


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8992 Accredited to ISO 15189:2022	Calderdale and Huddersfield NHS Foundation Trust	
	Issue No: 016 Issue date: 15 January 2025	
	Pathology Huddersfield Royal Infirmary Acre Street Lindley HD3 3EA United Kingdom	Contact: Alison Milner Tel: +44 (0) 1484 355365 E-Mail: Alison.Milner@cht.nhs.uk Website: www.cht.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Huddersfield Royal Infirmary Acre Street Lindley HD3 3EA United Kingdom	Chemistry, Haematology, Blood Transfusion testing	HRI
Address Calderdale Royal Hospital Salterhebble Halifax HX3 0PW United Kingdom	Chemistry, Haematology, Blood Transfusion, Microbiology/serology, Histopathology, non-gynae Cytopathology testing	CRH



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Site activities performed away from the laboratories:

Location details	Activity
Huddersfield Royal Infirmary	Phlebotomy (Outpatients) Blood issue fridge (designated secure room off the main corridor outside pathology) Body Store: Storage of bodies Record keeping (body identification and audit trail) Block, slide and record storage
Calderdale Royal Hospital	Phlebotomy (Outpatients) Blood issue fridge (sample reception waiting area and Labour ward) Body Store: Storage of bodies Record keeping (body identification and audit trail)



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant Siemens Advia XPT(HRI) Siemens Advia 1800 (CRH) Using suppliers methods unless otherwise stated and SOPs:	
Serum	Angiotensin Converting Enzyme	Enzymatic LI 820-260	HRI
Serum, plasma (Li Hep)	Albumin	Bromocresol green LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Alkaline Phosphatase	IFCC Standardised Method LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Alanine Transaminase	Enzymatic tris buffer, modified IFCC LI 820-260	HRI, CRH
Plasma (Li Hep)	Ammonia	Enzymatic end point LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Amylase	Enzymatic, blocked pNPG7 LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Aspartate Transaminase	Enzymatic, tris buffer modified IFCC LI 820-260	HRI
Serum, plasma (Li Hep)	Bicarbonate	Enzymatic LI 820-260	HRI, CRH
Serum	Bile acids	Colorimetric SOP 820-260	HRI
Serum, plasma (Li Hep), Urine	Calcium	Arsenazo LI 820-260	HRI, CRH
Serum, plasma (Li Hep), Urine	Chloride	Indirect ISE LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Creatine Kinase	IFCC Reference method at 37CL LI 820-260	HRI, CRH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant Siemens Advia XPT(HRI) Siemens Advia 1800 (CRH) Using suppliers methods unless otherwise stated and SOPs:	
Serum, plasma (Li Hep)	Total bilirubin	Vanadate oxidation LI 820-260	HRI, CRH
Serum, plasma (Li Hep), urine	Creatinine	Jaffe rate blanked compensated LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	C-reactive protein	Immunoturbidimetric LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Direct Bilirubin	Vanadate Oxidation LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	GGT	Gamma glut 3-carb 4-nitro, modified IFCC LI 820-260	HRI
Serum, plasma (Fluoride)	Glucose	Glucose Hexokinase LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	HDL-cholesterol	Direct HDL clearance method LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Iron	Ferrozine LI 820-260	HRI
Plasma (Li Hep)	Lactate	Lactate oxidase colorimetric LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	LDH	Pyruvate to lactate LI 820-260	HRI
Serum, plasma (Li Hep)	Lipase	Colorimetric SOP 820-260	HRI
Serum, plasma (Li Hep), urine	Magnesium	Colorimetric xylidyl blue LI 820-260	HRI, CRH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant Siemens Advia XPT(HRI) Siemens Advia 1800 (CRH) Using suppliers methods unless otherwise stated and SOPs:	
Serum, plasma (Li Hep), urine	Phosphate	Phosphomolybdate UV LI 820-260	HRI, CRH
Serum, plasma (Li Hep), urine	Potassium	Indirect ISE LI 820-260	HRI, CRH
Serum, plasma (Li Hep), urine	Sodium	Indirect ISE LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Total Cholesterol	Enzymatic LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Total protein	Biuret reaction end point LI 820-260	HRI, CRH
