


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8111</p> <p>Accredited to ISO 15189:2022</p>	<p>Northern Health & Social Care Trust</p> <p>Issue No: 010 Issue date: 12 August 2025</p>	
	<p>Antrim Laboratories Antrim Hospital 45 Bush Road Antrim BT41 2RL United Kingdom</p>	<p>Contact: Amanda Holmes Tel: +44 (0) 2894424103 Fax: +44 (0) 2894424981 E-Mail: Amanda.Holmes@northerntrust.hscni.net</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Antrim Laboratories Antrim Hospital 45 Bush Road Antrim BT41 2RL</p> <p style="text-align: right;">Local contact Amanda Holmes</p>	<p>Medical Microbiology Biochemistry Haematology Coagulation Blood Transfusion Cellular & Molecular Pathology FNA Clinic and Mortuary (body storage and release only)</p>	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Causeway Hospital Causeway Hospital 2 Newbridge Rd Coleraine BT52 1TP</p> <p style="text-align: right;">Local contact Amanda Holmes</p>	<p>Medical Microbiology: Plate inoculation and microscopy Biochemistry Bowel Screening Haematology Coagulation Blood Transfusion FNA Clinic</p>	B



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Site activities performed away from the locations listed above:

Location details	Activity
Whiteabbey Hospital Doagh Road Newtownabbey Belfast BT37 9RH	Blood fridge under the management responsibility of laboratory but no testing occurs at this site
Mid Ulster Hospital Hospital Road Magherafelt BT45 5EX	Blood fridge under the management responsibility of laboratory but no testing occurs at this site



