Schedule of Accreditation

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

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Royal Derby Hospital
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Derby
Derbyshire
DE22 3NE

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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	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	• Haematology • Blood Transfusion • Chemistry • Immunology • Cellular Pathology • Microbiology	A
Address Fertility Unit, Level 1 Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	• Andrology	B
Address Microbiology Department Chesterfield Royal Hospital Calow S44 5BL	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	• Microbiology	D
Address Blood Sciences Department Chesterfield Royal Hospital Calow S44 5BL	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	• Haematology • Blood Transfusion • Chemistry	E

Site activities performed away from the locations listed above:

Location details		Activity
Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE	**Local Contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Phlebotomy
Florence Nightingale Community Hospital London Road Derby Derbyshire DE1 2QY	**Local Contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Phlebotomy
Blood Bank satellite issue fridge - Fridge room, level 5 Royal Derby Hospital DE22 3NE	**Local Contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	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:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Blood Issue Fridge No testing occurs on this site, blood storage only
Blood satellite fridge - Labour ward HDU, M&G, level 1 Royal Derby Hospital DE22 3NE	**Local Contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	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:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	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:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Blood Issue Fridge No testing occurs on this site, blood storage only
Mortuary, Level 0 Royal Derby Hospital DE22 3NE	**Local Contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Body storage facilities
Blood issue fridge W9G9163 Theatre Phase 1 Main Theatres Chesterfield Royal Hospital S44 5BL	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Blood storage & issue only Fridge managed by Blood transfusion

Testing performed by the Organisation at the locations specified

Location details		Activity
Blood Issue Fridge W9F8652 Theatres Phase 2 Obs & Gynae theatres Chesterfield Royal Hospital S44 5BL	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Blood storage & issue only Fridge managed by Blood transfusion
Blood Product Issue fridge Trinity Ward Chesterfield Royal Hospital S44 5BL	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Anti-D Immunoglobulin storage and issue Fridge managed by Blood Transfusion
Ward areas, The Den, Antenatal Clinic Suite 9, NGS Macmillan Unit Chesterfield Royal Hospital S44 5BL	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Phlebotomy
OPD/ward areas Chesterfield Royal Hospital	**Local contact:** Contact: Mariska Faint-Uffen Tel: +44 (0) 7799339972	Sweat collection for diagnostic purposes using Wescor Macroduct iontophoretic sweat collection system

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	**Andrological** examination activities for the purposes of clinical diagnosis		
Semen	Post vasectomy		B
	Detection of sperm Sperm concentration	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP FERTSOP11	
Semen	Fertility testing	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure SOP FERTSOP48	
	Volume	Volume/weight	
	pH	Colorimetric strips	
	Sperm morphology **including** TZI scoring	Pre-stained slides (Cell-vu) microscopy (Bright field)	
	Sperm concentration	Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis:	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 I Sandwich electrochemiluminescence immunoassay	A
Serum/Plasma	AlphaFetoProtein (AFP)		
Serum/Plasma	Anti-Mullerian Hormone		
Serum/Plasma	CA12-5		
Serum/Plasma	CA15-3		
Serum/Plasma	CA19-9		
Serum/Plasma	CEA		
Serum/Plasma	C-Peptide		
Serum/Plasma	Free PSA		
Serum/Plasma	Total HCG		
Serum/Plasma	Insulin		
Serum/Plasma	Thyroglobulin		
Serum/Plasma	Thyroglobulin antibodies		

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis:	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 c501 Module using photometry	A
Serum/Plasma	Alpha-1-antitrypsin	Immunoturbidimetric	
Serum/Plasma	Amikacin	Kinetic microparticles in solution (KIMS)	
Plasma	Ammonia	Enzymatic with glutamate dehydrogenase	
Serum/Plasma	Carbamazepine	Homogeneous microparticle agglutination immunoassay	
Serum/Plasma	Complement C3	Immunoturbidimetric	
Serum/Plasma	Complement C4	Immunoturbidimetric	
Serum/Plasma	Ethanol	Enzymatic	
Serum/Plasma	Haptoglobin	Immunoturbidimetric	
Serum/Plasma	IgA	Immunoturbidimetric	
Serum/Plasma	Lactate dehydrogenase	UV absorbance IFCC recommended	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	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 c501 Module using photometry	A
Serum/Plasma	Methotrexate	Siemens Healthineers kit, AUTOCHSOP87	
Serum/Plasma	Phenobaribitone	Kinetic interaction of microparticles in solution (KIMS	
Serum/Plasma	Phenytoin	Kinetic interaction of microparticles in solution (KIMS)	
Serum/Plasma	Rheumatoid factor	Immunoturbidimetric	
Serum/Plasma	Teicoplanin	Thermo Scientific Quantitative Micoparticle system (QMS), AUTOCHSOP249	
Serum/Plasma	Theophylline	Kinetic microparticles in solution (KIMS)	
Serum/Plasma	Thyroid peroxidase antibodies	AUTOCHSOP213	
Serum/Plasma	Tobramycin	Homogeneous enzyme immunoassay	
Serum/Plasma	Valproate	Homogeneous enzyme immunoassay	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd)	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]	
Serum, Plasma, Urine	Sodium, Potassium, Chloride	Roche Cobas c702 Module using Indirect ISE	A
		Roche Cobas c702 Module using photometry	A
Serum, plasma	Albumin	Bromocresol purple	
Urine	Albumin	Immunoturbidimetric	
Serum, plasma	ALP	IFCC optimised assay	
	ALT	IFCC recommended with pyridoxalphosphate	
	Aspartate Aminotransferase	IFCC recommended with pyridoxal phosphate	
Serum, plasma	Amylase	IFCC enzymatic colorimetric (5 ethylidene-G_7PNP	
Serum, plasma	Bicarbonate	UV absorbance	
Serum, plasma	Bilirubin total	Olorimetric Diazo	
	Bilirubin conjugated	Vanadate oxidation	
Serum, plasma, urine	Calcium	Colorimetric NM-BAPTA	
Serum, plasma	Creatinine Kinase	NAC activated IFCC	
	C-Reactive Protein	Latex particle enhanced immunoturbidimetric	
	Creatinine	Enzymatic	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	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 Roche Cobas c702 Module using photometry	A
Urine	Creatinine	Jaffe	
CSF	Glucose and Total protein	Hexokinase Benzothonium chloride turbidimetric	
Serum, plasma, urine	Glucose	Hexokinase	
Serum, plasma	Gentamicin	Kinetic microparticles in solution (KIMS)	
	Gamma-GT	IFCC standardised enzymatic colorimetric	
	HDL Cholesterol	Homogenous enzymatic colorimetric	
	IgA	Immunoturbidimetric	
	IgG	Immunoturbidimetric	
	IgM	Immunoturbidimetric	
Serum, plasma	Iron	Colorimetric	
Plasma	Lactate	Enzymatic with lactate oxidase	
Serum, plasma	Magnesium	Colorimetric with Xylidyl blue	
	Paracetamol	Cambridge Life Sciences kit, AUTOCHSOP196	
Serum, plasma, urine	Phosphate	Molybdate UV absorbance	
Serum, plasma	Salicylate	Enzymatic UV absorbance	
	Total cholesterol	Enzymatic colorimetric	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	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	
		Roche Cobas c702 Module using photometry	A
Serum, plasma, urine	Total protein	Colorimteric biuret, Benzothonium chloride turbidimetric	
	Transferrin	Immunoturbidimetric	
	Triglyceride	Enzymatic colorimetric	
	Urea	Kinetic with urease and glutamate dehydrogenase	
	Urate	Enzymatic with uricase	
Serum, plasma	Vancomycin	Kinetic microparticles in solution (KIMS) Roche Cobas c502 module using photometry	
Plasma	Ammonia	Enzymatic with glutamate dehydrogenase	
Serum, plasma	Bile acid	DIALAB kit, AUTOCHSOP159	
	Ethanol	Enzymatic with alcohol dehydrogenase	
	Lactate dehydrogenase	UV absorbance IFCC recommended	
	Lithium	Colorimetric with substituted porphyrin compound Roche Cobas e801 Module using electrochemiluminescence Immunoassay	
	Cortisol		
	Digoxin		
	Oestradiol		

