

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: 006 Issue date: 27 August 2019

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



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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
Blood satellite fridge - Labour ward , M&G, level 1, 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 - 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	FERTSOP4	
	Fertility assessment: morphology	FERTSOP19	
	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: AUTOCHSOP198 – cobas 6000 PATHEXT161 - Roche cobas 6000 Operator Manual	A
Serum/Plasma	AlphaFetoProtein (AFP)	AUTOCHSOP150	
Serum/Plasma	Anti-Mullerian Hormone	AUTOCHSOP238	
Serum/Plasma	CA12-5	AUTOCHSOP201	
Serum/Plasma	CA15-3	AUTOCHSOP240	



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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: AUTOCHSOP198 – cobas 6000 PATHEXT161 - Roche cobas 6000 Operator Manual	A
Serum/Plasma	CA19-9	AUTOCHSOP202	
Urine	Drugs of abuse screen - Benzodiazepine, Cannabinoids, Opiate, Cocaine, Methadone and Amphetamines	AUTOCHSOP221	
Serum/Plasma	CEA	AUTOCHSOP203	
Serum/Plasma	Complement C3	AUTOCHSOP129	
Serum/Plasma	Complement C4	AUTOCHSOP130	
Serum/Plasma	C-Peptide	AUTOCHSOP166	
Serum/Plasma	Free PSA	AUTOCHSOP176	
Serum/Plasma	Insulin	AUTOCHSOP99	
		Photometric:	
Serum/Plasma	Alpha-1-acid glycoprotein (AGP)	AUTOCHSOP128	
Serum/Plasma	Alpha-1-antitrypsin	AUTOCHSOP127	
Serum/Plasma	Angiotensin Converting Enzyme (ACE)	AUTOCHSOP229	
Serum/Plasma	Bile acids	AUTOCHSOP131	



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Serum/Plasma	Caeruloplasmin	AUTOCHSOP131	
Serum/Plasma	Lactate Dehydrogenase	AUTOCHSOP189	
Urine	Creatinine (Jaffe)	AUTOCHSOP250	
Serum/Plasma	Carbamazepine	AUTOCHSOP82	
Serum/Plasma	Gentamicin	AUTOCHSOP84	
Serum/Plasma	Haptoglobin	AUTOCHSOP132	
Serum/Plasma	Methotrexate	AUTOCHSOP87	
Serum/Plasma	Thyroglobulin	AUTOCHSOP162	
Serum/Plasma	Thyroglobulin antibodies	AUTOCHSOP179	
		In house documented procedures based on standard methods and incorporating Roche cobas 8000 manufacturers' instructions as relevant: AUTOCHSOP192 – cobas 8000 PATHEXT144 - Roche cobas 8000 Modular Analyser Series Operator's Manual	A
Serum/Plasma	Amikacin	Immunoassay: AUTOCHEMSOP80	
Serum/Plasma	Cortisol	AUTOCHSOP158	



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Serum/Plasma	C-Reactive Protein	AUTOCHSOP172	
Serum/Plasma	Digoxin	AUTOCHSOP175	
Serum/Plasma	Ferritin	Immunoassay: AUTOCHSOP157	
Serum/Plasma	Folate	AUTOCHSOP156	
Serum/Plasma	Follicle Stimulating Hormone (FSH)	AUTOCHSOP155	
Serum/Plasma	Free beta HCG & Total HCG Quantitative Assay	AUTOCHSOP184 AUTOCHSOP30	
Serum/Plasma	Free T3	AUTOCHSOP154	
Serum/Plasma	Free T4	AUTOCHSOP153	
Serum/Plasma	Immunoglobulin A	AUTOCHSOP181	
Serum/Plasma	Immunoglobulin G	AUTOCHSOP185	
Serum/Plasma	Immunoglobulin M	AUTOCHSOP186	
Serum/Plasma	Luteinizing Hormone	AUTOCHSOP204	
Urine	Albumin (Microalbumin)	AUTOCHSOP191	
Serum/Plasma	NT-pro BNP	AUTOCHSOP194	
Serum/Plasma	Oestradiol	AUTOCHSOP193	
Serum/Plasma	Parathyroid Hormone level	AUTOCHSOP205	