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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
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Routine samples:</p> <p>Aspirates Cellular and fluid material contained on swabs Intra-uterine contraceptive devices Fluids Genital samples Pus Samples from sterile sites Tissues</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p><u>Microbiology</u></p> <p>Isolation of microorganisms of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Using manual inoculation and culture</p> <p>MIC-SWA-SOP-002 MIC-SWA-SOP-003 MIC-SWA-SOP-004 MIC-SWA-SOP-005</p> <p>MIC-SWA-SOP-009 MIC-SWA-SOP-010 MIC-SWA-SOP-015</p> <p>MIC-SWA-SOP-021 MIC-SWA-SOP-022</p> <p>MIC-SWA-SOP-030</p> <p>MIC-SWA-SOP-037 MIC-SWA-SOP-038 MIC-SWA-SOP-039 MIC-SWA-SOP-060</p>	A
<p>Urine</p>	<p>Isolation of microorganisms of clinical significance</p>	<p>Using manual inoculation and culture</p> <p>MIC-URI-SOP-001</p>	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
Faeces	Isolation of microorganisms of clinical significance	MIC-ENT-SOP-001 MIC-ENT-SOP-002	A
Faeces	<u>Detection of:</u> Salmonella sp Shigella sp E. coli VTEC (including E. coli 0157) Campylobacter sp Cryptosporidium sp Giardia lamblia	EntericBio Real Time PCR System: using EntericBio Gastropanel 2 and in-house procedure MIC-ENT-SOP-019	A
Sputum Bronchial Washings	Isolation of microorganisms of clinical significance	MIC-CT3-SOP-001 MIC-CT3-SOP-010	A
Cellular and fluid material contained on nasal and axilla/ groin swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual inoculation and incubation on chromogenic culture media as above and using: MIC-SWA-SOP-013	A
Sterile site samples: Fluid Cerebrospinal fluid (CSF) Catheter tips	Isolation of microorganisms of clinical significance	Manual inoculation & incubation using: MIC-SPE-SOP-002 MIC-SPE-SOP-004 MIC-SPE-SOP-005 MIC-SPE-SOP-008 MIC-SPE-SOP-012	A
Blood	Isolation of microorganisms of clinical significance	Liquid media culture using colourimetric detection by BactAlert Virtuo and using in-house procedures: MIC-SPE-SOP-009 MIC-SPE-SOP 003	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
CSF	Detection, identification, and quantification (inc. differential) of white blood cells	Microscopy & staining (Gram and differential) using: MIC-SPE-SOP-002 MIC-SPE-SOP-005	A
CSF	Detection, identification, and quantification (inc. differential) of red blood cells	MIC-SPE-SOP-002 MIC-SPE-SOP-005	
Bacterial and yeast cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual methods using: observed growth characteristics on solid agar; manual biochemical methods; latex agglutination; disc diffusion; manual staining methods MIC-IDN-SOP-002 MIC-LAB-DOC-003 MIC-IDN-SOP-021 MIC-IDN-SOP-022 MIC-IDN-SOP-028	A
		Automated methods using: by colorimetric measurement using bioMerieux Vitek 2 MIC-EQP-SOP-026	A
		Matrix-assisted laser desorption/ionisation using bioMerieux Maldi-Tof MIC-EQP-SOP-044	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual and/or automated antimicrobial susceptibility testing using the latest using EUCAST guidelines and: Colorimetric measurement by bioMerieux Vitek 2 MIC-EQP-SOP-026	A
		Disc diffusion MIC-SEN-SOP-005	A
		Gradient minimum inhibitory concentration determination MIC-SEN-SOP-002	A
Nasal and axilla/ groin swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	NG Kit Cepheid GeneXpert MIC-MOL-SOP-002	A
Blood, Sputum, Pus, Tissue, Urine, Bronchial washings, Swabs	Mycobacterial species of clinical significance	Using fluorimetric detection using liquid culture and BD MGIT 960 MIC-CT3-SOP-002	A
		Fluorescent microscopy using Auramine-phenol stain MIC-IDN-SOP-020	A
		Light microscopy using Ziehl-Neelsen stain MIC-IDN-SOP-025	A
Liquid Culture media	Mycobacterium tuberculosis	BD MGIT TBc Identification Test (TBc ID) rapid lateral flow MIC-CT3-SOP-009	A
Air dried vaginal discharge smears	Bacterial vaginosis	Microscopic Examination of air-dried vaginal smears MIC-SWA-SOP-033	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
Endocervical, rectal, throat and vaginal swabs, urine	<i>Chlamydia trachomatis</i> DNA/ <i>Neisseria gonorrhoeae</i> DNA	MIC-MOL-SOP-001 polymerase chain reaction using Roche Cobas 6800	A
Vaginal swab, urine	Detection of <i>Mycoplasma genitalium</i> and <i>Trichomonas vaginalis</i>	MIC-MOL-SOP-017 PCR using Cobas TV/MG- Qualitative nucleic acid test for Cobas 6800	A
Vaginal swab, urine	Identification of <i>Mycoplasma genitalium</i> and associated azithromycin resistance mutations	MIC-MOL-SOP-018 Real time PCR using SpeedX- ResistancePlus MG GeneXpert	A
Urine	Detection, identification and quantification of Red blood cells White blood cells Bacterial cells Squamous epithelial cells	Manual microscopic examination using : MIC-URI-SOP-001 Automated microscopic examination using UF5000i MIC-URI-SOP-002	A
Faeces	<i>C.difficile</i> GDH and Toxins A&B	Lateral flow enzyme immunoassay using: C. DIFF QUIK CHEK COMPLETE MIC-ENT-SOP-016	A
Faeces	Detection of <i>Clostridiodes difficile</i> toxin B (cdtB)	EntericBio Real Time PCR System using in-house procedure: MIC-ENT-SOP-020	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
Urethral, cervical & vaginal smears	Detection of bacteria of clinical significance for purposes of sexual health screen	Gram stain and light microscopy MIC-SWA-SOP-035	B
Urine	Detection of Legionella pneumophila antigen	Immunochromatographic membrane assay, quantitative Serogroup 1 using Alere BinaxNOW MIC-SER-SOP-005	A
Urine	Detection of Streptococcal pneumoniae antigen	Immunochromatographic membrane assay using Alere BinaxNOW MIC-SER-SOP-006	A