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	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	
		Roche Cobas e801 Module using electrochemiluminescence immunoassay	A
	Ferritin		
	Follicle stimulating hormone		
	Free T3		
	Free T4		
	Free beta HCG		
	Luteinising hormone		
	NT Pro BNP		
	Prolactin		
	Macroprolactin	AUTOCHSOP101	
	Progesterone		
	Parathyroid hormone		
	Folate		
	Sex hormone binding globulin		
	Testosterone		
	Total PSA		
	Troponin T		
	Thyroid stimulating hormone		

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	In house documented procedures based on standard methods and incorporating **Roche Ccobas 8000** manufacturers' instructions as relevant: AUTOCHSOP192 Use of Roche Cobas 8000 Analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide	
		Roche Cobas e801 Module using Immunoassay	A
	Vitamin B12	Line 2, 3	
	Vitamin D	Line 3	
		Chromsystems HPLC-ECD: SPCHEMSOP46 - HPLC	A
Urine	Metadrenaline, Normetadrenaline and 3-methoxytyramine	SPCHEMSOP3	
Urine	5-Hydroxy indole acetic acid (5HIAA)	SPCHEMSOP1	
		Chromsystems HPLC-fluorescence: SPCHEMSOP46 - HPLC	
Blood	Vitamin B1	SPCHEMSOP37	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)		
		In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: **Sebia**: SPCHEMSOP11 - SEBIA HYDRASYS SPCHEMSOP23 - USE OF SEBIA PHORESIS SOFTWARE SPCHEMSOP24 - USE OF SEBIA CAPILLARYS 2	A
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	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	
Sweat	Conductivity	**Wescor Macroduct® Sweat Collection System**, conductivity measurement POCSOP3	
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	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A
Serum and Urine	Osmolality	**Advanced Instruments 3320 and** - Advanced Instruments OSMO1 Osmometry - Freezing point depression AUTOCHSOP97 AUTOCHSOP242 - Chemistry Calculators PATHEXT1125 - Osmometer 3320 User Guide & Service Manual	A
CSF	CSF Xanthochromia	**UVIKON/Northstar BIO UV** SpectrophotometerSPCHEMSOP9 SPCHEMSOP26 – Spectrophotometer CRHSPE-LP-SPE043	A, E
		Advanced Instruments Osmometer using freezing point depression:	E
Serum, Plasma, Urine	Osmolality	CRHCHE-LP-RCH029	E

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: Hydrasys using hydra gel and electrophoresis	
Serum	Cryoglobulins	CRHSPE-LP-SPE035	E
	Paraproteins Quantification:	Sebia Hydrasys 2 Scan using hydra gel and electrophoresis and immunofixation Sebia Capillarys 2 using capillary zone electrophoresis:	E
Serum/Urine	IgG IgA IgM Kappa Lambda	CRHSPE-LP-SPE030/031	E
		ABSciex API5000Tandem Mass spectrometer LCMSMS SPCHEMSOP32 – API5000	A
Serum/Plasma	androstenedione	SPCHEMSOP42	
Serum/Plasma	testosterone	SPCHEMSOP42	
Blood	Cyclosporin	SPCHEMSOP28	
Blood	Sirolimus	SPCHEMSOP28	
Blood	Tacrolimus	SPCHEMSOP28	
Serum/plasma	17 OH- progesterone	SPCHEMSOP42	
Serum/Plasma	DHEAS	SPCHEMSOP42	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A,E
Blood	Carboxy-haemoglobin	**Werfen Gem5000** Blood gas analyser, spectrophotometric analysis POCSOP7 POCUG1	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 Non-HDL Cholesterol Normalised Carbamazepine Normalised Phenytoin Transferrin saturation Urine protein: creatinine	CHIAUTH44	A
	Calculated Tests:	Tests calculated from output of various methodologies from Roche Cobas Systems:	E
Serum/ Plasma and Urine	eGFR Adjusted Calcium 24 hr Urine Anionic gap	DOC47	
Serum/Plasma and Urine	Amylase/Creatinine clearance ratio Calcium excretion index Calcium creatinine ratio LDL	CRHCHE-LP-RCH048	E