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Serum/Plasma	Phenobarbitone	AUTOCHSOP88	
Serum/Plasma	Phenytoin	AUTOCHSOP89	
Serum/Plasma	Progesterone	AUTOCHSOP207	
Serum/Plasma	Prolactin & Macroprolactin	AUTOCHSOP151 AUTOCHSOP101	
Serum/Plasma	Prostate specific antigen	AUTOCHSOP208	
Serum/Plasma	Sex Hormone Binding Globulin	AUTOCHSOP211	
Serum/Plasma	Testosterone	AUTOCHSOP163	
Serum/Plasma	Teicoplanin	AUTOCHSOP249	
Serum/Plasma	Theophylline	AUTOCHSOP90	
Serum/Plasma	Thyroid Peroxidase Antibodies	AUTOCHSOP213	
		Immunoassay:	
Serum/Plasma	Thyroid Stimulating Hormone	AUTOCHSOP167	
Serum/Plasma	Tobramycin	AUTOCHSOP91	
Serum/Plasma	Troponin-T	AUTOCHSOP218	
Serum/Plasma	Valproate	AUTOCHSOP92	
Serum/Plasma	Vancomycin	AUTOCHSOP93	
Serum/Plasma	Vitamin B12	AUTOCHSOP197	



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Serum/Plasma	Vitamin D (25OH-D)	AUTOCHSOP243 Indirect Ion-Selective Electrode (ISE):	
Serum/Plasma & Urine	Sodium, Potassium & Chloride	AUTOCHSOP212 AUTOCHSOP206 AUTOCHSOP169 Photometric:	
Serum/Plasma	Alanine Aminotransferase (ALT)	AUTOCHSOP152	
Serum/Plasma	Albumin	AUTOCHSOP171	
Serum/Plasma	Alkaline Phosphatase (ALP)	AUTOCHSOP183	
Plasma	Ammonia Level	AUTOCHSOP81	
Serum/Plasma	Amylase	AUTOCHSOP199	
Serum/Plasma	Aspartate Aminotransferase	AUTOCHSOP200	
Serum/Plasma	Bicarbonate	AUTOCHSOP160	



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Serum/Plasma/ Urine	Calcium	AUTOCHSOP166	
Serum/Plasma	Conjugated Bilirubin	AUTOCHSOP170	
Serum/Plasma	Creatine Kinase	AUTOCHSOP173	
Serum/Plasma	Creatinine (Enzymatic)	AUTOCHSOP174	
Serum/Plasma & Urine	Ethanol Level	AUTOCHSOP83	
Serum/Plasma	Gamma-GT	AUTOCHSOP177	
Plasma, Serum, Urine, and CSF	Glucose	AUTOCHSOP178	
Serum/Plasma	HDL Cholesterol	AUTOCHSOP182	
Urine	Creatinine (Jaffe)	AUTOCHSOP250	
Serum/Plasma	Iron	AUTOCHSOP187	
Serum/Plasma	Lactate Dehydrogenase	AUTOCHSOP189	
Plasma	Lactate	AUTOCHSOP188 Photometric:	
Serum/Plasma	Lithium	AUTOCHSOP86	
Serum/Plasma	Magnesium	AUTOCHSOP190	
Serum/Plasma Serum/Plasma and Urine	Paracetamol Phosphate	AUTOCHSOP196 AUTOCHSOP195	