Serum (Li Hep)	Triglycerides	GPO- Trinder without blank LI 820-260	HRI, CRH
Serum, plasma (Li Hep)Urine	Uric Acid	Uricase/peroxidase endpoint LI 820-260	HRI, CRH
Serum, plasma (Li Hep)Urine	Urea	Urease rate reaction LI 820-260	HRI, CRH
Urine	Microalbumin	PEG Immunoturbidimetric LI 820-260	HRI
Urine, CSF	Protein	Pyrogallol red endpoint LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Carbamazepine	EMIT LI 820-260	HRI
Serum, plasma (Li Hep)	Phenytoin	EMIT LI 820-260	HRI
Serum, plasma (Li Hep)	Theophylline	EMIT LI 820-260	HRI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant Siemens Advia XPT(HRI) Siemens Advia 1800 (CRH) Using suppliers methods unless otherwise stated and SOPs:	
Serum, plasma (Li Hep)	Valproic acid	EMIT LI 820-260	HRI
Serum, plasma (Li Hep)	Salicylate	Enzymatic LI 820-260	HRI, CRH
Serum	Ethanol	Enzymatic kinetic LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Paracetamol	Enzymatic LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Immunoglobulin A, G and M	Immunoturbidimetric LI 820-260	HRI
Serum	Rheumatoid factor	Immunoturbidimetric LI 820-260	HRI
Serum, plasma (Li Hep)	Alpha-1-antitrypsin	Immunoturbidimetric LI 820-260	HRI
Serum	C3	Immunoturbidimetric LI 820-260	HRI
Serum	C4	Immunoturbidimetric LI 820-260	HRI
Serum	Haptoglobin	Immunoturbidimetric LI 820-260	HRI
Serum, plasma (Li Hep)	Transferrin	Immunoturbidimetric LI 820-260	HRI
Serum, plasma (Li Hep)	Lithium	Siemens lithium 2 method Lithium Colorimetric Endpoint LI 820-260,	HRI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant Siemens Advia XPT: Calculations from the results of the methods above:	
Serum	eGFR AKI LDL-cholesterol Total cholesterol/HDL ratio Globulin Corrected calcium Anion GAP		HRI, CRH
Serum	Free androgen index Iron Saturation index		HRI
Urine	Protein/creatinine ratio Calcium/creatinine ratio Urate/creatinine ratio Timed Electrolytes (Na,Cl,K,Ure)		HRI, CRH
Urine	Albumin/creatinine ratio 24 hour calcium 24 hr phosphate 24 hour urate 24 hour magnesium 24 hour protein		HRI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum, Urine	<u>Creatinine clearance</u>	Advia Centaur XPT immunoassay via Chemiluminescence, using suppliers methods unless otherwise stated	HRI, CRH
Serum, plasma (Li Hep)	Anti-TPO antibodies	Indirect IA LI 820-260	HRI
Serum	Alpha Fetoprotein	Direct IA LI 820-260	HRI
Serum, plasma (Li Hep)	Vitamin b12	Indirect IA LI 820-260	HRI
Serum	Brain natriuretic peptide (BNP)	Direct IA LI 820-260	HRI
Serum	CA-125	Direct IA LI 820-260	HRI
Serum	CA-15-3	Direct IA LI 820-260	HRI
Serum	CA-19-9	Direct IA LI 820-260	HRI
Serum	CEA	Direct IA LI 820-260	HRI
Serum	Cortisol	Indirect IA LI 820-260	HRI
Serum, plasma (Li Hep)	Ferritin	Direct IA LI 820-260	HRI
Serum	Folate	Direct IA LI 820-260	HRI
Serum	Follicle stimulating hormone	Direct IA LI 820-260	HRI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum	Free tri-iodothyronine (FT3)	Advia Centaur XPT immunoassay via Chemiluminescence, using suppliers methods unless otherwise stated Indirect IA LI 820-260	HRI
Serum, plasma (Li Hep)	Free thyroxine (FT4)	Indirect IA LI 820-260	HRI, CRH
Serum	Beta HCG	Direct IA LI 820-260	HRI, CRH
Serum	Luteinising Hormone	Direct IA LI 820-260	HRI
Serum, plasma (Li Hep)	Oestradiol	Direct IA LI 820-260	HRI
Serum	Progesterone	Direct IA LI 820-260	HRI
Serum	Prolactin	Indirect IA LI 820-260	HRI
Serum	Prostate specific antigen	Direct IA LI 820-260	HRI
Plasma (EDTA)	Parathyroid Hormone	Direct IA 2 site sandwich assay using direct chemiluminometric technology using monoclonal mouse anti-human PTH antibodies. LI 820-260	HRI
Serum, plasma (Li Hep)	Sex hormone binding globulin	Direct IA New generation assay, WHO standard NIBSC 08/266 LI 820-260	HRI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum, plasma (Li Hep)	Testosterone	Advia Centaur XPT immunoassay via Chemiluminescence, using suppliers methods unless otherwise stated Indirect IA LI 820-260	HRI
Serum, plasma (Li Hep)	HS Troponin-I	Direct IA LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Thyroid stimulating hormone	Direct IA LI 820-260 Siemens Centaur XPT immunoassay via Chemiluminescence, using suppliers methods unless otherwise stated	HRI, CRH