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):		
Serum/Plasma and Urine (cont'd)	Creatinine clearance Free androgen index FIB4 Non HDL- Cholesterol Transferrin Saturation Urine protein: Creatinine Globulins AKI	CRHCHE-LP-RCH048	E
	Quantitative determination of:	Roche Cobas c702 Module: Immunoturbidometric	E
Serum (unless otherwise stated)	Alpha 1 antitrypsin	CRHRMO-LP-RMO059	
	Phenobarbitone	CRHRMO-LP-RMO030	
	Complement C3 & C4	CRHSPE-LP-SPE033	
	Caeruloplasmin	CRHRMO-LP-RMO058	
Serum & Plasma	CRP	CRHRMO-LP-RMO014	
	IgA	CRHSPE-LP-SPE027	
	IgG		
	IgM		
	Haptoglobin	CRHSPE-LP-SPE034	
	Phenytoin	CRHRMO-LP-RMO031	
	Theophylline	CRHRMO-LP-RMO036	
Urine	Albumin	CRHRMO-LP-RMO028	
	Quantitative determination of:	Roche Cobas c702 Module: Spectrophotometry	E
Serum, Plasma	Albumin	CRHRMO-LP-RMO001	
Serum, Plasma	Alkaline Phosphatase	CRHRMO-LP-RMO002	
Serum, Plasma	Alanine Transferase	CRHRMO-LP-RMO003	
Serum, Plasma, Urine	Amylase	CRHRMO-LP-RMO005	
Serum, Plasma	Aspartate transferase	CRHRMO-LP-RMO006	
Serum, Plasma	Bicarbonate	CRHRMO-LP-RMO007	
Serum, Plasma	Bilirubin Total	CRHRMO-LP-RMO008	
Serum, Plasma	Creatinine (enzyme assay)	CRHRMO-LP-RMO013	
Urine	Creatinine (Jaffe assay)	CRHRMO-LP-RMO013	
CSF, Urine, Serum & Plasma	Total Protein	CRHRMO-LP-RMO037 CRHRMO-LP-RMO038	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):		
	Quantitative determination of: (cont'd)	Roche Cobas c702 Module: Spectrophotometry	E
Serum, Plasma, Urine	Calcium	CRHRMO-LP-RMO009	
Serum, Plasma	Direct Bilirubin	CRHRMO-LP-RMO017	
Serum, Plasma	Total Cholesterol	CRHRMO-LP-RMO011	
Serum, Plasma	Creatine Kinase	CRHRMO-LP-RMO012	
Serum, Plasma, CSF	Glucose	CRHRMO-LP-RMO015 CRHRMO-LP-RMO020	
Plasma, CSF	Lactate	CRHRMO-LP-RMO24	
Serum, Plasma	Triglycerides	CRHRMO-LP-RMO038	
Serum, Plasma	GGT	CRHRMO-LP-RMO018	
Serum, Plasma	Iron	CRHRMO-LP-RMO022	
Serum, Plasma, CSF	Lactate dehydrogenase	CRHRMO-LP-RMO025	
Serum, Plasma	Magnesium	CRHRMO-LP-RMO027	
Plasma	Ammonia	CRHRMO-LP-RMO004	
Serum, Plasma	Paracetamol	CRHRMO-LP-RMO029	
Serum, Plasma	Phosphate	CRHRMO-LP-RMO032	
Serum	Salicylate	CRHRMO-LP-RMO034	
Serum, Plasma	Transferrin	CRHRMO-LP-RMO043	
Serum, Plasma, Urine	Urate	CRHRMO-LP-RMO040	
Serum, Plasma, Urine	Urea	CRHRMO-LP-RMO039	
	Quantitative determination of:	Roche Cobas e801 Module: Using Chemiluminescence Immunoassay:	E
Serum, Plasma	Vitamin B12	CRHSPE-LP-SPE017	
Serum	Pro BNP	CRHSPE-LP-SPE025	
Serum, Plasma	CA 125	CRHSPE-LP-SPE021	
Serum, Plasma	CEA	CRHSPE-LP-SPE022	
Serum, Plasma	Cortisol	CRHSPE-LP-SPE014	
Serum	Digoxin	CRHSPE-LP-SPE016	
Serum, Plasma	Ferritin	CRHSPE-LP-SPE018	
Serum, Plasma	FSH	CRHSPE-LP-SPE008	
Serum, Plasma	Free thyroxine (FT4)	CRHSPE-LP-SPE005	
Serum, Plasma	Free tri-iodothyronine	CRHSPE-LP-SPE006	
Serum, Plasma	HCG	CRHSPE-LP-SPE024	
Serum, Plasma	LH	CRHSPE-LP-SPE007	
Serum	Oestradiol	CRHSPE-LP-SPE009	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):		
	Quantitative determination of: (cont'd)	Roche Cobas e801 Module: Using Chemiluminescence Immunoassay:	E
Plasma	Parathyroid hormone	CRHSPE-LP-SPE015	
Serum	Progesterone	CRHSPE-LP-SPE013	
Serum	Prolactin/Macroprolactin	CRHSPE-LP-SPE010	
Serum, Plasma	Total PSA	CRHSPE-LP-SPE012	
Serum, Plasma	Folate	CRHSPE-LP-SPE019	
Serum	SHBG	CRHRMO-LP-RMO63	
Serum	Testosterone	CRHSPE-LP-SPE011	
Serum, Plasma	Thyroid peroxisomal antibody	CRHSPE-LP-SPE023	
Serum, Plasma	TSH	CRHSPE-LP-SPE004	
Serum, Plasma	Troponin T	CRHSPE-LP-SPE020	
Serum	Vitamin D	CRHSPE-LP-SPE052	
Serum	Lithium	CRHRMO-LP-RMO64	
Serum, plasma	Procalcitonin	BSC-CP-SOP-8	
	Quantitative determination of:	Roche Cobas c702 Module: Microparticle agglutination	E
Serum	Carbamazepine	CRHRMO-LP-RMO010	
		Roche Cobas c702 Module : Using Indirect ISE:	E
Serum, Plasma, Urine	Sodium	CRHRMO-LP-RMO033	
	Potassium	CRHRMO-LP-RMO035	
	Chloride	CRHRMO-LP-RMO068	
	Quantitative determination of:	Roche Cobas c702 Module: Enzymatic Colorimetric analysis	E
Serum, Plasma	HDL Cholesterol	CRHRMO-LP-RMO021	
	Quantitative determination of:	Roche Cobas c702 Module: Enzyme immunoassay	E
Serum	Gentamicin	CRHRMO-LP-RMO019	
Serum	Vancomycin	CRHRMO-LP-RMO062	
Serum	Valproate	CRHRMO-LP-RMO041	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Biochemistry** examination activities for the purpose of clinical diagnosis (cont'd):		
	Urine drugs of abuse screen to include:	Abbott/Alere Dipstix analysis by chromatographic assay:	E
Urine	Barbiturates Amphetamine Benzodiazepine Buprenorphine Cocaine Methamphetamine Methadone Phencyclidine THC Cannabis Tricyclic antidepressants Opiates Bicarbonate	CRHRMO-LP-RMO044	