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Serum/Plasma	Rheumatoid Factor	AUTOCHSOP209	
Serum/Plasma	Salicylate	AUTOCHSOP210	
Serum/Plasma	Total Bilirubin	AUTOCHSOP214	
Serum/Plasma	Total Cholesterol	AUTOCHSOP169	
Serum/Plasma	Total Protein	AUTOCHSOP215	
Urine and CSF	Total Protein	AUTOCHSOP222	
Serum/Plasma	Transferrin	AUTOCHSOP217	
Serum/Plasma	Triglyceride	AUTOCHSOP217	
Serum/Plasma and Urine	Urate (Uric Acid)	AUTOCHSOP219	
Serum/Plasma and Urine	Urea	AUTOCHSOP220	
Serum	Zinc	AUTOCHSOP94 Chromosystems HPLC-ECD: SPCHEMSOP46 - HPLC	
Urine	Metadrenaline, Normetadrenaline and 3-methoxytyramine	SPCHEMSOP3	
Urine	5-Hydroxy indole acetic acid (5HIAA)	SPCHEMSOP1 Chromosystems HPLC-UV: SPCHEMSOP46 - HPLC SPCHEMSOP37	
Blood	Vitamin B1		



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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	
Faeces	Faecal Occult Blood (FOB)	Beckmancoulter Photometric Hemocult POCSOP4 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	



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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	SPCHEMSOP29	
Faeces	Helicobacter pylori stool antigen	OXOID Amplified IDEA HpStARTM / Dynex DS2: ELISA POCSOP32 IMMSOP48	
Sweat	Chloride	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	
Sweat	Conductivity	Wescor Macroduct® Sweat Collection System, conductivity measurement POCSOP3	



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HUMAN BODY TISSUES AND FLUIDS (CONT'D)	Biochemistry <u>examination activities for the purpose of clinical diagnosis (cont'd):</u>		
Serum/Plasma	IgA anti-tTg antibody IgG anti-tTg antibody	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: 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	A
Serum and Urine	Osmolality	Advanced Instruments 3320 Osmometry - Freezing point depression AUTOCHSOP97 AUTOCHSOP242 - Chemistry Calculators PATHEXT1125 - Osmometer 3320 User Guide & Service Manual	
Urine	Porphobilinogen & porphyrin screen	Bio-Rad/UVIKON Spectrophotometer Photometric SPCHEMSOP8 – Porphyrins/PBG SPCHEMSOP26 - Spectrophotometer	
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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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 & Urine	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	CHIAUTH44	



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HUMAN BODY FLUIDS (CONT'D): Serum/Plasma & Urine	<p>Biochemistry <u>examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Calculated Tests: Non-HDL Cholesterol Normalised Carbamazepine Normalised Phenytoin Porphobilinogen/Creatinine ratio Porphyrin/Creatinine ratio 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>	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens	<p>Histopathology <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>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</p>	A



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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>Histopathology</u> <u>examination activities for the purpose of clinical diagnosis:</u></p> <p>Routine staining for identification of basophilic and eosinophilic structures</p>	<p>Macroscopic and Microscopic examination supported by:</p> <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> <p><u>Frozen section</u> H+E staining- HSSSOP13</p> <p><u>Routine FFPE Automated</u> H & E Staining using the Leica ST5010 Stainer – SOP HRLSOP9 Haematoxylin & Eosin Stain – SOP HRLSOP9 and HRLSOP12</p>	<p>A</p>



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HUMAN BODY FLUIDS (CONT'D):	<u>Histopathology 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.	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): Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples	<u>Histopathology examination activities for the purpose of clinical diagnosis:</u> Pnumocystis /Fungi Leprosy TB Collagen/fibrin Melanin and agrentaffin granules Ferric Iron Reticulin fibres Mast cells Insoluble Calcium Salts	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. Grocott - HSSSOP12 (Automated). Wade Fite - HSSSOP33 Ziehl Neelsen - HSSSOP35 MSB - HSSSOP19 Masson Fontana- HSSSOP16 Perls - HSSSOP24 (Automated). Retic - HSSSOP27 (Automated). Toludine Blue - HSSSOP31 Von Kossa - HSSSOP32	A



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HUMAN BODY FLUIDS (CONT'D):	Histopathology <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	Fibrin and muscle	Masson Trichrome - HSSSOP17 (Automated).	
	Neutral fats	Oil Red O - HSSSOP20	
	Copper associated protien	Runianic Acid - HSSSOP28	
	Hepatitis B surface antigen	Shikata's Orcein - HSSSOP29	