Serum, plasma (Li Hep)	Total Vitamin D	Indirect IA LI 820-260	HRI
Serum	Digoxin	Competitive IA LI 820-260	HRI
Serum, plasma (Li Hep)	Vancomycin	Competitive IA LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Gentamicin	Competitive IA LI 820-260	HRI, CRH
Serum	Detection of monoclonal protein (IgG, IgM, IgA and associated kappa and lambda light chains) with densitometric quantitation	Sebia Hydrasys, agarose gel electrophoresis Serum protein electrophoresis SOP 810 503	HRI
Urine	Detection of bence jones protein (kappa and lambda free light chains with densitometric quantitation)	Urine protein electrophoresis SOP 810 503	HRI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum	Isotyping of monoclonal proteins (IgG, IgA, IgM, kappa, lambda)	Sebia Hydrasys, agarose gel electrophoresis (cont'd) Serum Immunofixation SOP 810 506	HRI
Urine	Isotyping of kappa and lambda free light chains	Urine immunofixation SOP 810 506	HRI
Serum	Alkaline phosphatase isoenzymes	With lectin substrate SOP 810 505	HRI
Serum, Urine	Osmolality	Advanced instruments Osmo 1 micro-osmometer, Freezing point depression SOP 800 257	CRH HRI
CSF	Xanthochromia	Spectrophotometry: Biotek UVIKON spectrophotometer SOP 800 206	HRI
Sweat	Chloride	Elitech Wescor macroduct, coulometry SOP 820 465	HRI
Fluid, Urine	pH	Manual, potentiometric pH meter SOP 800 196	HRI
Whole blood - EDTA/ Fluoride	Glycated Haemoglobin	Menarini HB9210 Boronate Affinity HPLC SOP 820-260	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Citrated whole blood	Platelet count	Sysmex XN-9000, spectrophotometry, aperture impedance, flow cytometry and scattergram interpretation SOP 620-768, SOP 620-767	HRI, CRH
EDTA whole blood	Full Blood Count (Red blood cells, White blood cells, Hb, MCH, MCHC, MCV, PCV, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets, Reticulocytes, MRV, Nucleated RBC's)		
EDTA whole blood	Erythrocyte sedimentation rate	Starrsed Auto-Compact, infra-red absorption readings of red cell sedimentation SOP 620-769	HRI
		Starrsed Inversa, infra-red absorption readings of red cell sedimentation SOP 610-1	CRH
EDTA whole blood	Blood film assessment (peripheral); White cell differential counts and morphological comments	Staining by May Grunwald and Giemsa; Manual light microscopy SOP 620 016	HRI, CRH
EDTA whole blood, Gel whole blood, Plain whole blood	Infectious Mononucleosis screen for the Heterophile antibody	Clearview IM kit, immunochromatographic test cartridge format SOP 620 018	HRI, CRH
EDTA whole blood	Detection of malaria parasites	Thin (Giemsa/May Grunwald) and thick (fields stain A & B) blood film examination using manual microscope SOP 620 028, SOP 620 029	HRI, CRH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA whole blood	Malaria antigens (HRP2 and pLDH) Detects P Falciparum, Others (P Vivax, P Ovale, P Malariae) and/or mixed infections (excepting P. knowlesi)	CareStart Malaria test kit, monoclonal antibody immunochromatographic test cartridge format SOP 600 620	HRI, CRH
EDTA & Gel whole blood	Sickle cell solubility	Sickle-chex screening kit, qualitative solubility test kit SOP 620 404	HRI, CRH
EDTA whole blood	G6PD	Vilber-Lourmat UV light box, UV fluorescence SOP 620 603	HRI
Citrated Plasma	APTT	Sysmex CS-2500 analyser, optical density detection SOP 620 774	HRI, CRH
	Prothrombin Time	SOP 620 773	HRI, CRH
	D-Dimer	SOP 620 775	HRI, CRH
	Lupus anticoagulant screen	SOP 600 243	HRI
	Factor assays	SOP 600 244	HRI
	Von Willebrand screen	SOP 600 245	HRI
	Clauss Fibrinogen	SOP 620 776	HRI, CRH
	Thrombin Time	SOP 620 777	HRI, CRH



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HUMAN BODY FLUIDS (cont'd)	<u>Transfusion examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA whole blood	Blood Grouping by antigen detection: <ul style="list-style-type: none"> A B and O groups Rhesus groups 	BioRad IH-1000, BioRad gel column technique SOP 720-3 Manual blood grouping, BioRad gel column technique SOP 720-9	HRI, CRH