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Histopathology** examination activities for the purpose of clinical diagnosis: (cont'd)	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.	
	Routine staining for identification of basophilic and eosinophilic structures	Frozen section H+E staining- HSSSOP13 Routine FFPE Automated - Sakura Tissue-Tek Prisma with Film coverslipper - HRLSOP41 Haematoxylin & Eosin Stain – SOP HRLSOP9 and HRLSOP12	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	
	Pnumocycstis /Fungi	Grocott - HSSSOP12 (Automated)	
	Leprosy	Wade Fite - HSSSOP33	
	TB	Ziehl Neelsen - HSSSOP35	
	Collagen/fibrin	MSB - HSSSOP19	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Histopathology** examination activities for the purpose of clinical diagnosis: (cont'd)	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.	
Fixed and fresh tissue, excisional resection specimens and incisional biopsies and surgical including Non-gynae samples (cont'd)	Melanin and agrentaffin granules	Masson Fontana- HSSSOP16	A
	Ferric Iron	Perls - HSSSOP24 (Automated).	
	Reticulin fibres	Retic - HSSSOP27 (Automated).	
	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	
	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	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis:	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples		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	A
	Normal/neoplastic tissue of epithelial origin	AE1/AE3*- Reacts with the 65-67, 64, 59, 58, 56.5, 56, 54, 52, 50, 48 and 40 kDa cytokeratins.	
	Non-neoplastic, neoplastic liver disease,tumours of the testis and ovary such as yolk sac tumour	AFP- Alpha-1-fetoprotein (AFP)*	
	ALK-positive anaplastic large cell lymphoma	ALK1**	
	Androgen Receptor – member of the superfamily of ligand responsive transcription regulators.	AR^	
	Desmoid tumors, colorectal cancer and colon adenoma.	B-CATENIN*	
	Follicular lymphomas and diffuse lymphoproliferative diseases.	BCL2*	
	Diffuse large B-cell lymphomas, follicular lymphomas and Burkitt lymphomas/ leukaemia	BCL6*	
	Adenocarcinoma V malignant mesothelioma and BBC v SCC of Skin	BEREP4**	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Germ cell tumours, choriocarcinoma, granulosa cell tumour, hydatiform mole and seminoma	B-HCG*	
	Serous ovarian carcinoma and mesothelioma	CA125*	
	Gastrointestinal and pancreatic cancers	CA19.9*	
	Identification of thyroid medullary carcinoma and thyroid C cells	Calcitonin*	
	Primarily for identification of mesothelial cells and malignant mesothelioma of the epithelial type. Other tumours such as granulosa cell tumour also express calretinin.	Calretinin*	
	Identification of tumors of epithelial origin and non-small cell lung cancer and in distinguishing carcinomas from other malignant tumors of non-epithelial origin.	CAM5.2*	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Identification of thymoma, precursor T-lymphoblastic leukaemia/lymphoma and Langerhans' cell histiocytosis.	CD1 A*	
	Identification of T cells and their neoplasms such as T- and/or NK-cell lymphomas and mycosis fungoides.	CD3**	
	Identification of thymocytes, T-helper cells and related tumour's such as peripheral T-cell lymphoma (unspecified), anaplastic large cell lymphoma and mycosis fungoides.	CD4*	
	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.	CD5*	
	Identification of cytotoxic / suppressor T cells and their neoplastic counterparts.	CD8*	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples		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	
	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.	CD10*	
	Identification of mononuclear Hodgkin cells and Reed-Sternberg cells in Hodgkin lymphoma.	CD15**	
	Identification of the B-cell lineage and different types of B-cell lymphoma.	CD20*	
	Identification of follicular dendritic cells, mature B cells and structural alterations in the meshwork of follicular dendritic cells.	CD21**	
	Normal B lymphocytes and malignant lymphomas. Mantle cell lymphoma is generally negative for CD23.	CD23**	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Reed-Sternberg cells in Hodgkin lymphoma and anaplastic large cell lymphoma	CD30**	
	Endothelial cells, and benign and malignant vascular disorders.	CD31*	
	Vascular and lymphatic vessels and tumours of vascular origin	CD34*	
	Low-grade B-cell lymphoma, peripheral T-cell lymphoma and myeloid disorders	CD43*	
	Natural killer (NK) cells, NK-like T cells, neural/neuroendocrine tissues and their neoplasms	CD56*	
	Hodgkin lymphoma (lymphocyte-predominant subtype), T-cell large granular lymphocyte disorder, oligodendroglioma and neuroendocrine tumour	CD57*	
	Macrophages, other members of the mononuclear phagocyte lineage, and neoplasm of myeloid and macrophage/monocyte origin	CD68*	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	B cells during all stages of differentiation and of B-cell neoplasm	CD79a*	
	Glioblastomas and ependymomas of the CNS, certain islet cell tumours of the pancreas, Ewing's sarcoma, granulosa cell tumour and primitive peripheral neuroectodermal tumours	CD99*	
	Mesenchymal tumours of the gastrointestinal tract.	CD117**	
	Plasma cells and multiple myeloma, and for sub classification of diffuse large B-cell lymphoma	CD138*	
	Adenocarcinoma and carcinoids of the gastrointestinal tract	CDX2*	
	Various tumours such as lung adenocarcinoma, meningioma and medullary carcinoma of the thyroid.	CEA (Mono) and CEA (Poly)*	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Neuroendocrine cells and tumours with neuroendocrine differentiation.	Chromogranin A*	
	Distinguishing stratifying epithelial cell types from simple epithelial cell types.	CK14*	
	Epithelial tumours with cytokeration 19 expression	CK19*	
	Normal GI epithelia and urothelium Gastrointestinal tumours, mucinous ovarian tumours and Merkel cell carcinoma.	CK20*	
	Prostatic adenocarcinoma and prostatic intraepithelial neoplasia (PIN) or its benign mimics such as atypical hyperplasia.	CK34Be12*	
	Cytokeratin 5 in normal and neoplastic tissues.	CK5*	
	Squamous epithelium and neoplasms	CK5/6*	
	Classification of NSCLC	CK5/6 + P40 Dual Stain * **	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Glandular and transitional epithelia and neoplasia of type	CK7*	
	Epithelial Cell Tumours	CK8/18*	
	C-myc oncogene	C-MYC*	
	Mantle cell lymphoma.	Cyclin D1*	
	Smooth and striated muscle cells and reactive mesothelial cells, tumours leiomyoma and rhabdomyo-sarcoma.	Desmin*	
	Plasma membrane of gastrointestinal stromal tumors (GISTs)	DOG-1*	
	Lymphatic marker	D2-40 * **	
	Epstein-Barr virus-infected cells	EBV**	
	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.	E-Cadherin*	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis: (cont'd)	Microscopic examination supported by automated staining with positive stain controls:	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Tumours of epithelial origin in a wide variety of tissues light chains	EMA*	
	Expression of ER containing cells, e.g. Normal and neoplastic breast cells	Estrogen Receptor^	
	Vascular tumours and benign haemangioma variants and haemangioendotheliomas	Factor 8 (FVIII)*	
	Breast carcinoma and metastatic tumours	GCDFP-15*	
	Human Herpes Virus Type 8	HHV-8^	
	Hepatocellular tumours.	Hepatocyte*	
	Melanomas and other tumors demonstrating melanoma/melanocytic differentiation	HMB45*	
	HER2 antigen	HER2^	
	GATA3		