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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>Accumulation of A1AT in the hepatocytes of A1AT deficient liver.</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: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</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>ALPHA1- Alpha-1-antitrypsin (A1AT)</p> <p>AR</p> <p>B-CATENIN</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-gynae 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: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHC SOP16, HIHC SOP34 HIHC SOP20. HIHC SOP27, HIHC SOP32</p> <p>BCL2</p> <p>BCL6</p> <p>BEREP4</p> <p>B-HCG</p> <p>CA125</p> <p>CA19.9</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Identification of thyroid medullary carcinoma and thyroid C cells</p> <p>Primarily for identification of mesothelial cells and malignant mesothelioma of the epithelial type. Other tumours such as granulosa cell tumour also express calretinin.</p> <p>Identification of tumors of epithelial origin and non-small cell lung cancer and in distinguishing carcinomas from other malignant tumors of non-epithelial origin.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>Calcitonin</p> <p>Calretinin</p> <p>CAM5.2</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-gynaecological samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Identification of thymoma, precursor T-lymphoblastic leukaemia/lymphoma and Langerhans' cell histiocytosis.</p> <p>Identification of T cells and their neoplasms such as T- and/or NK-cell lymphomas and mycosis fungoides.</p> <p>Identification of thymocytes, T-helper cells and related tumours such as peripheral T-cell lymphoma (unspecified), anaplastic large cell lymphoma and mycosis fungoides.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>CD1 A</p> <p>CD3</p> <p>CD4</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Identification of B- and T-cell malignancies including B-cell chronic lymphoid leukaemia/ small lymphocytic lymphoma, mantle cell lymphoma and T-cell lymphoma and leukaemia.</p> <p>Identification of cytotoxic / suppressor T cells and their neoplastic counterparts.</p> <p>Identification of Burkitt lymphoma/leukaemia , follicular lymphoma (except grade III),precursor B-cell lymphoblastic leukaemia/lymphoma and renal cell carcinoma of the clear cell type.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>CD5</p> <p>CD8</p> <p>CD10</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Identification of mononuclear Hodgkin cells and Reed-Sternberg cells in Hodgkin lymphoma.</p> <p>Identification of the B-cell lineage and different types of B-cell lymphoma.</p> <p>Identification of follicular dendritic cells, mature B cells and structural alterations in the meshwork of follicular dendritic cells.</p> <p>Normal B lymphocytes and malignant lymphomas. Mantle cell lymphoma is generally negative for CD23.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>CD15</p> <p>CD20</p> <p>CD21</p> <p>CD23</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Reed-Sternberg cells in Hodgkin lymphoma and anaplastic large cell lymphoma</p> <p>Endothelial cells, and benign and malignant vascular disorders.</p> <p>Vascular and lymphatic vessels and tumours of vascular origin</p> <p>Low-grade B-cell lymphoma, peripheral T-cell lymphoma and myeloid disorders</p> <p>Natural killer (NK) cells, NK-like T cells, neural/neuroendocrine tissues and their neoplasms</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD43</p> <p>CD56</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Hodgkin lymphoma (lymphocyte-predominant subtype), T-cell large granular lymphocyte disorder, oligodendroglioma and neuroendocrine tumour</p> <p>Macrophages, other members of the mononuclear phagocyte lineage, and neoplasm of myeloid and macrophage/monocyte origin</p> <p>B cells during all stages of differentiation and of B-cell neoplasm</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>CD57</p> <p>CD68</p> <p>CD79a</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Glioblastomas and ependymomas of the CNS, certain islet cell tumours of the pancreas, Ewing's sarcoma, granulosa cell tumour and primitive peripheral neuroectodermal tumours</p> <p>Mesenchymal tumours of the gastrointestinal tract.</p> <p>Plasma cells and multiple myeloma, and for sub classification of diffuse large B-cell lymphoma</p> <p>Adenocarcinoma and carcinoids of the gastrointestinal tract</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>CD99</p> <p>CD117</p> <p>CD138</p> <p>CDX2</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Various tumours such as lung adenocarcinoma, meningioma and medullary carcinoma of the thyroid.