EDTA whole blood	Detection of the following Antibodies: <ul style="list-style-type: none"> Rhesus blood group antibodies: <ul style="list-style-type: none"> anti-Cw, anti-C, anti-c, anti-D, anti-E, anti-e Kell system blood group antibodies: <ul style="list-style-type: none"> anti-K, anti-k, anti-Kpa Kidd blood group antibodies: <ul style="list-style-type: none"> anti-Jka, anti-Jkb Duffy blood group antibodies: <ul style="list-style-type: none"> anti-Fya, anti-Fyb Lutheran blood group antibodies: <ul style="list-style-type: none"> anti-Lua MNS blood group antibodies: <ul style="list-style-type: none"> anti-M, anti-N, anti-S, anti-s Lewis blood group antibodies: <ul style="list-style-type: none"> anti-Lea, anti-Leb P blood group antibodies: <ul style="list-style-type: none"> anti-P1 	BioRad IH-1000, BioRad gel column technique (screen) SOP 720-3 Manual antibody screening, BioRad gel column technique SOP 720-10 BioRad IH-1000, BioRad gel column technique (Antibody identification (Panels)) SOP 720-5 Manual antibody identification, BioRad gel column technique SOP 720-13	HRI, CRH



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HUMAN BODY FLUIDS (cont'd)	<u>Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA whole blood	Compatibility testing;- Compatibility testing of patients plasma with donor cells	BioRad IH-1000, BioRad gel column technique SOP 720-4 Manual crossmatching, BioRad gel column technique SOP 720-11	HRI, CRH
EDTA whole blood	Direct Antiglobulin test (DAT)	BioRad IH-1000, BioRad gel column technique SOP 720-6 Manual Direct antiglobulin test, BioRad gel column technique SOP 720-12	HRI, CRH
EDTA whole blood	Neonatal blood group +DAT • A B and O groups • RhD groups	BioRad IH-1000, BioRad gel column technique SOP 720-7 Manual newborn groups, BioRad gel column technique SOP 720-14	HRI, CRH
EDTA whole blood	Red cell phenotyping for Antigens of the following systems: Rh – C,D,E,c,e Kell – K, Duffy – Fya, Fyb Kidd – Jka, Ss - S, s	BioRad IH-1000, BioRad gel column technique SOP 720-8 Manual BioRad gel column technique (pre prepared cassette) SOP 720-15 Manual BioRad gel column technique (using cells & antisera) SOP 720 038	HRI, CRH
EDTA whole blood	Foetal/maternal haemorrhage screen	Acid Elution Technique using Guest Medical Foetal red cell detection kit (Kleihauer kit) SOP 720-38	CRH



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Swabs (Skin surface wound, eye throat, ear, mouth, genital, nose, pernasal). Tissue samples samples/biopsies Sputum Bronchoalveolar lavage IV cannulae Corneal scrapes Wound drain fluids Sterile site fluids CSF</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>General Microbiology</p> <p>Isolation and characterisation of microorganisms of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant</p> <p>Manual inoculation and media culture SOP 320-007 SOP 320-009 SOP 320-069 SOP 320-074 SOP 320-075 SOP 320-077 SOP 320-080 SOP 320-082 SOP 320-089 SOP 320-090 SOP 320-093 SOP 320-095 SOP 320-097 SOP 320-098 SOP 320-104 SOP 320-106 SOP 320-108 SOP 320-111 SOP 320-131 SOP 320-190</p>	CRH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Pre-Inoculated culture plates –GUM clinic	General Microbiology (cont'd) Isolation and identification of <i>Neisseria gonorrhoeae</i>	Media culture SOP 320-106	
Blood	Culture and detection of microorganisms of clinical significance	Becton Dickinson BDFx – liquid culture/fluorescent growth detection, and manual inoculation and culture SOP 320-002	
Swabs (Nose. Groin, lesions), urine	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual inoculation and culture on chromogenic medium (Brilliance MRSA) SOP 320-100	
Breast milk	Sterility check	Manual inoculation and media culture SOP 320-171	
Faeces	Isolation of bacterial pathogens <i>Campylobacter</i> spp. <i>Shigella</i> spp. <i>Salmonella</i> sp. <i>Escherichia coli</i> O157 <i>Vibrio</i> spp. <i>Yersinia</i> spp.	Manual inoculation and media culture SOP 320-001	
Rectal swabs, faeces	Detection of Carbapenemase Producing Enterobacteriaceae (CPE)	Manual inoculation and chromogenic media culture SOP 320-518 Confirmation using Coris BioConcept OXA-48 K-SeT immunochromatographic kit SOP-320-513	
Urine	Isolation of bacterial and fungal species of clinical significance	Manual culture methods SOP 320-004	



