


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8992 Accredited to ISO 15189:2012	Calderdale and Huddersfield NHS Foundation Trust	
	Issue No: 010 Issue date: 10 May 2022	
	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	
Serum	Angiotensin Converting Enzyme	Siemens Advia XPT(HRI) Siemens Advia 1800 (CRH) Using suppliers methods unless otherwise stated and SOPs: 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)	Total Bilirubin	Vanadate oxidation LI 820-260	HRI, CRH
Serum, plasma (Li Hep), Urine	Calcium	Arsenazo LI 820-260	HRI, 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 (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	Chloride	Indirect ISE LI 820-260	HRI, CRH
Serum, plasma (Li Hep)	Creatine Kinase	IFCC Reference method at 37CL 820-260	HR, CRH
Serum, plasma (Li Hep)	Conjugated 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



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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)	Lipase	Colorimetric SOP 820-260	HRI
Serum, plasma (Li Hep), urine	Magnesium	Colorimetric xylydyl blue LI 820-260	HRI, CRH
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 Immunoturbidimetic LI 820-260	HRI
Urine, CSF	Protein	Pyrogallol red endpoint 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)	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
Serum, plasma (Li Hep)	Valproic acid	EMIT LI 820-260	HRI
Serum, plasma (Li Hep)	Lithium	Colorimetric endpoint 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



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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	C4	Siemens Advia XPT(HRI) Siemens Advia 1800 (CRH) Using suppliers methods unless otherwise stated and SOPs: Immunoturbidimetric LI 820-260	HRI
Serum	Haptoglobin	Immunoturbidimetric LI 820-260	HRI
Serum, plasma (Li Hep)	Transferrin	Immunoturbidimetric LI 820-260	HRI
Serum	eGFR AKI LDL-cholesterol Total cholesterol/HDL ratio Globulin Corrected calcium	Siemens Advia XPT: Calculations from the results of the methods above:	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 Advia Centaur XPT immunoassay via Chemiluminescence, using suppliers methods unless otherwise stated	
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 Advia Centaur XPT immunoassay via Chemiluminescence, using suppliers methods unless otherwise stated (cont'd)	
Serum	Free tri-iodothyronine (FT3)	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 (cont'd)	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



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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	
Urine	Detection of bence jones protein (kappa and lambda free light chains with densitometric quantitation)	Sebia Hydrasys, agarose gel electrophoresis (cont'd) Urine protein electrophoresis SOP 810 503	HRI
Serum	Isotyping of monoclonal proteins (IgG, IgA, IgM, kappa, lambda)	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 3320 and 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	Systemex XN-9000, spectrophotometry, aperture impedance, flow cytometry and scattergram interpretation SOP 620-768, SOP 620-767	
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)		HRI, CRH
EDTA whole blood	Erythrocyte sedimentation rate	Starrsed Auto-Compact, infra-red absorption readings of red cell sedimentation SOP 620-769	HRI, 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 & Gel whole blood	Haemoglobin variants screen	Primus Ultra2 HPLC analyser, ion exchange chromatography and high performance liquid chromatography SOP 620 243	HRI
EDTA whole blood	G6PD	Vilber-Lourmat UV light box, UV fluorescence SOP 620 603	HRI



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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 Plasma		Sysmex CS-2500 analyser, optical density detection	
	APTT	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> (cont'd)	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 Rapid determination of ABO & RhD blood group, Tube agglutination SOP 720 015	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 <ul style="list-style-type: none"> • 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 Source Bioscience Kit (Kleihauer) SOP 720-048	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><u>General Microbiology</u></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>	<p>CRH</p>



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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 (cont'd)	CRH
Pre-Inoculated culture plates –GUM clinic	General Microbiology (cont'd) Isolation and identification of Neisseria gonorrhoeae	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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<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 (cont'd)</u></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 (cont'd)</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>	<p>CRH</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>General Microbiology (cont'd)</p> <p>Identification of microorganisms of clinical significance and Antibiotic susceptibility testing of isolated bacterial pathogens</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant (cont'd)</p> <p>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</p>	CRH
Cultures isolated in-house from all samples listed above	<p>Antibiotic susceptibility testing</p> <p>Colistin susceptibility testing</p>	<p>Manual and/or automated antimicrobial susceptibility testing using EUCAST methodology. Disc diffusion & gradient MIC determination SOP 320-076</p> <p>ComASP Colistin Broth microdilution method LI 320-1187</p>	
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	



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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 (cont'd)	CRH
	<u>General Microbiology</u> (cont'd)		
Genital swabs	Detection of Trichomonas Vaginalis	Broth culture and light microscopy SOP 320-106	CRH
Genital swabs	Detection of Bacterial Vaginosis	Gram stain and light microscopy SOP 320-106	
Faeces	Identification of faecal ova, cysts and parasites	Concentration method using centrifugation and light microscopy of concentrate SOP 320-101	
Faeces	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 Quik 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	
Urine	Pregnancy testing (HCG detection)	Manual immunochromatographic assay using Surestep One step Pregnancy test SOP 320-005	