</p> <p>Neuroendocrine cells and tumours with neuroendocrine differentiation.</p> <p>Distinguishing stratifying epithelial cell types from simple epithelial cell types.</p> <p>Epithelial tumours with cytokeration 19 expression</p> <p>Normal GI epithelia and urothelium Gastrointestinal tumours, mucinous ovarian tumours and Merkel cell carcinoma.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>CEA (Mono) and CEA (Poly)</p> <p>Chromogranin A</p> <p>CK14</p> <p>CK19</p> <p>CK20</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Prostatic adenocarcinoma and prostatic intraepithelial neoplasia (PIN) or its benign mimics such as atypical hyperplasia.</p> <p>Cytokeratin 5 in normal and neoplastic tissues.</p> <p>Squamous epithelium and neoplasms</p> <p>Glandular and transitional epithelia and neoplasia of type</p> <p>Epithelial Cell Tumours</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>CK34Be12</p> <p>CK5</p> <p>CK5/6</p> <p>CK7</p> <p>CK8/18</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>C-myc oncogene</p> <p>Mantle cell lymphoma.</p> <p>Smooth and striated muscle cells and reactive mesothelial cells, tumours leiomyoma and rhabdomyo-sarcoma.</p> <p>Plasma membrane of gastrointestinal stromal tumors (GISTs)</p> <p>Epstein-Barr virus-infected cells</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>C-MYC</p> <p>Cyclin D1</p> <p>Desmin</p> <p>DOG-1</p> <p>EBV</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Ductal carcinoma of the breast. E-cadherin also stains normal breast duct and various tumours such as oesophageal adenocarcinoma and squamous carcinoma, and transitional cell carcinoma of the bladder.</p> <p>Tumours of epithelial origin in a wide variety of tissues light chains</p> <p>Expression of ER containing cells, e.g. Normal and neoplastic breast cells</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>E-Cadherin</p> <p>EMA</p> <p>Estrogen Receptor</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Vascular tumours and benign haemangioma variants and haemangioendothelios</p> <p>Breast carcinoma and metastatic tumours</p> <p>Human Herpes Virus Type 8</p> <p>Hepatocellular tumours.</p> <p>Melanomas and other tumors demonstrating melanoma/melanocytic differentiation</p> <p>HER2 antigen</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>Factor 8 (FVIII)</p> <p>GCDFP-15</p> <p>HHV-8</p> <p>Hepatocyte</p> <p>HMB45</p> <p>HER2</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-gynae samples</p>	<p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Normal and neoplastic cells of neuronal and neuroendocrine origin</p> <p>Germ cell tumours</p> <p>Tumor suppressor protein</p> <p>Viral capsid protein of HIV-1</p> <p>P40 protein. P40 is selectively expressed in lung SCC</p> <p>For identification of wild-type and mutant-type p53 protein and accumulation in human neoplasia</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32</p> <p>NSE</p> <p>OCT3/4</p> <p>P16</p> <p>P24</p> <p>P40</p> <p>P53</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-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>Malignant germ cell tumours</p> <p>Mismatch repair protien 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: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>P63</p> <p>PanCK</p> <p>PAX8</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-gynae 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>Neuroendocrine neoplasms and tumours with neuroendocrine differentiation.</p>	<p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32</p> <p>Renal Cell Carcinoma</p> <p>S100</p> <p>SMA</p> <p>SMM-HC</p> <p>Synaptophysin</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: Leica BOND Max Leica BOND III Ventana Ultra SOPS- HIHC SOP16, HIHC SOP34 HIHC SOP20. HIHC SOP27, HIHC SOP32</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 T2000 Processor Hologic T5000 Processor Papanicolaou Staining and coverslipping using: Sakura Tissue-Tek Prisma Stainer and Film 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 and HOLOGIC – PANTHER Molecular analyser: SOP CCSOP033 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>Sample preparation using the Hologic Thinprep Liquid Based Cytology method in conjunction with manufacturer's instructions using:</p> <p>Non-gynaecological (diagnostic) cytology - Sample preparation following in-house method and Hologic Thinprep method in conjunction with manufacturer's instructions using: Hologic T2000 Processor 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>CNGCSOP6, CNGCSOP12 and CNGCSOP13</p> <p>Microscopy: CNGCSOP9 CPGENSOP2 CCSOP7</p>	<p>A</p>