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cultures isolated in-house from all samples listed above</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>General Microbiology (cont'd)</p> <p>Identification of microorganisms of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant</p> <p>Manual; biochemical/ monoclonal antibody/ latex-antigen detection methods</p> <p>SOP 320-049 SOP 320-704 SOP 320-705 SOP 320-706 SOP 320-707 SOP 320-708 SOP 320-709 SOP 320-710 SOP 320-711 SOP 320-712 SOP 320-713 SOP 320-714 SOP 320-715 SOP 320-716 SOP 320-717 SOP 320-718 SOP 320-719 SOP 320-720 SOP 320-721 SOP 320-722 SOP 320-723 SOP 320-724</p> <p>Automated; Bruker Maldi-TOF Biotyper using calculation of a similarity of a mass spectrometry based pattern profile of an unknown organism SOP 320-756</p>	CRH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Cultures isolated in-house from all samples listed above	General Microbiology (cont'd)		
	Identification of microorganisms of clinical significance and Antibiotic susceptibility testing of isolated bacterial pathogens	Automated – BD Phoenix ID: Biochemical Reactions to provide a profile which is compared to a database. Sensitivity: MIC using EUCAST SOP 320-758 BD Phoenix	
	Antibiotic susceptibility testing	Manual and/or automated antimicrobial susceptibility testing using EUCAST methodology. Disc diffusion & gradient MIC determination SOP 320-076	
	Colistin susceptibility testing	ComASP Colistin Broth microdilution method LI 320-1187	
Urine	Detection and quantification of red cells, white cells, bacteria, epithelial cells, urinary casts and yeast cells	IRIS IQ Sprint: automated Urine Microscopy system and particle recognition SOP 320-745	
CSF	Detection and quantification of red cells, white cells	Manual light microscopy using Kova Slide counting chambers. SOP 320-009	
Joint Fluid	Identification of sodium urate crystals and calcium pyrophosphate crystals	Manual light microscopy SOP 320-111	
Faeces	Detection of Cryptosporidia	Fluorescent microscopy using Auramine O and Thiazine red stains SOP 320-049	
Faeces, Sellotape slides	Identification of ova, cysts and parasites	Concentration method using centrifugation and light microscopy of concentrate SOP 320-101	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Faeces	<u>General Microbiology</u> (cont'd) Detection of C.difficile GDH Detection of C.difficile toxin A and B	Manual enzyme immunoassay: Techlab C.Diff Quik Chek Manual enzyme immunoassay Techlab C. diff ToxA/B Quick Chek SOP 320-505 (See Molecular section for confirmatory testing)	
Serum	Quantification of Anti Streptolysin O titres	Latex agglutination using Rheumajet ASO Kit SOP 320-099	
Urine	Detection of Legionella and Pneumococcal urinary antigen	Manual immunochromatographic assay using Binax Now Legionella urinary antigen card and Binax Now Streptococcus pneumoniae urinary antigen card SOP 320-128	
Lower respiratory tract samples, swabs, tissue, urine	Isolation/identification of Mycobacteria species	Auramine fluorescent staining, microscopy Becton Dickinson MGIT Fluorometric growth detection. SOP 320-003	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Skin scraping Hair cuttings Nail clippings	Mycology Isolation and identification of fungi of clinical significance	Culture, macroscopic examination and fluorescent microscopy SOP 320-010	CRH
Male urethral swabs, urine and throat swabs	Molecular testing Detection of: Clostridioides difficile toxin DNA	Becton Dickinson BD MAX system. Automated extraction, purification and amplification of DNA/RNA SOP 320-757	
Throat/nasal swabs	RSV RNA		
Faeces	Enteric Viral panel: Norovirus GI & GII RNA Rotavirus A RNA Adenovirus F40/41 DNA Sapovirus (genogroups I, II, IV, V) RNA Human Astrovirus (hAstro) RNA		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Nasopharyngeal (Throat/nasal) swabs	Molecular testing (cont'd) Respiratory panel: Influenza A RNA Influenza A, subtype H1N1/2009 RNA Influenza A subtype H1 RNA Influenza A subtype H3 RNA Influenza B RNA Coronavirus 229E RNA Coronavirus HKU1 RNA Coronavirus NL63 RNA Coronavirus OC43 RNA Parainfluenza Virus 1 RNA Parainfluenza Virus 2 RNA Parainfluenza Virus 3 RNA Parainfluenza Virus 4 RNA RSV A/B RNA Human Metapneumovirus A/B RNA Adenovirus DNA Rhinovirus/Enterovirus RNA Mycoplasma pneumoniae DNA Legionella pneumophila DNA Bordetella pertussis DNA Chlamydia pneumoniae	Qiagen Qiasat DX analyser; RT-PCR SOP 320-765	