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	Microscopic examination supported by automated staining with positive stain controls (cont'd):	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	IgG4 related sclerosing disease has been recognized as a systematic disease entity characterised by an elevated serum igG4 level.	IgG4^	
	Ovarian sex cord and stromal tumours	Inhibin*	
	Plasma cells and lymphoid cells containing kappa light chains	Kappa**	
	Proliferating cells in normal and neoplastic tissues	KI67**	
	Plasma cells and lymphoid cells containing lambda light chains	Lambda**	
	Tumours of lymphoid origin	Leucocyte Common Antigen**	
	Mismatch repair gene associated with HNPCC	MSH2^	
	Mismatch repair gene MSH6 associated with HNPCC	MSH6^	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd):	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	Microscopic examination supported by automated staining with positive stain controls (cont'd):	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Melanocytes and Melanomas.	Melan A**	
	Type II pneumyocytes and in most lung adenocarcinomas and some renal cell carcinomas	Napsin A**	
	Classification of NSCLC	Napsin A + TTF1 Dual Stain * **	
	Normal and neoplastic cells of epithelial origin.	MNF116**	
	Sub classification of lymphoid malignancies	MUM1**	
	Myoglobin Demonstrated inskeletal and cardiac muscle but not in smooth muscle.	Myoglobin**	
	Differentiation of prostatic cancers	NKX3.1^	
	Normal and neoplastic cells of neuronal and neuroendocrine origin	NSE**	
	Germ cell tumours	OCT3/4**	
	Tumor suppressor protein	P16**	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	Microscopic examination supported by automated staining with positive stain controls (cont'd):	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	P40 protein. P40 is selectively expressed in lung SCC	P40**	
	For identification of wild-type and mutant-type p53 protein and accumulation in human neoplasia	P53**	
	Basal epithelial cells	P63**	
	Cytokeratins	PanCK**	
	Protien of the paired box (PAX) family of transcription factors	PAX8^	
	PD-L1 testing in NSCLC	PD-L1 (SP263) ^	
	Malignant germ cell tumours	PLAP**	
	Mismatch repair gene marker	PMS2^	
	Progesterone receptor levels in breast cancer tissue	Progesterone Receptor^	
	Tumours of prostatic origin prostate adenocarcinoma.	Prostate Specific Antigen (PSA) & Racemase (AMACAR)**	
	Renal cell carcinoma vs. non-renal cell tumours	Renal Cell Carcinoma**	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	Microscopic examination supported by automated staining with positive stain controls (cont'd):	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Malignant melanoma, chondroblastoma, schwannoma	S100**	
	Smooth muscle cells, myofibroblasts, and myoepithelial cells and their tumours	SMA**	
	For identification of myoepithelial cells and smooth muscle neoplasm.	SMM-HC**	
	Melanoma Marker	SOX10 * **	
	Neuroendocrine neoplasms and tumours with neuroendocrine differentiation.	Synaptophysin **	
	Non Small cell lung cancer (NSCLC)	ROS1^	
	Precursor B- and T-cell lymphoblastic lymphoma/ leukemia, and for identification of thymoma.	TdT**	
	Differentiation of mesothelioma from adenocarcinoma: Identification of vascular tumours	Thrombomodulin**	
	Tumours of thyroid origin	Thyroglobulin**	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Immuno-histochemistry** examination activities for the purpose of clinical diagnosis (cont'd):	Microscopic examination supported by automated staining with positive stain controls (cont'd):	
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)		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	A
	Primary vs. metastatic tumours in the lung and thyroid	TTF1**	
	Cells of mesenchymal origin in normal and neoplastic tissues	Vimentin**	
	Wilms's tumour, malignant mesotheliomas	WT1**	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Cytopathology** examination activities for the purpose of clinical diagnosis:	Sample preparation using the **Hologic Thinprep** Liquid Based Cytology method in conjunction with manufacturer's instructions using:	
Liquid Based Cytology (LBC) suspension of cervical/vaginal cells	Preparation and screening for detection or exclusion of pathological abnormalities	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	A
Samples collected from the cervix and stored in Liquid Based Cytology Collection Fluid	Detection of high-risk HPV mRNA	HOLOGIC –TOMCAT pre-analytics instrument, CSRSOP53 and HOLOGIC – PANTHER Molecular analyser: SOP CCSOP33 HPV Hologic Panther – Aptima HPV Assay.	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES AND FLUIDS (cont'd)	**Cytopathology** examination activities for the purpose of clinical diagnosis: (cont'd)		
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	Preparation and screening for detection or exclusion of pathological abnormalities	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 CNGCSOP4, CNGCSOP6,CNGCSOP8, and CNGCSOP15	A
Bodily fluids Urine Ascitic Fluid Bronchial Washing / brushing Fine needle aspirate Pericardial fluid Pleural fluid	Pap staining of fixed pre-prepared slides	Myreva SS-33 – Automated staining machine for PAP stain. CNGCSOP17	A
Slides prepared in house as above	Morphological assessment and interpretation/ diagnosis	Microscopy: CPGENSOP2 CCSOP7	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	**Haematology** examination activities for the purpose of clinical diagnosis	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A, E
Blood	Glucose-6-Phosphate Dehydrogenase Screen (G6PD)	**Trinity Biotech** semi-quantitative fluorescent blood spot test SPHAEMSOP26	A
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	**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	A
	Nucleated red blood cells (NRBC) Neutrophils Lymphocytes Monocytes Eosinophils Recticulocytes HCT Basophils	Sysmex XN10 and XN 20 Fluorescence flow cytometry, electrical impedance BSC-HAEM-SOP-1 BSC-HAEM-SOP-6	E