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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	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): Plasma Plasma Plasma Plasma Plasma Blood	<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
		COAGSOP5	
		COAGSOP7	
		In house documented procedures based on standard methods and incorporating Sysmex CS5100 manufacturers' instructions as relevant:	A
		COAGSOP4	
		Immunoassay:	
		COAGSOP6	
		In house documented manual procedures based on visual end point tilt tube method: Clifton Water Bath	
		COAGSOP36	
		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	COAGSOP39	
Plasma	Protein C	COAGSOP12	
Blood	Erythrocyte Sedimentation Rate (ESR)	Mechatronics InteRRliner & Autocompact ESR Analysers AUTOHASOP57 - InteRRliner and Autocompact: Processing ESR Samples	



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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
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	



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<p>HUMAN BODY FLUIDS (CONT'D):</p> <p>Whole blood (EDTA)</p>	<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,Kp a,Kpb,Fya,Fy, JkaJkb,Lea,Leb,P1, M,N,S,s,Lua,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:</p> <p>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,Kp a,Kpb,Fya,Fyb,Jka,J kb,Lea,Leb,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 IMMSOP34	
	Anti-ds-DNA antibodies	IMMSOP35	
	Anti-ENA antibodies	IMMSOP37	
	Anti-Jo-1 antibodies	IMMSOP36	
	Anti-RNP antibodies	IMMSOP36	
	Anti-Sm antibodies	IMMSOP36	
	Anti-SS-A antibodies (Ro)	IMMSOP36	
	Anti-SS-B antibodies (La)	IMMSOP36	
	Glomerular basement membrane antibodies	IMMSOP33	
	Intrinsic factor antibody	IMMSOP38	
	Myeloperoxidase antibodies	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	
		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	
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	SPCHEMSOP18	



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HUMAN BODY FLUIDS (CONT'D): Serum/Plasma	<u>Immunology</u> <u>examination activities for the purpose of clinical diagnosis</u> <u>(cont'd):</u> 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	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 SPCHEMSOP18	A



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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 Immunofluorescence</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):	Immunology <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	
Skin, Tissue	<ul style="list-style-type: none"> • IgA • IgG • IgM • C3 • Fibrinogen 	Skin Biopsy for Direct Immunofluorescence: IMMSOP1 IMMSOP26, IMMSOP31, IMMSOP22	



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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><u>Microbiology</u> <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 iQ@200 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 micro-organisms 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 MICSENSOP2 – Antibiotic Sensitivity Testing</p> <p>Automated identification and antibiotic sensitivity testing using SOP: MICSENSOP4 - Vitek2® Procedures.</p> <p>Identification of microorganisms of clinical significance by reaction to biochemical reagents: MICGENSOP43 - Bench tests and basic identification methods MICGENSOP44 - 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>	A



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HUMAN BODY FLUIDS (CONT'D): Sputum, Bronchial Washings, Nasopharyngeal Aspirates, Tracheal Aspirates, Pleural fluids, Lymph Nodes, Tissues, Fluids, Pus and CSF's	Microbiology <u>examination activities for the purpose of clinical diagnosis</u> General isolation and characterisation of Mycobacterium (typical and atypical).	In house documented procedures based on PHE SMI's: <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.	A
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 Advitiy 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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HUMAN BODY FLUIDS (CONT'D): Genital, rectal and throat swab and urine	Microbiology <u>examination activities for the purpose of clinical diagnosis</u> Chlamydia NAATs detection Gonorrhoea NAATs detection	In house documented procedures based on PHE SMI's: Automated Roche Cobas 4800 extraction and amplification platform MICRSERSOP30 – Cobas 4800 CT/NG test	A
END			