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
Serum/Plasma	Quantitative determination of: Sodium, Potassium, Chloride	Roche Cobas ISE Module (ion selective electrodes) With reference to: BIO-AUT-SOP- 157 BIO-AUT-SOP-158 BIO-AUT-SOP-159	A, B
Urine	Sodium, Potassium, Chloride	BIO-AUT-SOP-157 BIO-AUT-SOP-158 BIO-AUT-SOP-159 Roche Cobas 8000 analyser (multi assay photometry) with reference to:	
Serum/Plasma	Alanine Transaminase	BIO-AUT-SOP-113	
Serum/Plasma	Albumin	BIO-AUT-SOP-111	
Urine	Albumin Creatinine Ratio	Calculated Result BIO-AUT-SOP-212 BIO-AUT-SOP-213	
Serum/Plasma	Alkaline Phosphatase	BIO-AUT-SOP-112	
Plasma	Ammonia	BIO-AUT-SOP-140	
Serum/plasma	Amikacin	BIO-AUTO-SOP-436	
Serum/Plasma and Urine	Amylase	BIO-AUT-SOP-114	
Serum/Plasma	Aspartate Transaminase	BIO-AUT-SOP-115	
Serum/Plasma	Bilirubin Direct	BIO-AUT-SOP-125	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Roche Cobas 8000 analyser (multi assay photometry) with reference to:	A, B
Serum/Plasma	Bilirubin Total	BIO-AUT-SOP-128	
Serum/Plasma	C Reactive Protein	BIO-AUT-SOP-124	
Serum,/plasma & Urine	Calcium	BIO-AUT-SOP-116	
Serum/Plasma	Calcium Adjusted	Calculated Result BIO-AUT-SOP-II6 BIO-AUT-SOP-111 BIO-QUA-PRO-010	
Urine	Calcium Creatinine Clearance Ratio	Calculated Result BIO-AUT-SOP-111 BIO-AUT-SOP-116 BIO-AUT-SOP-123 BIO-AUT-SOP-213	
Urine	Calcium Creatinine Ratio	Calculated Result BIO-AUT-SOP-111 BIO-AUT-SOP-116	
Serum/Plasma	Bicarbonate(CO2)	BIO-AUT-SOP-118	
Serum/Plasma	Cholesterol	BIO-AUT-SOP-117	
Serum/Plasma	Cholesterol HDL Ratio	Calculated result BIO-AUT-SOP-117 BIO-AUT SOP-122	
Serum/Plasma	Complement C3	BIO-AUT-SOP-154	A
Serum/Plasma	Complement C4	BIO-AUT-SOP-155	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Roche Cobas 8000 analyser (multi assay photometry) with reference to:	
Serum/Plasma	Cortisol	BIO-AUT-SOP-320	A
Serum/Plasma and urine	Creatinine	BIO-AUT-SOP-123 BIO-AUT-SOP-213	A, B
Serum/Plasma and urine	Creatinine Clearance	Calculated Result BIO-AUT-SOP-123 BIO-AUT-SOP-213	
Serum/Plasma	Creatinine Kinase	BIO-AUT-SOP-119	
Serum/Plasma	Digoxin	BIO-AUT-SOP-308	
Serum/Plasma	Ethanol	BIO-AUT-SOP-201	
Serum/Plasma	Estimated Glomerular Filtration Rate	Calculated Result BIO-AUT-SOP-123 BIO-AUT-SOP-432	
Serum/Plasma	Ferritin	BIO-AUT-SOP-307	
Serum/Plasma	Folic Acid	BIO-AUT-SOP-305	
Serum/Plasma	Follicle Stimulating Hormone	BIO-AUT-SOP-316	A
Serum/Plasma	Free Thyroxine	BIO-AUT-SOP-302	A, B
Serum/Plasma	Free Tri-iodothyronine	BIO-AUT-SOP-311	A
Serum/Plasma	Gamma Glutamyl Transpeptidase	BIO-AUT-SOP-126	A, B
Serum/Plasma	Gentamicin	BIO-AUT-SOP-235	
Serum	Globulin	Calculated Result BIO-AUT-SOP-111 BIO AUT-SOP-133	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Roche Cobas 8000 analyser (multi assay photometry) with reference to:	
Serum/Plasma	Glucose	BIO-AUT-SOP-127	A, B
Serum/Plasma	High Density Lipoprotein	Calculated Result BIO-AUT-SOP-122	A, B
Serum/Plasma	Human Chorionic Gonadotrophin	BIO-AUT-SOP-318	A
Serum/Plasma	Immunoglobulin A	BIO-AUT-SOP-151	A
Serum/Plasma	Immunoglobulin G	BIO-AUT-SOP-152	A
Serum/Plasma	Immunoglobulin M	BIO-AUT-SOP-153	A
Serum/Plasma	Iron	BIO-AUT-SOP-130	A, B
Serum/Plasma	Lactate Dehydrogenase	BIO-AUT-SOP-216	A,B
Serum/Plasma	Lithium	BIO-AUT-SOP-205	A,B
Serum/Plasma	Low Density Lipoprotein	Calculated Result BIO-AUT-SOP-117 BIO-AUT SOP-122 BIO-AUT-SOP-134	A,B
Serum/Plasma	Lutinising Hormone	BIO-AUT-SOP-315	A
Serum/Plasma and urine	Magnesium	BIO-AUT-SOP-131	A, B
Serum/Plasma	NT Pro BNP	BIO-AUT-SOP-322	B
Serum/Plasma	Oestradiol	BIO-AUT-SOP-317	A
Serum/Plasma	Paracetamol	BIO-AUT-SOP-206	A, B
Plasma	Parathyroid Hormone	BIO-AUT-SOP-319	A