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Coagulation** examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A, E
		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	
		In house documented procedures based on standard methods and incorporating **Sysmex CS5100** manufacturers' instructions as relevant:	A
Plasma	Prothrombin & International normalised ratio (INR)	COAGSOP4	
Plasma	PT & INR	Stago Start Max using mechanical clot detection method. COAGSOP51	A
		Immunoassay:	
		Sysmex CS5100i automated clotting assays, light transmission	E
Plasma	Routine Coagulation testing for: Prothrombin Time (PT) INR Activated Partial Thromboplastin Time (APTT) Fibrinogen	BSC-COAG-SOP-020	
Plasma	D-Dimers	COAGSOP6	A
		In house documented manual procedures based on visual end point tilt tube method: Clifton Water Bath	
Plasma	Manual Clotting Tests PT & APTT	COAGSOP36	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Coagulation** examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	
Blood	Factor VIII inhibitor	**Sysmex CS2500** Photometric Bethesda Method – COAGSOP37	A
		Sysmex CS-2500 Photometric	A
Plasma	Factor assays Factor II Factor V Factor VII Factor VIII Factor IX Factor X Factor XI Factor XII	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	Chromogenic FVIII bovine	COAGSOP45	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Coagulation** examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	
Blood	Detection of: Prothrombin 20210A	Hain GenoXtract and Fluorocycler PCR, COAGSOP21	A
Blood	Factor V Leiden	Hain GenoXtract and Fluorocycler PCR, COAGSOP21	A
HUMAN BODY FLUIDS	**Haematology** examination activities for the purpose of clinical diagnosis	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A, E
Blood	Erythrocyte Sedimentation Rate (ESR)	Starrsed RS_ESR analyser AUTOHASOP90.	A
		Starrsed InetRRliner ESR analyser AUTOHASOP91	A
		Starrsed Interrliner ESR machine, Westergren sedimentation. BSC-HAEM-SOP-3	E
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	A
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	A
	Pre-caterisation of cells	Sysmex DI-60 Digital Morphology Analyser for automated blood film morphology AUTOHASOP65, AUTOHASOP43.	A
		Manual preparation of slide or Sysmex SP-10 (May-Grunwald and Giemsa) Hematek 3000-Modified Wrights stain	E
Blood	Red cell, white cell and platelet morphology and white cell differential	BSC-HAEM-SOP-6, 7, 20	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Haematology** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A, E
Blood	Automated staining	Sysmex SP-50 automated blood film staining. AUTOHASOP89	A
Bone Marrow	Automated staining	Sysmex SP-50 automated blood film staining. AUTOHASOP89	A
Blood	Glandular fever: heterophile antibodies to Epstein Barr Virus	**Accusay** mono Immunoassay AUTOHASOP10	A
Blood, Plasma	Infectious Mononucleosis Heterophile antibody	Accusay Mono ICT BSC-HAEM- SOP-50	E
Blood	Haemoglobin A1C (HbA1C)	**Bio-Rad D100** HPLC system SPHAEMACSOP16 SPHAEMACSOP17	A
		Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme, as defined in the laboratory QA evidence requirements.	A, E
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	A
Blood	Sickle Solubility test	Streck SickleDex kit SPHAEMSOP28	A
Urine	Haemosiderin	**Manual** Colorimetric stain assay SPHAEMSOP27 AUTOHASOP17 – Iron Stain	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Haematology** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	
Plasma	Detection of Malarial antigens of: P. *falciparum* Pan-detection for P. *malariae*, P. *ovale* & P. *vivax*	**CareStart**™ Malaria HRP2/pLDH Combo Immunoassay AUTOHASOP34	A
Blood	Detection of Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae, Plasmodium knowlesi	Manual staining of thick and thin films using Fields stain AUTOHASOP9.	A
	Blood Transfusion examination activities for the purpose of clinical diagnosis:	Documented in-house procedures based on manufacturer's instructions for **BioRad analysers, IH1000**:	A
Whole blood (EDTA)	Automated blood grouping by antigen detection: • ABO blood groups • Rh blood group antigens: C,c,D,E,e K (K1) blood group antigens	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	A
	Automated antibody Identification for the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb, Fya,Fy, JkaJkb,Lea,Leb,P1,M,N,S, s,Lua,Lub, Xga	BBSOP4 Automated (IAT) identification of red cell antibodies.	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd):	**Blood Transfusion** examination activities for the purpose of clinical diagnosis (cont'd)		
Whole Blood	Blood Group by detection and identification of antigens: A D Positive A D Negative AB D Positive AB D Negative B D Positive B D Negative O Positive O Negative	Automated BioRad analysers, IH1000, ABO/D forward and reverse grouping, Manual usingBiorad cards, screening on IgG cards by Gel column agglutination and centrifugation BSC-BB-SOP-018 – IH1000 BSC-BB-SOP-134 – Manual ABO/D typing and antibody screen	E
Whole Blood	Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, c, e, C^w K, k, Kp^a , Kp^b , Fy^a , Fy^b , Jk^a, Jk^b Le^a, Le^b S, s, M, N P_1 Lu^a , Lu^b X^{ga}	Automated BioRad analysers, IH1000 BSC-BB-SOP-138 BSC-BB-SOP-136	E
Plasma	Red Cell antibody identification: anti-C, D, E, c, e, C^w K, Kp^a Fy^a , Fy^b , Jk^a, Jk^b Le^a, Le^b S,s,M, N P_1 Lu^a , Anti-A1	BSC-BB-SOP-106	E

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd):	**Blood Transfusion** examination activities for the purpose of clinical diagnosis (cont'd)		
	Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, C^w Kp^a	Manual using Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation BSC-BB-SOP-138 BSC-BB-SOP-136	
	Red Cell antibody identification: anti-C, D, E, c, e, Kell (K1)	Manual using Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation BSC-BB-SOP-138 BSC-BB-SOP-136	
Red Cells	Direct Antiglobulin Test (DAT)	IH1000 automated or manually read Diamed ID Microtyping cards: Coombs direct antiglobulin test. BBSOP19	A
Red Cells	Direct Antiglobulin Test (DAT)	DAT card using LISS/Monospecific IgG gel column technology and centrifugation BSC-BB-SOP-147	E

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Blood Transfusion** examination activities for the purpose of clinical diagnosis: (cont'd)	Documented in-house procedures based on manufacturer's instructions for **BioRad analysers, IH1000**:	
	Red cell phenotyping: • 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)	BBSOP56	A
Whole blood (EDTA)	Manual blood grouping by antigen detection: • ABO blood groups • Rhesus blood group antigens: C,c,D,E,e K (K1) blood group antigens	ABO/D Forward + Reverse Group, K and Rh Phenotype by **Gel column agglutination and centrifugation**. BBSOP14 BBSOP43 BBSOP6	A
Whole Blood	Blood Group by detection and identification of antigens: A D Positive A D Negative AB D Positive AB D Negative B D Positive B D Negative O Positive O Negative	Automated BioRad analysers, IH1000 ABO/D forward and reverse grouping, Manual using and Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation BSC-BB-SOP-018 – IH1000 BSC-BB-SOP-134 – Manual ABO/D typing and antibody screen	E
	Manual antibody screening and identification using cells containing the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb, Fya,Fyb,Jka,Jkb,Lea,Leb,P 1,M,N,S,s,Lua Lub, Xga	BioRad -Gel column agglutination and centrifugation technology: BBSOP4	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Blood Transfusion** examination activities for the purpose of clinical diagnosis:	Documented in-house procedures based on manufacturer's instructions for **BioRad analysers, IH1000**:	
	Compatibility Testing: Serological Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma.	Documented in-house procedures based on BioRad manufacturer's instructions for column technology and centrifugation. BBSOP18	A
	Detection and Estimation of Foetal Maternal Haemorrhage	**Clin-Tech Kleihauer** Method BBSOP7	A
	Acid Elution& confirmation of FMH >2mL	**Navios** Flow Cytometer SPHAEMSOP19	
Maternal whole blood	Detection of fetal cells in maternal whole blood	Manual microscopy using Kleihauer Betke staining for foetal cells BSC-BB-SOP-28	E