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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 (cont'd)	CRH
Lower respiratory tract samples, swabs, tissue, urine	General Microbiology (cont'd) Isolation/identification of Mycobacteria species	Auramine fluorescent staining, microscopy Becton Dickinson MGIT Fluorometric growth detection. SOP 320-003	
Endocervical swabs, male urethral swabs, female and male urine specimens. Lesion and throat swabs	Molecular testing DNA detection: Chlamydia, Neisseria gonorrhoeae and Herpes simplex	Becton Dickinson VIPER Strand Displacement Amplification (SDA) SOP 320-514	
Urine, self-taken vaginal swabs, cervical swabs	DNA detection: Trichomonas vaginalis		
Male urethral swabs, urine and throat swabs	Detection of: Neisseria gonorrhoeae DNA Influenza A + B RNA Clostridioides difficile toxin DNA RSV RNA	Becton Dickinson BD MAX system. Automated extraction, purification and amplification of DNA/RNA SOP 320-757	
Throat/nasal swabs			
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)	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Molecular testing</u></p> <p>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</p> <p><u>Mycology</u></p> <p>Isolation and identification of fungi of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant (cont'd)</p> <p>Qiagen Qiasat DX analyser; RT-PCR SOP 320-765</p>	CRH
Throat/nasal swabs			
Skin scarping Hair cuttings Nail clippings		<p>Culture, macroscopic examination and fluorescent microscopy SOP 320-010</p>	



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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 (cont'd)	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	
Serum	Procalcitonin	Biomerieux Vidas immunoassay analyser SOP 320-150 SOP 320-727 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		



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Faeces</p> <p>Plasma (lithium heparin)</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Serology/Virology</u> (cont'd)</p> <p>Detection of Clostridioides difficile GDH Antigen & Toxins A&B</p> <p>Detection of interferon-gamma following stimulation of T – cells in-vitro, as an indicator of Tuberculosis specific antigen cell mediated response</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant (cont'd)</p> <p>Quantiferon TB Gold Plus</p>	<p>CRH</p>



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<p>Bronchoscopy samples Cerebrospinal fluid samples Fine needle aspirates Serous fluids Sputum samples Urine samples</p> <p>Bronchoscopy samples Cerebrospinal fluid samples Fine needle aspirates Serous fluids Sputum samples Urine samples (cont'd)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u></p> <p><u>Cytopathology</u></p> <p>Papanicolaou (PAP) staining for nuclear and cytoplasmic detail</p> <p>Reading and interpretation of slides from processed tissues and fluids</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Centrifuge Cytospin Microscope 020 091 Non-gynae specimen process</p> <p>Staining: Automated - Sakura Tissue-Tek Prisma staining machine and coverslipper: SOP 420 008</p> <p>Interpretive Microscopy: SOP 020 091 Non-gynae specimen process SOP 020 091 Non-gynae specimen process SOP 420 503 Breast FNA SOP 420 524 Thyroid cancers SOP 420 518 Bronchial and lung cancers SOP 420 509 Kidney tumours SOP 420 510 Bladder tumours SOP 420 519 Lymphnodes</p>	<p>CRH</p>



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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 (cont'd)</u></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 420 003 Cut up SOP 420 019 Biomedical Scientist Cut up SOP 420 069 Advanced practitioner cut up</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. Leica EG 1150 tissue embedder. SOP 420 005 Tissue processing</p> <p>Embedding: SOP 420 006 Embedding</p> <p>Decalcification: SOP 420 004 Decalcification</p> <p>Microtomy: Leica RM 2245 microtome x2 Leica RM 2235 microtome x3 Thermo Scientific Finesse E+ microtome SOP 420 007 Microtomy</p> <p>Frozen sections for urgent diagnostic histopathology : Thermo Scientific Cryotome FSE SOP 420 015 Frozen sections</p>	<p>CRH</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples (cont'd)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology (cont'd)</u></p> <p>H&E staining for tissue architecture and nuclear detail</p> <p>Papanicolaou (PAP) staining for nuclear and cytoplasmic detail</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Haematoxylin and Eosin staining Papanicolaou (PAP) staining; Sakura Tissue-Tek Prisma staining machine and coverslipper: SOP 420 008 stainer/coverslipper for automated H&E and PAP staining</p> <p>SOP 420 015 Rapid H&E on frozen sections only</p>	<p>CRH</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Tissue samples (cont'd)	<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>Special staining for the identification of:</p> <p>Mucins</p> <p>Carbohydrates</p> <p>Elastic fibres</p> <p>Helicobacter</p> <p>Gram +ve and –ve organisms</p> <p>Fungi</p> <p>Basement membranes</p> <p>Amyloid</p> <p>Collagen</p> <p>Lipofuchsin</p> <p>Connective tissues</p> <p>Melanin</p> <p>Connective tissues</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>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 420 009 Special stains</p> <p>Alcian blue AB/PAS</p> <p>Diastase- PAS</p> <p>Elastic Van Gieson</p> <p>Giemsa</p> <p>Gram-Twort</p> <p>Grocott</p> <p>Hexamine Silver</p> <p>Highmans Congo Red</p> <p>HVG</p> <p>Long ZN</p> <p>M.S.B. for connective tissues</p> <p>Masson Fontana</p> <p>Masson Trichrome</p>	CRH