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Roche Cobas 8000 analyser (multi assay photometry) with reference to:	
Serum/Plasma and urine	Phosphate	BIO-AUT-SOP-132	A, B
Serum/Plasma	Progesterone	BIO-AUT-SOP-313	A
Serum/Plasma	Prolactin	BIO-AUT-SOP-314	A
Serum/Plasma	Prostate Specific Antigen	BIO-AUT-SOP-306	A, B
Cerebrospinal Fluid	Protein & Glucose	BIO-AUT-SOP-214 BIO-AUT-SOP-127	A
Serum/Plasma	Protein Total	BIO-AUT-SOP-133	A, B
Urine	Protein	BIO-AUT-SOP-214	
Serum/Plasma	Rheumatoid Factor	BIO-AUT-SOP-156	A
Serum/Plasma	Salicylate	BIO-AUT-SOP-208	A, B
Serum/Plasma	%Saturation of Ferritin	Calculated Result BIO-AUT-SOP-130 BIO-AUT-SOP-138	A, B
Serum/Plasma	Teicoplanin	BIO-AUT-SOP-237	B
Serum/Plasma	Theophylline	BIO-AUT-SOP-209	B
Serum/Plasma	Thyroid Peroxidase	BIO-AUT-SOP-312	B
Serum/Plasma	Thyroid Stimulating Hormone	BIO-AUT-SOP-310	A, B
Serum/Plasma	Transferrin	BIO-AUT-SOP-138	
Serum/Plasma	Triglyceride	BIO-AUT-SOP-134	
Serum/Plasma	Troponin T	BIO-AUT-SOP-303	
Serum/Plasma	Urea	BIO-AUT-SOP-137	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Roche Cobas 8000 analyser (multi assay photometry) with reference to:	
Serum/Plasma and urine	Uric Acid	BIO-AUT-SOP-136	A, B
Serum/Plasma	Vancomycin	BIO-AUT-SOP-036	A
Serum/Plasma	Vitamin B12	BIO-AUT-SOP-304	A, B
Serum	Protein	Serum protein capillary electrophoresis using Helena Nexus 8 BIO-PRT-SOP-110	A
Serum	Cryoprotein	Serum protein capillary electrophoresis using Helena Nexus 8 BIO-PRT-SOP-116	A
Urine	Bence Jones Protein	Agarose Gel Electrophoresis using Helena SAS-3 and SAS-4 BIO-PRT-SOP-114	A
Urine	Bence Jones Protein	BIO-PRT-SOP-108	A
Blood	HbA1c	Serum protein capillary electrophoresis using Helena Nexus 8 BIO-PRT-SOP-116	A
Urine	Osmolality	Advanced Instruments analyser (freezing point depression) with specific reference to: BIO-AUT-SOP-437	A, B
Cerebrospinal Fluid CSF	Xanthochromia	Spectrophotometry with specific reference to: BIO-GEN-SOP-011	A



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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 (cont'd)</p> <p>Sweat</p> <p>Faeces</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Sweat test: Chloride</p> <p>Quantitative Faecal haemoglobin</p>	<p>Roche Cobas 8000 analyser (multi assay photometry) with reference to:</p> <p>Collection of sweat using WESTCOR / SHERWOOD system, Sherwood Chloride Analyser 926 with specific reference to: BIO-GEN-SOP-003 BIO-GEN SOP-002</p> <p>FIT (Immunological) with specific reference to: CBI0-BOW-SOP-011</p>	<p>A</p> <p>B</p>



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HUMAN BODY FLUIDS Blood (unless otherwise stated)	<u>Haematology examinations for the purposes of clinical diagnosis</u> Full Blood Count Analysis Haemoglobin Red cell count PCV MCV MCH MCHC RDW White cell count Platelet count Neutrophils Lymphocytes Monocytes Eosinophils Basophils Nucleated Red Cells	Documented procedures & manufacturer's instructions for Sysmex XN analysers (using electrical impedance, laser light scattering and dye boding measurement principles) with specific reference to: HAE-AUT-SOP-002	A, B
	Reticulocyte count (automated)		
	Blood film staining	Documented procedures & manufacturer's instructions for Siemens Hematek Slide Stainer using Wrights-Giemsa stain. HAE-SPE-SOP-027 HAE-SPE-SOP-030	A, B
	Film examination – peripipheral blood	Documented procedures to evaluate morphological features of peripheral blood film smears with specific reference to: HAE-SPE-SOP-016	A,B



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HUMAN BODY FLUIDS Blood (unless otherwise stated)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	I	
	Erythrocyte sedimentation rate (ESR)	Documented procedures & manufacturer's instructions for Starrsed V8 interliner (Westergen reference method) and RS Compact analysers with specific reference to: HAE-AUT-SOP-12	A, B
	Sickle Cell Screen	Documented procedures & manufacturer's instructions for Clintech Sickle test (solubility) with specific reference to: HAE-SPE-SOP-006	A, B
Urine / bone marrow	Haemosiderin – staining and morphology	Documented procedures & manufacturer's instructions for Iron stain and urinary Haemosiderin with specific reference to: HAE-SPE-SOP-028	A
	Infectious Mononucleosis Screening (IM heterophile antibodies)	Documented procedures & manufacturer's instructions for Clearview IM kit with specific reference to: HAE-SPE-SOP-014	B



