antibody Screen</p> <p>Crithidia Immuno-fluorescence</p>	<p>In house documented procedures based on standard methods and incorporating manufacturers' instructions for ThermoPhadia ImmunoCap 250: PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER</p> <p>IMMSOP46</p> <p>ASP1200 Automated slide processor, Immunofluorescence: IMMSOP51 IMMSOP47 IMMSOP1 IMMSOP42</p> <p>Manual, Indirect Immunofluorescence: IMMSOP1</p> <p>IMMSOP16</p> <p>IMMSOP18</p>	A



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HUMAN BODY FLUIDS (CONT'D):	<u>Immunology</u> <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant	A
Serum/Plasma	Endomysial antibody – IgA Endomysial antibody - IgG	IMMSOP11	
	Intercellular/skin antibodies - IgG	IMMSOP10	
Serum	Liver/Kidney microsomal antibodies.	IMMSOP43	
Serum/Plasma	Mitochondrial antibodies – IgG	IMMSOP43	
	Smooth muscle antibodies - IgG	IMMSOP43	
	Parietal cell antibodies	IMMSOP49	



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<p>HUMAN BODY FLUIDS (CONT'D):</p> <p>Material from swabs from wounds, skin, lines, eyes, ears, throats, ulcers and nose. Line Tips</p> <p>Material from swabs from Nose, Groin, Throat, Axilla, Perineum and Wounds.</p> <p>Faeces</p> <p>Sputum, Bronchial Washings, Nasopharyngeal Aspirates, Tracheal Aspirates, Cough Swabs and Endotracheal tubes</p> <p>Material from swabs from Rectum, Wound and Invasive Device Sites. Faeces, CSU and Sputum. (Patients transferred from other major hospitals only).</p>	<p>Microbiology <u>examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance.</p> <p>Isolation of MRSA and MSSA</p> <p>General isolation and characterisation of Salmonella, Shigella, Campylobacter, Ecoli O157, Vibrio and Yersinia.</p> <p>General isolation and characterisation of Respiratory Tract infections (excluding TB) for micro-organisms of clinical significance</p> <p>Carbapenemase Resistant Enterobacteriaceae (CRE) and Carbapenemase Resistant Organisms (CRO)</p>	<p>In house documented procedures based on PHE SMI's:</p> <p>Manual culture using SOP's:</p> <p>MICNEWSOP20 - Processing diagnostic swabs.</p> <p>MICSCRSOP3 – MRSA screen. MICSCRSOP10 – Investigation of swabs for Staphylococcus aureus</p> <p>MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile).</p> <p>MICCL3SOP7 - Culture of Respiratory Specimens (except Mycobacterium sp).</p> <p>MICSCRSOP11 – Carbapenemase producing organism screening</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (CONT'D):</p> <p>Material from swabs: - from vagina, vulva, vulvo-vaginal, rectal, urethral, mouth and endocervix.</p> <p>CSF's, Ascitic, Peritoneal, Pleural, Pericardial, Amniotic, Joint/bursa and CAPD fluid.</p> <p>Tissue, Biopsies, synovium, nodes, tissue swabs and bone.</p> <p>Pus, drain fluids, semen, breast milk, seroma, aspirate, washouts, fluid swabs and bile</p> <p>Urine - MSU, CSU, Nephrostomy, Supra pubic aspirate and Bag urine.</p>	<p>Microbiology <u>examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance.</p> <p>Quantification of white and red blood cells and bacteria. Culture leading to general isolation and characterisation of micro-organisms of clinical significance.</p> <p>The quantification of white and red blood cells, bacteria and epithelial cells. Leading to general isolation and characterisation of micro-organisms of clinical significance.</p>	<p>In house documented procedures based on PHE SMI's:</p> <p><u>Manual</u> culture and microscopy (wet prep) using SOP: MICSCRSOP9 – Investigation of Genital Tract specimens MICSCRSOP12 – Investigation of mouth swabs for Candida spp.</p> <p><u>Manual</u> culture and microscopy (including Gram stain) using SOP: MICBBSOP1– Investigation and Identification of Body Bench Samples</p> <p><u>Manual</u> culture and <u>automated</u> microscopy using SOP: MICURSOP7 - Microbiological Investigation of Urine, in conjunction with the equipment manual using the Systemx UF5000 automated urine microscopy analyser.</p>	A