Female endocervical, low vaginal, Throat, Rectal swabs and urine specimens	Chlamydia trachomatis Neisseria gonorrhoeae	Hologic Panther Automated PCR analyser, real time PCR SOP 320 774	
Vaginal, labial, vulval, penile, skin swabs	HSV 1 and 2		
Female endocervical, low vaginal swabs and urine specimens	Mycoplasma genitalium		
Female low vaginal, swabs and urine specimens	Trichomonas vaginalis		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Serum	<u>Serology/Virology</u> *HIV 1 / 2 Antibody/Antigen detection *Hepatitis B surface antigen *Syphilis / T pallidum IgM / IgG antibody Rubella IgG antibody Hepatitis C antibody Hepatitis core antibody Hepatitis B surface antibody	Siemens Centaur XPT– Random access immunoassay analyser SOP 320-746, SOP 820-350 *Including documented -in-house methods to meet the requirements of the IDPS screening programme as defined in the July 2018 version of 'Infectious diseases in pregnancy screening: laboratory QA evidence requirements' (18 July upload) for antenatal screening Diasorin Liason XL Automated Chemiluminescence analyser SOP 320- 760	
Faeces	Calprotectin Helicobacter pylori antigen		
Serum	Chlamydia trachomatis IgG VZV IgG Measles IgG Parvovirus IgG and IgM EBV serology Hepatitis A total antibody Hepatitis A IgM Toxoplasma IgG and IgM Borrelia IgG and IgM CMV IgG and IgM Bordetella pertussis IgG SARS-CoV-2 antibody HBcT2		
Faeces	Detection of Clostridioides difficile GDH Antigen		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant	CRH
Plasma (lithium heparin)	Serology/Virology (cont'd) Detection of interferon-gamma following stimulation of T – cells in-vitro, as an indicator of Tuberculosis specific antigen cell mediated response	Quantiferon TB Gold Plus	
Faeces	Rotavirus antigen	PRO-LAB Proflow rapid membrane immunoassay. SOP 320-747	
	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	CRH
Bronchoscopy samples Cerebrospinal fluid samples Fine needle aspirates Serous fluids Sputum samples Urine samples	<u>Cytopathology</u> Papanicolaou (PAP) staining for nuclear and cytoplasmic detail Reading and interpretation of slides from processed tissues and fluids	Centrifuge Cytospin Microscope SOP 020 091 Non-gynae specimen process Staining: Automated - Sakura Tissue-Tek Prisma staining machine and coverslipper: SOP 020-088 Interpretive Microscopy: SOP 020 091 Non-gynae specimen process SOP 020 091 Non-gynae specimen process SOP LI 020 706 Breast Seroma fluid SOP 020-713 Thyroid cancers SOP 020-680 Bronchial and lung cancers SOP 020-677 Kidney tumours SOP 020-678 Bladder tumours SOP 020-519 Lymphnodes	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p><u>Histopathology</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Specimen dissection: SOP 020-300 Cut up SOP 020-683 Biomedical Scientist Cut up SOP 020-699 Higher specialist Advanced practitioner and expert practitioner cut up SOP 020-603 Foetus, placenta and POC handling SOP 020-714 Gynaecological dissection SOP 020-715 Head and neck dissection SOP 020-800 Osteoarticular and soft tissue dissection SOP 020-804 Placenta dissection SOP 020-805 Haemaopoetic dissection SOP 020-803 Endocrine dissection SOP 020-801 Genitourinary dissection</p> <p>Tissue processing: Leica ASP 6025 tissue processors for fatty tissue and routine histology tissue. Thermo Scientific Excelsior tissue processor for diagnostic biopsies and cell blocks. Histocore Arcadia embedders. SOP 020-702.Tissue processing</p> <p>Embedding: SOP 020-600 Embedding</p> <p>Decalcification: SOP 020-604 Decalcification</p> <p>Microtomy: Leica RM 2245 microtome x2 Leica RM 2235 microtome x4 SOP 020-070 Microtomy</p>	CRH



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	CRH
Tissue samples (cont'd)	<u>Histopathology</u> (cont'd) H&E staining for tissue architecture and nuclear detail Papanicolaou (PAP) staining for nuclear and cytoplasmic detail	Frozen sections for urgent diagnostic histopathology : Thermo Scientific Cryotome FSE SOP 020-115 Frozen sections Haematoxylin and Eosin staining Papanicolaou (PAP) staining: Sakura Tissue-Tek Prisma staining machine and coverslipper: SOP 020-088 stainer/coverslipper for automated H&E and PAP staining SOP 020-115 Rapid H&E on frozen sections only	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	CRH