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Tissue samples (cont'd)	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Special staining for the identification of (cont'd):</p> <p>to remove melanin pigment</p> <p>Mast cells</p> <p>Hepatitis B</p> <p>Mucins, fungi and carbohydrates</p> <p>Ferric iron</p> <p>Reticulin fibres</p> <p>Mineralised bone and calcium deposits</p> <p>Leprosy bacilli</p> <p>TB bacilli</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Melanin Bleach</p> <p>Methylene blue</p> <p>Shikata Orcein</p> <p>P.A.S.</p> <p>Perl's Prussian Blue</p> <p>Gordon and Sweets Reticulin</p> <p>Von Kossa</p> <p>Wade + Fite</p> <p>Z N</p>	CRH



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Tissue samples and cell blocks	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Immunochemistry for the identification of:</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunochemistry: Roche Ventana Benchmark Ultra-automated method SOP 420 016 immunohistochemistry</p> <p>Using antibodies to:</p>	CRH
	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	



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Tissue samples and cell blocks (cont'd)	<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>Immunochemistry for the identification of (cont'd):</p> <p>Endothelial cells</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:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Using antibodies to:</p> <p>CD34</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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HUMAN BODY TISSUE AND FLUIDS (cont'd) Tissue samples and cell blocks (cont'd)	<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>Immunochemistry 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:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</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>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Using antibodies to:</p> <p>PSA</p> <p>S100</p> <p>SMA</p> <p>SMM</p> <p>SMOOTHELIN</p> <p>SYNAPTOPHYSIN</p> <p>TTF-1</p> <p>VIMENTIN</p> <p>WT1</p> <p>SOP 420 079 Her 2 testing Using antibodies to: HER2</p>	<p>CRH</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples and cell blocks (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 (cont'd)</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Reading and interpretation of slides from processed tissues and fluids</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Interpretive Microscopy: SOP 420 501 Breast palpable lesion SOP 420 502 Breast impalpable lesion SOP 420 503 Breast FNA SOP 420 504 Breast cores SOP 420 505 Colorectal cancers SOP 420 506 Colorectal poly and dysplasia SOP 420 507 Gastrectomy for stomach tumours SOP 420 508 Oesophagectomy for oesophageal tumours SOP 420 509 kidney tumours SOP 420 510 Bladder tumours SOP 420 511 Prostate tumours SOP 420 512 Testicular tumours SOP 420 513 Routine hysterectomy</p>	<p>CRH</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples (cont'd)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Reading and interpretation of slides from processed tissues and fluids (cont'd)</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Interpretive Microscopy: SOP 420 514 Hysterectomy for endometrial cancer SOP 420 515 Hysterectomy for smooth muscle tumours SOP 420 516 Cervical biopsies SOP 420 517 Ovarian tumours SOP 420 518 Bronchial and lung biopsies for cancer SOP 420 519 Lymphnodes SOP 420 520 Malignant melanomas SOP 420 521 ER and PR scoring SOP 420 522 Skin tumours SOP 420 524 Thyroid cancers SOP 420 525 Hepatitis C liver biopsies SOP 420 531 Bowel cancer screening specimens SOP 420 079 Her 2 testing SOP 420 523 Reporting of frozen sections</p>	<p>CRH</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Semen</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Andrology</u></p> <p>Post vasectomy analysis for presence (motile/non-motile) or absence of spermatazoa</p> <p>Infertility testing for the following properties:</p> <p>pH Spermatozoa Concentration Spermatozoa Motility Spermatozoa Viability Spermatozoa Morphology Round cell count</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Light microscopy Manual method according to WHO (2010) guidelines 5th Edition and British Andrology Society guidelines for the assessment of post vasectomy semen samples (2002)</p> <p>Light microscopy using counting chamber Manual method according to WHO (2010) guidelines 5th Edition SOP 520 012 Infertility tests</p>	<p>CRH</p>
END			