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HUMAN BODY FLUIDS Blood (unless otherwise stated – cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
	Malaria screen for P. falciparum P. vivax P. ovale P. malariae P. knowlesi	Documented procedures relating to screening and identification of Plasmodium species using Wrights-Giemsa and Field's staining techniques with specific reference to: HAE-SPE-SOP-010 HAE-SPE-SOP-011	A, B
	Detection of HRP2 and PLDH for identification of P. falciparum and differentiation from other malarial sp	Diasys CareUS Kit manual method with specific reference to: HAE-SPE-SOP-010 HAE-SPE-SOP-011	
	Microfilariae screening	Documented procedures relating to identification of microfilariae using Wrights-Giemsa and Field's staining techniques with specific reference to: HAE-SPE-SOP-010	A, B
	Coagulation testing: Prothrombin time / INR	Documented procedures & manufacturer's instructions for ACL TOP 750 (Antrim) and ACL TOP 550 (Causeway) coagulation analysers (using turbidometric, absorbance and immunological measurements) with specific reference to: HAE-COA-SOP-002	A, B
	Activated Partial Thromboplastin Time (APTT)	HAE-COA-SOP-003	A, B
	Thrombin Time	HAE-COA-SOP-005	A, B
Fibrinogen	HAE-COA-SOP-004	A, B	



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HUMAN BODY FLUIDS Blood (unless otherwise stated)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions for ACL TOP 750 (Antrim) and ACL TOP 550 (Causeway) coagulation analysers (using turbidometric, absorbance and immunological measurements) with specific reference to: HAE-COA-SOP-006 HAE-COA-SOP-007 HAE-COA-SOP-008 Documented procedures & manufacturer's instructions for ACL TOP 750 (Antrim) and ACL TOP 550 (Causeway) coagulation analysers (using turbidometric, absorbance and immunological measurements) with specific reference to: HAE-COA-SOP-012 HAE-COA-SOP-009 HAE-COA-SOP-010 HAE-COA-SOP-011	
	D-dimer		A,B
	Factor Assays (VIII & IX only)		A
	Thrombophilia testing:		A
	Activated Protein C Resistance		A
	Antithrombin III		A
	Protein C		A
	Protein S		A



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HUMAN BODY FLUIDS Red cells and plasma (unless otherwise stated)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis</u>	Documented procedures and manufacturers instruction for IH 500 analyser (gel technology) with specific reference to:	A, B
	Blood Grouping Automated ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative Seraclone Anti A, Anti B and Anti AB Monoclonal Anti D1, Anti D2 and Anti D negative	HAE-BB-SOP-077	
	Blood Grouping ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative	Manual BioRad Gel Card HAE-BB-SOP-004	
	Manual tube technique	HAE-BB-SOP-005	A,B



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HUMAN BODY FLUIDS Red cells and plasma (unless otherwise stated) (cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis</u> (cont'd)	Documented procedures and manufacturers instruction for IH 500 analyser (gel technology) with specific reference to:	
	Infant Grouping / Cord Bloods	Automated HAE-BB-SOP-077	A, B
	ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative		A, B
	Antibody Screening		A, B
	Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb Lutheran -Lua P-P1	Automated HAE-BB-SOP-077	A, B
	Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb Lutheran -Lua P-P1	Manual BioRad Gel Card HAE-BB-SOP-004	A, B



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HUMAN BODY FLUIDS Red cells and plasma (unless otherwise stated)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)</u>	Documented procedures and manufacturers instruction for IH 500 analyser (gel technology) with specific reference to:	A, B
	Cross matching	Automated HAE-BB-SOP-077 Manual BioRad Gel Card HAE-BB-SOP-004	
	RBC Genotyping (Rh and Kell typing)	Automated HAE-BB-SOP-077 Manual BioRad Gel Card HAE-BB-SOP-004 Manual tube technique HAE-BB-SOP-033	A, B



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HUMAN BODY FLUIDS Red cells and plasma (unless otherwise stated - cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)</u>	Documented procedures and manufacturers instruction for IH 500 analyser (gel technology) with specific reference to:	A, B
	Antibody Identification	Automated HAE-BB-SOP-077	
	Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb Lutheran –Lua P–P1	Manual BioRad Gel Card HAE-BB-SOP-004	A, B
	Coombs test / monospecifics Detection of monospecific antiglobulins DAT	Manual tube technique HAE-BB-SOP-0006 Automated HAE-BB-SOP-077 Manual BioRad Gel Card HAE-BB-SOP-004 Manual tube technique HAE-BB-SOP-007	
Kleihauer test for the detection and estimation of foetal haemoglobin.	Foetal Red Cell Detection Kit (Guest medical) (staining) with acid elution and morphology with specific reference to: HAE-BB-SOP-014	A, B	