Tissue samples (cont'd)	<u>Histopathology</u> (cont'd)		
	Special staining for the identification of:	Special staining: Manual methods according to UKNEQAS CPT best methods and Bancroft, J.D. & Gamble, M. (2003) Theory and practice of histological techniques, 5th edition, Edinburgh. Churchill Livingstone. SOP 020-537 Special stains	
	Mucins	Alcian blue AB/PAS	
	Carbohydrates	Diastase- PAS	
	Elastic fibres	Elastic Van Gieson	
	Helicobacter	Giemsa	
	Gram +ve and -ve organisms	Gram-Twort	
	Fungi	Grocott	
	Basement membranes	Hexamine Silver	
	Amyloid	Highmans Congo Red	
	Collagen	HVG	
	Connective tissues	M.S.B. for connective tissues	
	Melanin	Masson Fontana	
	Connective tissues	Masson Trichrome	
	to remove melanin pigment	Melanin Bleach	
	Mast cells	Methylene blue	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	CRH
Tissue samples (cont'd)	<u>Histopathology</u> (cont'd) Special staining for the identification of (cont'd):	Special staining: Manual methods according to UKNEQAS CPT best methods and Bancroft, J.D. & Gamble, M. (2003) Theory and practice of histological techniques, 5th edition, Edinburgh. Churchill Livingstone. SOP 020-537 Special stains	
	Mucins, fungi and carbohydrates	P.A.S.	
	Ferric iron	Perl's Prussian Blue	
	Reticulin fibres	Gordon and Sweets Reticulin	
	Mineralised bone and calcium deposits	Von Kossa	
	TB bacilli	Z N	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	CRH
Tissue samples and cell blocks	<u>Histopathology</u> (cont'd)		
	Immunocytochemistry for the identification of:	Immunocytochemistry: Roche Ventana Benchmark Ultra-automated method SOP 020-116 immunohistochemistry	
		Using antibodies to:	
	Cytokeratins in epithelial cells	34BE12	
	Cytokeratins in epithelial cells	AE1/3	
	Protein present in lymphocytes	BCL-2	
	Antigen in epithelium	BEREP4	
	Antigen in fallopian tube epithelium	CA125	
	Antigen present in colon cancer	CA19.9	
	Protein in mesothelial cells	CALRETININ	
	Cytokeratins in epithelial cells	CAM 5.2	
	Antigen on T lymphocytes	CD3	
	Antigen on some lymphoid cells	CD10	
	Antigen on B lymphocytes	CD20	
	Reed-Sternberg cells	CD30	
	Endothelial cells	CD31	
	High grade CIN	P16	
	Endothelial cells	CD34	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples and cell blocks (cont'd)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p><u>Histopathology</u> (cont'd)</p> <p>Immunocytochemistry for the identification of (cont'd):</p> <p>Nerve and neuroendocrine cells</p> <p>Macrophages and mononuclear cells</p> <p>Antigen in intestinal epithelium</p> <p>Protein in gastro-intestinal cells</p> <p>Granules in neuroendocrine cells</p> <p>Cytokeratin in epithelium</p> <p>Cytokeratin in specific epithelium</p> <p>Cytokeratin in gastro-intestinal cells</p> <p>Smooth and striated muscle cells</p> <p>Protein in epithelial cells</p> <p>Protein in epithelial cells</p> <p>Nuclear receptor</p>	<p>Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunocytochemistry: Roche Ventana Benchmark Ultra-automated method SOP 020-116 immunohistochemistry</p> <p>Using antibodies to:</p> <p>CD56</p> <p>CD68</p> <p>CDX2</p> <p>CEA</p> <p>CHROMOGRANIN</p> <p>CK 5/6</p> <p>CK7</p> <p>CK20</p> <p>DESMIN</p> <p>E-CADHERIN</p> <p>EMA</p> <p>ER</p>	CRH



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples and cell blocks (cont'd)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p><u>Histopathology</u> (cont'd)</p> <p>Immunocytochemistry for the identification of (cont'd):</p> <p>Urothelial carcinoma in prostate and bladder lesions; breast carcinomas of epithelial origin</p> <p>Glycoprotein in specific epithelium</p> <p>Activated/neoplastic melanocytes</p> <p>Helicobacter pylori bacterium</p> <p>Hormone in testicular cells</p> <p>Nuclear protein in proliferating cells</p> <p>Lymphocytes</p> <p>Cytokeratin in epithelial cells</p> <p>Presence or absence of a mutant copy of the p53 gene</p> <p>Nuclear protein in epithelial cells</p> <p>Antigen in melanocytes</p> <p>Enzyme produced by trophoblasts</p> <p>Nuclear receptor</p>	<p>Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunocytochemistry: Roche Ventana Benchmark Ultra-automated method SOP 020-116 immunohistochemistry</p> <p>Using antibodies to:</p> <p>GATA3</p> <p>GCDFP</p> <p>HMB45</p> <p>H PYLORI</p> <p>INHIBIN</p> <p>KI67 (MIB 1)</p> <p>LCA (CD45)</p> <p>MNF116</p> <p>P53</p> <p>P63</p> <p>PANMEL</p> <p>PLAP</p> <p>PR</p>	CRH