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Immunology** examination activities for the purpose of clinical diagnosis:	In house documented procedures based on standard methods and incorporating **Dynex DS2** immunoassay manufacturers' instructions as relevant IMMSOP48	A
Serum/Plasma	Anti-Cardiolipin abs IgG	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	
	Proteinase 3	IMMSOP40	
	SCL-70 antibody	IMMSOP36	
Serum	Anti-Beta-2 Glycoprotein IgG antibodies	Orgentec ELISA ORG 521 IMMSOP63	
Serum	Anti -Beta-2 glycoprotein IgM antibodies	Orgentec ELISA ORG 521 IMMSOP63	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Immunology** examination activities for the purpose of clinical diagnosis (cont'd):	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 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	SPCHEMSOP18	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Immunology** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions forThermoPhadia ImmunoCap 250: PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER	
Serum/Plasma (cont'd)	Specific IgE testing: Soya Strawberry Timothy Grass Tomato Tree mix Tuna Wheat Weed mix Walnut Wasp	SPCHEMSOP18	A
Serum/Plasma	Anti-cyclic citrullinated peptide antibodies	IMMSOP46	
	Anti-nuclear antibodies (IgG)	**ASP1200 Automated slide processor**, Immunofluorescence: IMMSOP51 IMMSOP47 IMMSOP1 IMMSOP42 **Manual, Indirect Immunofluorescence**: IMMSOP1	
	Anti-nuclear cytoplasmic antibody Screen	IMMSOP16	
	Crithidia Immuno-fluoresence	IMMSOP18	
	Endomysial antibody – IgA Endomysial antibody - IgG	IMMSOP11	
	Intercellular/skin antibodies - IgG	IMMSOP10	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd):	**Immunology** examination activities for the purpose of clinical diagnosis (cont'd):	In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant	A
Serum	Liver/Kidney microsomal antibodies.	IMMSOP43	
Serum/Plasma	Mitochondrial antibodies - IgG	IMMSOP43	
	Smooth muscle antibodies - IgG	IMMSOP43	
	Parietal cell antibodies	IMMSOP49	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions **Manual culture** using SOP's:	A, D
Material from swabs from wounds, skin, lines, eyes, ears, throats, ulcers and nose. Line Tips	General isolation and characterisation of micro-organisms of clinical significance.	MICNEWSOP20 - Processing diagnostic swabs.	A
Cellular and fluid material contained on swabs, catheter tips and IUCDs Aspirates Fluids Genital samples Pus Samples from sterile sites Semen Tissues Urine	Isolation of microorganisms of clinical significance	Manual inoculation, incubation and culture using: CRHMIC-LP-GB030, GB033 CRHMIC-LP-GEN02, GB004 CBM06,GB013,GB034 CRHMIC-LP-UR001 GB003,GB014, GB002, GB015, GB002, GB016,	D
Material from swabs from Nose, Groin, Throat, Axilla, Perineum and Wounds.	Isolation of MRSA and MSSA	MICSCRSOP3 – MRSA screen. MICSCRSOP10 – Investigation of swabs for Staphylococcus aureus	A
Swabs , Fluids, urines, tips and sputum	Isolation of MRSA	Manual culture on chromogenic agar/broths using SOP CRHMIC-LP-AST06	D
Faeces	General isolation and characterisation of Salmonella, Shigella, Campylobacter, Ecoli O157, Vibrio and Yersinia.	MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile).	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	A, D
Faeces	General isolation and characterisation of *Salmonella*, *Shigella*, *Campylobacter* & *E. coli* 0157	Manual culture and using selective agar with SOPs CRHMIC-LP-EB004, GB004, EB003, EB011	D
Faeces and bowel contents	Detection of *Clostridium difficile* GDH antigen and toxins A & B	Immunochromatopgraphic assay using SOP CRHMIC-LP-EB010 in conjunction with manufacturers' instructions using C. difficile Quik Chek complete.	D
Faeces	Detection of *Helicobacter pylori* antigen	Immunochromatographic technique using SOP CRHMIC-LP-EB008 and Proflow H pylori kit	D
Sputum, Bronchial Washings, Nasopharyngeal Aspirates, Tracheal Aspirates, Cough Swabs and Endotracheal tubes	General isolation and characterisation of Respiratory Tract infections (excluding TB) for micro-organisms of clinical significance	MICCL3SOP7 - Culture of Respiratory Specimens (except Mycobacterium sp).	A
Respiratory specimens: Sputum, Bronchoalveolar lavage, Bronchial aspirate, brushings and washings, Cellular material contained on swabs, Endotracheal tube specimens, Nasopharyngeal aspirate, Pleural fluid	General isolation and characterisation of micro-organisms of clinical significance	Manual media culture using SOPs CRHMIC-LP-RB003, CBM06, CL302, GB034	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Material from swabs from Rectum, Wound and Invasive Device Sites. Faeces, CSU and Sputum. (Patients transferred from other major hospitals only).	Carbapenemase Resistant Enterobacteriaceae (CRE) and Carbapenemase Resistant Organisms (CRO)	MICSCRSOP11 – Carbapenemase producing organism screening	A
Material from swabs: from vagina, vulva, vulvo-vaginal, rectal, urethral, mouth and endocervix.	General isolation and characterisation of micro-organisms of clinical significance.	Manual culture and **microscopy** (wet prep) using SOP: MICSCRSOP9 – Investigation of Genital Tract specimens MICSCRSOP12 – Investigation of mouth swabs for Candida spp.	A
CSF's, Ascitic, Peritoneal, Pleural, Pericardial, Amniotic, Joint/bursa and CAPD fluid. Tissue, Biopsies, synovium, nodes, tissue swabs and bone. Pus, drain fluids, semen, breast milk, seroma, aspirate, washouts, fluid swabs and bile	Quantification of white and red blood cells and bacteria. Culture leading to general isolation and characterisation of micro-organisms of clinical significance.	Manual culture and microscopy (including Gram stain) using SOP: MICBBSOP1– Investigation and Identification of Body Bench Samples	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	A, D
Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues CSF Ascitic fluids	Detection and identification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae	Staining (inc. Gram) and microscopic examination using:	D
CSF / Ascitic	General isolation and characterisation of micro-organisms of clinical significance	Manual microscopy and manual inoculation and media culture using SOPs CRHMIC-LP-GB016, CBM06, GB034	D
Urine - MSU, CSU, Nephrostomy, Supra pubic aspirate and Bag urine.	The quantification of white and red blood cells, bacteria and epithelial cells. Leading to general isolation and characterisation of micro-organisms of clinical significance.	Manual culture and automated microscopy using SOP: MICURSOP7 - Microbiological Investigation of Urine, in conjunction with the equipment manual using the **Sysmex UF5000** automated urine microscopy analyser.	A
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Automated urinalysis, image capture and recognition using: SOP CRHMIC-LP-UR001, in conjunction with equipment manual using UF1000i, UR003	D