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<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, and resection tissue. (Tissue associated with the following pathways; endocrine, gastrointestinal, gynaecological, head & neck, skin, urinary tract & testis, bone & soft tissue, breast, lung and lymph nodes)</p>	<p><u>Routine Histopathology</u></p> <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Macroscopic and microscopic examination.</p>	A
		<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p>	A
		<p>Dissection Fisher Scientific 150mm / 6" Steel Rule CMP-MTN-160 300MM / 12" Steel Rule CMP-MTN-161 Afos Dissection Table</p>	A
		<p>Tissue processing Sakura TTEexpressX120 CMP-DIS-025 CMP-MTN-148</p>	A
		<p>Sakura VIP 5 & 6 Tissue processor CMP-SPC-007 CMP-MTN-027 CMP-MTN-028</p>	A
<p>Tissue embedding Sakura Tissue Tek Embedding Centre and Solmedia Diapath Canova embedding centre CMP-SPC-007 CMP-MTN-144</p>	A		
<p>Tissue sectioning Lieca Microtomes CMP-MTN-062 CMP-MTN-065 Sakura Tissue TEK AutoSections CMP-MTN-176 CMP-SPC-008</p>	A		



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin embedded tissue</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Routine morphological staining For the detection of:</p> <p>Basophilic and eosinophilic structures</p> <p>Special Staining for the detection of:</p> <p>Microorganisms such as Helicobacter pylori</p> <p>Demonstrate polysaccharides in the cell walls of fungi</p> <p>Iron pigment</p> <p>Acid mucopolysaccharides (mucin)</p> <p>Neutral polysaccharides such as glycogen, starch, cellulose, glycolipids and glycoproteins</p> <p>PAS stain with enzymatic digestion with diastase to differentiate glycogen from other neutral polysaccharides</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Automated H&E Staining using HE600 and procedures: CMP-STN-026 CMP-MAN-133</p> <p>Manual staining procedure with reference to: CMP-SPS-006 or Automated Staining using: Roche Ventana Special Stains stainer and Benchmark Special Stains in conjunction with manufacturer's instructions CMP-SPC-003 CMP-SPS-005 CMP-MTN-102</p> <p><u>Automated Staining:</u></p> <p>Giemsa Staining Kit</p> <p>GMS II Staining Kit (Grocott/Methenamine Silver)</p> <p>Iron Staining Kit</p> <p>Mucicarmine Staining Kit</p> <p>PAS Staining Kit</p> <p>Diastase Kit Periodic Acid Schiff's - Diastase (PAS-D)</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified	A
Formalin Fixed Paraffin embedded tissue (cont'd)	Reticular fibres	<u>Automated Staining</u> Reticulum II Staining Kit	
	Acid Mucopolysaccharides	Alcian Blue Kit	
	Differentiate collagen from muscle tissue	Trichrome Staining Kit	
	Warthin Starry	Steiner II Staining Kit	
	Elastic fibres	Elastic Staining Kit	
	Acid fast bacilli	AFBII	
	Amyloid	Congo red	
	Connective tissue and fibrin	<u>Manual staining:</u> Martius Scarlet Blue CMP-SPC-006	A
	Gram +ve & -ve microorganisms	Gram Staining Kit	
	Haemopoietic cells	Giemsa	
	Calcium	Von Kossa	
	Melanin	Masson Fontana	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following:</u>	Using manufacturer's instructions for Roche Ventana IHC stainer Benchmark Ultra and Laboratory procedure: CMP-ICC-007, CMP-ICC-008, CMP-MTN-022 and the following antibodies:	
	CEA - Cell surface glycoprotein, overexpressed in colonic and other tumours	Anti-CEA polyclonal Biogenix antibody	
	CD19 - B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma.	Anti-Human CD19 Biogenix antibody	
	P504S - Prostatic tumours / PIN	Anti-P504S Racemase Biogenix antibody	
	Bcl-2 - Follicular lymphomas	Bcl-2 (SP66)	
	Bcl-6 - Germinal centre lymphocytes, Non Hodgkins lymphoma / DLBCL	Bcl-6 (G1191E/A8)	
	B-Catenin - Adenocarcinoma	Beta-Catenin (14)	
	BOB.1 - B cell populations found in reactive lymphoid tissues	BOB.1 (SP92)	
	CA125 - Ovarian epithelial malignancies	CA-125 (OC125)	
	Calcitonin - 480 c cells and tumours	Calcitonin (SP17)	
	Calretinin - Neurons, mesothelial cells, steroid producing cells, neuroendocrine cells, sweat glands.	Calretinin (SP65)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following: (cont'd)</u>	Using manufacturer's instructions for Roche Ventana IHC stainer Benchmark Ultra and laboratory procedures: CMP-ICC-007 and the following antibodies:	A
	CD-138 - Plasma cells	CD-138 (B-A38)	
	CD15 - Reed Sternberg cells, granulocytes, monocytes	CD15 (MMA)	
	CD1A - precursor T-lymphoblastic leukemia/lymphoma and Langerhans' cell histiocytosis.	CD1A (EP3622)	
	CD20 - B cells	CD20 (L26)	
	CD21 - follicular lymphoma and angioimmunoblastic T-cell lymphoma.	CD21 (2G9)	
	CD23 - B cells, monocytes, FDCs	CD23 (SP23)	
	CD3 - T cells	CD3 (2GV6)	
	CD30 - RS cells, Hodgkin cells, ALCL	CD30 (BER-H2)	
	CD31 - Endothelial cells, platelets, monocytes, granulocytes, some B cells	CD31 (JC70)	