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<p>HUMAN BODY FLUIDS (CONT'D):</p> <p>Blood, CAPD, Joint Aspirates, Pleural Fluid & Pericardial Fluid</p> <p>Cultures isolated in-house from above samples.</p>	<p>Microbiology <u>examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation and characterisation of microorganisms of clinical significance</p> <p>Measurement of antibiotic sensitivity.</p> <p>Identification of microorganisms of clinical significance</p>	<p>In house documented procedures based on PHE SMI's:</p> <p>BD Bactec FX blood culture fluorescent growth detection system, by detection of pH changes due to CO₂ production. <u>Manual</u> culture and Microscopy using SOP: MICBCSOP11 – Blood Culture Procedures</p> <p>Antibiotic sensitivity testing (disc diffusion) and MICE (breakpoint strips) determination using BSAC standards MICESENSOP2 – Antibiotic Sensitivity Testing</p> <p>Automated identification and antibiotic sensitivity testing using SOP: MICESENSOP4 - Vitek2® Procedures.</p> <p>Identification of microorganisms of clinical significance by reaction to biochemical reagents: MICESENSOP43 - Bench tests and basic identification methods MICESENSOP44 - SOP APPLICATION AND USAGE OF API/ID32 KITS</p> <p>Identification of microorganisms of clinical significance by matrix assisted laser desorption ionization-time of flight mass spectrometry: Bruker/BD Microflex Biotyper (MALDI-TOF) Mass Spectrometry. MICMALDISOP1-MALDI-TOF MS Test Procedure</p>	<p>A</p>



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HUMAN BODY FLUIDS (CONT'D):	Microbiology <u>examination activities for the purpose of clinical diagnosis</u>	In house documented procedures based on PHE SMI's:	A
Sputum, Bronchial Washings, Nasopharyngeal Aspirates, Tracheal Aspirates, Pleural fluids, Lymph Nodes, Tissues, Fluids, Pus and CSF's	General isolation and characterisation of Mycobacterium (typical and atypical).	<u>Manual</u> microscopy for the detection of Acid Fast Bacilli (Mycobacterium) by Auramine-Phenol Stain and confirmation by Ziehl-Neelsen stain. MICCL3SOP15 – Investigation of specimens for Mycobacterium species. Automated culture using BDBactec MGIT 960 system . Detection of pH changes due to the presence of CO ₂ . MICCL3SOP15 - Investigation of Specimens for Mycobacterium species.	
Hair, Skin and Nails	General Isolation and characterisation of fungi of clinical significance	Fluorescence microscopy , wet-film microscopy, plate culture using SOP: MICMYCSOP1 - Investigation of Superficial Specimens for Mycoses by direct microscopy of KOH digested samples and the culture on non-chromogenic selective media.	
Faeces, urine and Sellotape slides	Examination for the presence of parasites (ova, cysts, trophozoites and worms (OCP) of clinical significance. Detection of Schistosoma haematobium ova. Detection of Cryptosporidium oocysts	Light Microscopy using SOP MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile) using unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration (parasep system method). MICENTSOP8 – Investigation of faeces and other samples for parasites. Direct fluorescence microscopy using Auramine Phenol staining	
Faeces	Rotavirus detection	Rapid membrane test for the qualitative detection of rotavirus antigen in human stool using Immunocard STAT Rotavirus using SOP: MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile).	