Blood, CAPD, Joint Aspirates, Pleural Fluid & Pericardial Fluid	General isolation and characterisation of micro-organisms of clinical significance	**BD Bactec FX** blood culture fluorescent growth detection system, by detection of pH changes due to CO_2 production. Manual culture and **Microscopy** using SOP: MICBCSOP11 – Blood Culture Procedures	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	A, D
Blood, CAPD, Joint Aspirates, Pleural Fluid & Pericardial Fluid (cont'd)	Identification of microorganisms of clinical significance	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	A
Blood	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	Liquid media culture using SOP CRHMIC-LP-BC003 in conjunction with manufacturers' instructions for BD BACTEC FX automated system BC004, BC005	D
Skin, Hair and nail clippings	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) using: SOP CRHMIC-LP-MYC013	D
Blood	All Malarial Parasites known to cause human disease	CRHMIC-LP-GB005 using light microscopy and Giemsa Stain	D
Blood	Malarial Parasites to include: Plasmodium falciparum Pan malarial antigen	Immunochromatographic assay using CRHMIC-LP-GB005 and Binax NOW malaria kit.	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	A, D
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).	Manual 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 **BD Bactec MGIT 960 system**. Detection of **pH** changes due to the presence of CO_2. MICCL3SOP15 - Investigation of Specimens for Mycobacterium species.	A
Sputum, fluid, urine, tissue and swabs	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. *Mycobacterium* spp.)	Manual microscopy for the detection of Acid Fast Bacilli (Mycobacterium) by Auramine-Phenol staining and incident-light fluorescence microscopy and confirmation ZN staining using light microscopy using: CRHMIC-LP-RB005, CL302, EB009 in conjunction with BD TB MGIT, RB001	D
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	A
Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: SOPs CRHMIC-LP-EB005	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Serological** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	A, D
Faeces	Detection of Cryptosporidium	Fluorescent microscopy method (auramine stain) and confirmation using Cold ZN incident-light microscopic examination	D
Urine - MSU, CSU, Nephrostomy, Sub Phrenic Aspirate and Bag urine.	detection of Legionella pneumophilia antigen and Streptococcus pneumonia antigen.	Manual Immunochromatographic assay - **Binax NOW** Legionella pneumophilia antigen and Streptococcus pneumonia antigen kits: MICURSOP8 – Urinary antigen detection for Legionella and Streptococcus pneumoniae	A
Urine	Detection of Legionella urinary antigen	Immunochromatographic assay using SOP CRHMIC-LP-SE044 and Alere Binax NOW for legionella Ag detection	D
Urine	Detection of S.pneumoniae urine antigen	Immunochromatographic assay using SOP CRHMIC-LP-SE053 and Alere Binax NOW for s.pneumoniae Ag detection	D
Faeces	Detection of Norovirus	Immunochromatographic assay SOP CRHMIC-LP-EB007 using Ridascreen Norovirus kit	D
Serum/plasma	HIV p24 antigen/antibody (HIV1/2)	Immunochromatographic detection method using the SOP: MICSERSOP7 - **Determine** HIV1/2 Ag/Ab	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Serological** examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:	A, D
		Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme as defined in the laboratory QA evidence requirements' (targets marked *)	A
Serum	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 /8000** Immunoassay MICSERSOP4 -	A
Serum	Detection of HIV antibody	Bio-Rad Geenius Immunochromatographic SOP - MICSERSOP64	A
Serum	Detection of HIV ½ Antibody	Vidas HIV Duo Quick SOP MICSERSOP58	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Microbiology** examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme as defined in the laboratory QA evidence requirements' (targets marked *)	A, D
Serum	Hepatitis A IgM Hepatitis B Surface Antibody Hepatitis B Core IgG and IgM Hepatitis B Surface antigen* Rubella IgG Hepatitis C antibody HIV 1 & 2 antibody and p24 antigen* Treponema IgG and IgM*	In-house procedures in conjunction with manufacturers instructions using Roche COBAS C8000 e801/e802 (testing performed in blood sciences) with reference to CRHMIC-LP-SE133	D
Serum or plasma	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	Biomerieux **VIDAS** automated ELISA & associated SPR's, MICSERSOP58- Procedure for running assay on the Vidas	A
Serum	Detection of the following: Hepatitis B surface antigen, Hepatitis B core Total antibody	Biomerieux **VIDAS** automated ELISA MICSERSOP58	A
	Anti-streptolysin (ASO)	**Biokit rheumajet ASO latex slide test** MICSERSOP3 – ASO Titre	A
	Aspergillus antibody	**ThermoPhadia ImmunoCap 250** Immunoassay MICSERSOP39 and AUTOCHISOP233	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Molecular** examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	A, D
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	A
		RT PCR using BD Max and SOP CRHMIC-LP-GB035 in conjunction with manufacturer's instructions	D
Faeces	tcdB gene in C.difficile DNA		
Faeces	Molecular detection of DNA of: Salmonella species Shigella/EIEC Campylobacter STEC		A
Pernasal COPAN eswab	Qualitative detection of the Bordetella PCR pertussis/ parapertussis	Hologic Panther Fusion using the Bordetella assay, multiplex real-time PCR**SOP MICSERSOP59**	
Throat swab and combined Nose/ throat swabs in Viral Transport Media	Qualitative detection of the following: Respiratory virus (SARS-CoV-2, Influenza A, Influenza B, RSV, Rhinovirus, Parainfluenza 1,2,3,4, Human Metapneumovirus, Adenovirus).	Hologic Panther Fusion using the Multiplex Respiratory assay's MICSERSOP59, MICSERSOP62	A
Serum and plasma	Quantitative detection of HIV-1, HBV, HCV	Hologic Panther Aptima MICSERSOP59	A
Throat swab and combined Nose/ throat swabs in Viral Transport Media	Molecular examination: Detection of SARS-CoV-2, Influenza A/ B/ RSV	BD Max Respiratory Multiplex assay using the BD Max system MICSERSOP63	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Molecular** examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	A, D
Aptima Multitest for vaginal, rectal, throat, penile meatal, and lesions. Aptima Urine collection kit for male and female urine specimens. Aptima Unisex swab for female endocervical or male urethral swab specimens	Detection of DNA for Chlamydia trachomatis and Neisseria gonorrhoeae	Hologic Panther Aptima Combo 2 qualitative TMA assay SOP MICSERSOP59	A
Aptima Multitest for vaginal, rectal, throat, penile meatal, and lesions. Aptima Urine collection kit for male and female urine specimens. Aptima Unisex swab for female endocervical or male urethral swab specimens	Confirmation of Neisseria gonorrhoea DNA detection	Hologic Panther Aptima Neisseria gonorrhoeae TMA assay SOP MICSERSOP59	
END			