	CD34 -Vascular endothelium. Lymphoid and myeloid progenitor cells	CD34 (QBEnd/10)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following: (cont'd)</u> CD61 - Platelets, megakaryocytes, monocytes, macrophages, endothelial cells CD68 - Macrophages, monocytes, neutrophils, basophils, large lymphocytes CD79a - B cells CD8 - or identification of cytotoxic/suppressor T cells CDX-2 - Intestinal epithelial cells Chromogranin A - Neuroendocrine cells and tumours CINtec p16 - P16 protein overexpression CMV - Cytomegalovirus infection in human tissues Cyclin D1 - Mantle cell lymphomas, myelomas CAM5.2 - Secretory epithelia CK 14 - Neoplasms of squamous cell origin CK 19 - Ductal and glandular epithelial	Roche Ventana stainer Benchmark Ultra (cont'd) CD61, CELL MARQUE CD68 (KP-1) CD79a (SP18) CD8 (SP57) CDX-2 (EPR2764Y) Chromogranin A (LK2H10) CINtec p16 CMV Blend (8B1.2, 1G5.2 & 2D4.2) Cyclin D1 (SP4-R) Cytokeratin (CAM 5.2) Cytokeratin 14 (SP53) Cytokeratin 19, CELL MARQUE	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following: (cont'd)</u>	Roche Ventana stainer Benchmark Ultra (cont'd)	
	CK 20 - Gastric and intestinal epithelium, urothelium, Merkel cells of skin	Cytokeratin 20 (SP33)	
	CK 5/6 - Glandular and transitional epithelia	Cytokeratin 5/6 (D5/16B4)	
	CK 7 - Glandular and transitional epithelia	Cytokeratin 7 (SP52)	
	CK HMW - High molecular weight cytokeratin	Cytokeratin HMW (34E12)	
	AE1/AE3 - Epithelium	Cytokeratin, Pan (AE1/AE3 & PCK26)	
	Desmin - Desmin in striated and smooth muscle	Desmin (DE-R-11)	
	DOG-1 - Gastro intestinal stromal tumours	DOG-1 (SP31)	
	E-Cad - Epithelial cells	E-Cadherin (36)	
	Ber-Ep4- Epithelial cells	Ep-CAM (BER-EP4)	
	EMA - Normal and neoplastic epithelia	Epithelial Membrane Antigen (E29)	
	FACTOR 8- Dermal dendritic cells, endothelial cells	FACTOR 8-R AG, CELL MARQUE	
	GATA3 - T-cells and endothelial cells.	GATA3 (L50-823)	
	GCDFP-15 - marker of apocrine differentiation	GCDFP-15 (EP1582Y) PAB, CELL MARQUE	
	Glypican-3	Glypican-3 (1G12)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following: (cont'd)</u>	Roche Ventana stainer Benchmark Ultra (cont'd)	
	HPL -	Human Placental Lactogen, Cell Marque	
	Inhibin - Granulosa cell and Sertoli cell tumours	Inhibin (R1)	
	Kappa - Kappa immunoglobulin light chains	Kappa Rabbit Polyclonal Primary, CONFIRM anti	
	Ki-67 - G1,S,G2 and mitotic phase cells	Ki-67 (30-9)	
	Lambda - Lambda immunoglobulin light chains	Lambda Rabbit Polyclonal Primary, CONFIRM anti	
	MART-1/melan A - Melanocytes	MART-1/melan A (A103)	
	HMB45 - Melanocytic tumours	Melanosome (HMB45)	
	HBME-1- malignant mesothelial cells	MESOTHELIAL CELL(HBME-1)	
	MUM1 - subset of B cells in the light zone of the germinal centre	MUM1 (MRQ-43)	
	Myeloperoxidase - discrimination between lymphoid and myeloid disorders	Myeloperoxidase (PolyAb)	
	Myosin - Smooth muscle cells	Myosin, Smooth Muscle (SMMS-1)	
	OCT-2 - identification of pro-, pre-, and mature B cells and in the classification of lymphomas	OCT-2 (MRQ-2) PAB, CELL MARQUE	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following: (cont'd)</u>	Roche Ventana stainer Benchmark Ultra (cont'd)	
	P57 – P57 protein	P57 (KP10) PAB, CELL MARQUE	
	p63 - P63 protein	p63 (4A4)	
	c-KIT – identification of CD117 gastrointestinal stromal tumours	PATHWAY c-KIT (9.7)	
	PAX5 - identification of pro/pre-B cells, mature B cells and in the classification of lymphomas	PAX5 (SP34)	
	PAX8 - Expressed in the excretory system, thyroid gland and Wilms tumours.	PAX8 (MRQ-50)	
	PD-1 – identification of immune cells and cells of epithelial origin.	PD-1 (NAT105) PAB, CELL MARQUE	
	PLAP - Seminoma, some germ cell tumours	PLAP (NB10)	
	PSA - Prostatic glands	PPSA (ER-PR8)	
	Renal Cell - classification of renal cell carcinoma	Renal Cell Carcinoma (PN-15)	
	S100 - Neuroectodermal tissues	S100 (polyclonal) PAB, CONFIRM anti	
	Synaptophysin - Neuroendocrine tumours, neurons	Synaptophysin (SP11)	
	p53 - P53 protein	p53 (DO-7)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Formalin Fixed Paraffin embedded tissue (cont'd)	<u>Immunohistochemistry (IHC) to detect the following: (cont'd)</u>	Roche Ventana stainer Benchmark Ultra (cont'd)	
	Thyroglobulin - classification of tumours of thyroid origin	Thyroglobulin (2H11+6E1)	
	TTF-1 - Thyroid and lung cells	TTF-1 (SP141)	
	Vimentin - Mesenchymal cells	Vimentin (V9)	
	Breast Panel	Estrogen Receptor (SP1) Progesterone Receptor (1E2) PATHWAY Her-2 (4B5)	
	Miss- Match Repair Panel	MSH-2 (G219-1129) MSH6 (44) MLH-1 (M1) PMS2 (EPR3947)	
	CD10 - Lymphoblastic, Burkitts, follicular lymphomas. Germinal centres, perineurium, breast myoepithelial cells	CD10 (SP67)	
	CD4 - naplastic large cell lymphoma and mycosis fungoides.	CD4 (SP35)	
	CD45 - Majority of leucocytes	CD45 (LCA) (RP2/18)	
	CD5 - Tcells , subset of B cells in mantle zone	CD5 (SP19)	