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HUMAN BODY FLUIDS (CONT'D):	Microbiology <u>examination activities for the purpose of clinical diagnosis</u>	In house documented procedures based on PHE SMI's:	A
Faeces	Detection of Clostridium difficile GDH, toxin's A & B	DYNEX DS2 analyser using the microassay plates C.diff GDH and C.difficile Tox A/B II using: MICENTSOP5 – Testing for C Difficile	
Urine - MSU, CSU, Nephrostomy, Sub Phrenic Aspirate and Bag urine.	detection of Legionella pneumophila antigen and Streptococcus pneumonia antigen.	Manual Immunochromatographic assay - Binax NOW Legionella pneumophila antigen and Streptococcus pneumonia antigen kits: MICURSOP8 – Urinary antigen detection for Legionella and Streptococcus pneumoniae	
Serum/plasma	HIV p24 antigen/antibody (HIV1/2)	Immunochromatographic detection method using the SOP: MICSERSOP7 - Determine HIV1/2 Ag/Ab	
	IgG and IgM antibody to Parvovirus B19	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: Automated EIA - Dynex DS2 : Using the microassay plates and Novalisa kit using: MICSERSOP12 – Qualitative Determination of IgG and IgM antibodies to Erythrovirus (Parvovirus) B19	
	Detection of Hepatitis B surface antigen. Detection of Hepatitis B core Antibody. Detection of Hepatitis B antibody Detection of Hepatitis C antibody. Detection of Rubella IgG antibody. Detection of HIV Antibody/Antigen Detection of Syphilis IgG/IgM	Roche cobas 6000/8000 Immunoassay MICSERSOP4 - Procedure for Serology Testing (HBsAg, Hep B cAb, Hep B Ab HCV Ab, Syphilis and Rubella IgG). MICSERSOP28 - ROCHE HIV COMBI for the detection of HIV Antibody/Antigen.	



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HUMAN BODY FLUIDS (CONT'D): Serum or plasma	<p>Microbiology <u>examination activities for the purpose of clinical diagnosis</u></p> <p>Detection of Hepatitis A IgM. Detection of Varicella-Zoster IgG. Detection of Rubella IgM. Detection of CMV IgG, CMV IgM and CMV IgG Advity Detection of Measles IgG Detection of Mumps IgG Detection of Hepatitis C antibody</p> <p>Detection of RSV antigen</p> <p>Toxoplasma</p> <p>Anti-streptolysin (ASO)</p> <p>Aspergillus antibody</p> <p>HIV viral load testing Hepatitis C viral load testing</p>	<p>In house documented procedures based on PHE SMI's:</p> <p>Biomerieux VIDAS automated ELISA & associated SPR's, using the SOP's: MICSERSOP8 – Hepatitis A IgM Detection. MICSERSOP24 - Varicella-Zoster IgG Detection MICSERSOP16 - Rubella IgM Detection MICSERSOP5, 29 and 36 CMV testing MICSERSOP40- HCV antibody (confirmation assay) MICSERSOP41 Mumps IgG antibody detection MICSERSOP47 Measles IgG antibody detection MICSERSOP25 - Use of the Vidas in conjunction with the manufacturer's instructions for the VIDAS machine</p> <p>TRU RSV lateral flow immunoassay MICSERSOP14 – Tru RSV rapid RSV Detection</p> <p>Biokit toxocell latex slide test MICSERSOP21 – Toxoplasma Latex test</p> <p>Biokit rheumajet ASO latex slide test MICSERSOP3 – ASO Titre</p> <p>ThermoPhadia ImmunoCap 250 Immunoassay MICSERSOP39 and AUTOCHISOP233</p> <p>Automated Roche Taqman extraction and amplification platform MICSERSOP35 – Processing of viral loads</p>	A



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Genital, rectal and throat swab and urine	Chlamydia NAATs detection Gonorrhoea NAATs detection	Automated Roche Cobas 4800 extraction and amplification platform MICSERSOP30 – Cobas 4800 CT/NG test	
Throat swab in viral transport media	Molecular detection of Influenza A and B, RSV	PCR using ELITech Ingenius analyser and MICSERSOP51	A
CSF	Molecular detection of HSV1, HSV2, VZV, Enterovirus	PCR using ELITech Ingenius analyser and MICSERSOP50	
END			