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples and cell blocks (cont'd)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p><u>Histopathology</u> (cont'd)</p> <p>Immunocytochemistry for the identification of (cont'd):</p> <p>Protein in prostatic epithelium</p> <p>Protein in nerve cells</p> <p>Smooth muscle cells</p> <p>Smooth muscle cells</p> <p>Cells within the muscularis propria</p> <p>Granules in neuroendocrine cells</p> <p>Nuclear protein in lung and thyroid</p> <p>Filament in mesenchymal cells</p> <p>Protein in specific tissues</p> <p>Oncoprotein in breast cancer</p> <p>MMR Proteins</p> <p>CMV</p>	<p>Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunocytochemistry: Roche Ventana Benchmark Ultra-automated method SOP 020-116 immunohistochemistry</p> <p>Using antibodies to:</p> <p>PSA</p> <p>S100</p> <p>SMA</p> <p>SMM</p> <p>SMOOTHIELIN</p> <p>SYNAPTOPHYSIN</p> <p>TTF-1</p> <p>VIMENTIN</p> <p>WT1</p> <p>SOP 020-079 Her 2 testing Using antibodies to: HER2</p> <p>MLH-1 MSH-2 MSH6 PMS2</p> <p>CMV</p>	CRH



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Tissue samples and cell blocks (cont'd) Tissue samples	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u> <u>Histopathology (cont'd)</u> Reading and interpretation of slides from processed tissues and fluids	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: Interpretive Microscopy: SOP 020-501 Breast palpable lesion SOP 020-502 Breast impalpable lesion SOP LI 020 706 Breast Seroma fluid SOP 020-504 Breast cores SOP 020-703 Colorectal cancers SOP 020-703 Colorectal polyp and dysplasia SOP 020-677 kidney tumours SOP 020-678 Bladder tumours SOP 020-679 Prostate tumours SOP 020-512 Testicular tumours SOP 020-705 Routine hysterectomy SOP 020-603 Foetus, placenta and POC handling SOP 020-714 Gynaecological dissection SOP 020-715 Head and neck dissection SOP 020-800 Osteoarticular and soft tissue dissection SOP 020-804 Placenta dissection SOP 020-805 Haemaopoetic dissection SOP 020-803 Endocrine dissection SOP 020-801 Genitourinary dissection SOP 020-698 Hysterectomy for endometrial cancer SOP 020-515 Hysterectomy for smooth muscle tumours SOP 020-674 Cervical biopsies SOP 020-706 Ovarian tumours SOP 020-680 Bronchial and lung biopsies for cancer SOP 020-519 Lymphnodes SOP 020-520 Malignant melanomas SOP 020-711 ER and PR scoring SOP 020-681 Skin tumours SOP 020-713 Thyroid cancers SOP 020-802 Hepatitis C liver biopsies	CRH



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination:	CRH
Tissue samples (cont'd)	<u>Histopathology (cont'd)</u> Reading and interpretation of slides from processed tissues and fluids (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant: Interpretive Microscopy: SOP 020-670 Bowel cancer screening specimens SOP 020-079 Her 2 testing SOP 020 115 Reporting of frozen sections SOP 020-067 Sentinel lymph nodes	
HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>		CRH
Semen	<u>Post vasectomy:</u> Detection of motile/non-motile sperm	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 020-809 Post vasectomy specimens	



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HUMAN BODY FLUIDS (cont'd)	<u>Andrological examination activities for the purposes of clinical diagnosis</u> (cont'd)		CRH
Semen (cont'd)	<u>Fertility testing:</u>	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedure SOP 020-810 Infertility tests	
	Volume	Volume/weight	
	pH	Colorimetric strips	
	Sperm morphology including TZI scoring and Round Cell Count	Stained slides (Papanicolau) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	
	Sperm vitality	Stained slide (Eosin dye exclusion test) microscopy (Bright field)	
END			