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HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A, B
Fine needle aspirates FNA	<u>FNA Clinics</u> Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting Preparation of FNA specimens received in CytoLyt CMP-CYT-008 FNA preparation at Breast Clinics CMP-CYT-008 FNA Aspiration and Needle wash procurement CMP-CYT-008 Manual Romanowsky stain SOP- Manual Histochemical Staining CMP-CYT-008	A, B
Sputum	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Sputum SOP – Diagnostic Sputum Cytopathology CMP-CYT-001	A
Bronchial Brushing Bronchial Lavage Bronchial Washings		SOP – Diagnostic Bronchoscopic Cytopathology CMP-CYT-003	
Urine		SOP – Diagnostic Urine Cytopathology CMP-CYT-002	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fluids: Pleural Fluid, Peritoneal Fluid, Pericardial Fluid, Peritoneal Washings, Cyst Fluids, Hydrocoele</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>SOP – Diagnostic Fluid Cytopathology CMP-CYT-010</p> <p>Hologic ThinPrep 5000 (T5/T5000) Processor S/N 90681F13DO Hologic ThinPrep 5000 (T5/T5000) Autoloader S/N C0144I13D0 and <u>SOPs</u>:</p> <p>ThinPrep T5000 and AutoLoader Maintenance and Operation: CMP-GYN-001, T5000 Maintenance Log: CMP-MTN-003, ThinPrep 5000 Processor Operator's Manual [Hologic]: CMP-MTN-056 CMP-MTN-003 CMP-GYN-001</p>	<p>A</p>
<p>END</p>			