


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8111</p> <p>Accredited to ISO 15189:2012</p>	<h3>Northern Health &amp; Social Care Trust</h3> <p>Issue No: 004    Issue date: 23 April 2021</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: center;"><b>Local contact</b> Amanda Holmes</p>	<p>Medical Microbiology Biochemistry Haematology Coagulation Blood Transfusion Cellular &amp; 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: center;"><b>Local contact</b> 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:**

<b>Location details</b>	<b>Activity</b>
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
HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>		
	<u>Microbiology</u>	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant	
Routine samples: Aspirates Cellular and fluid material contained on swabs Intra-uterine contraceptive devices Fluids Genital samples Pus Samples from sterile sites Tissues	Isolation of microorganisms of clinical significance	Using manual inoculation and culture MIC-SWA-SOP-001 MIC-SWA-SOP-002 MIC-SWA-SOP-003 MIC-SWA-SOP-004 MIC-SWA-SOP-005  MIC-SWA-SOP-009 MIC-SWA-SOP-010 MIC-SWA-SOP-015 MIC-SWA-SOP-016 MIC-SWA-SOP-021 MIC-SWA-SOP-022  MIC-SWA-SOP-030  MIC-SWA-SOP-037 MIC-SWA-SOP-038 MIC-SWA-SOP-039 MIC-SWA-SOP-060	A
Gastric aspirate	Detection, identification and quantification of: White blood cells	MIC-SWA-SOP-011	A
Urine	Isolation of microorganisms of clinical significance	Using manual inoculation and culture MIC-URI-SOP-001	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 MIC-ENT-SOP-013	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-005	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 and	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 and yeast cultures isolated in-house from all samples listed above	Identification of clinically significant bacteria	Matrix-assisted laser desorption/ionisation using bioMerieux MalDI-ToF MIC-EQP-SOP-044	A
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)	Nucleic Acid extraction, PCR amplification and detection using: 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 using microscopy	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 and vaginal swabs, urine	<i>Chlamydia trachomatis</i> DNA/ <i>Neisseria gonorrhoeae</i> DNA	MIC-MOL-SOP-001 polymerase chain reaction using Roche Cobas 480	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	A
Blood/ Serum/ Plasma	Infectious mononucleosis (IM) heterophile antibodies	Lateral flow membrane chromatographic immunoassay using: using Clearview IM II MIC-SER-SOP-004	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 Clostridium difficile 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>		
Plasma Serum	Anti-Streptolysin O titre (ASOT)	Manual agglutination method using : MIC_SER_SOP_002 and Omega Avitex ASO  Manual Titration Method using : bioMerieux ASL	A
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
Serum	Mycobacterium tuberculosis	BD MGIT TBc Identification Test (TBc ID) rapid lateral flow MIC-CT3-SOP-009	A





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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for:	
Serum/Plasma unless otherwise stated	Quantitative determination of:  Sodium, Potassium, Chloride	Roche Cobas ISE Module (ion selective electrodes) With reference to: BIO-AUT-SOP- 137	A, B
Urine	Sodium, Potassium, Chloride	BIO-AUT-SOP-129  Roche Cobas 8000 analyser (at site A) and Roche Cobas 6000 analyser (at site B) (multi assay photometry) with reference to:	
	Alanine Transaminase	BIO-AUT-SOP-113	
	Albumin	BIO-AUT-SOP-111	
Urine	Albumin Creatinine Ratio	Calculated Result BIO-AUT-SOP-212 BIO-AUT-SOP-213	
	Alcohol	BIO-AUT-SOP-201	
	Alkaline Phosphatase	BIO-AUT-SOP-112	
	Ammonia	BIO-AUT-SOP-140	
Urine also	Amylase	BIO-AUT-SOP-114	
	Aspartate Transaminase	BIO-AUT-SOP-115	
	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</u> (cont'd)	Roche Cobas 8000 analyser (at site A) and Roche Cobas 6000 analyser (at site B) (multi assay photometry) with reference to:	A, B
Serum/Plasma unless otherwise stated (cont'd)	Bilirubin Total	BIO-AUT-SOP-128	
	C Reactive Protein	BIO-AUT-SOP-124	
Urine	Calcium	BIO-AUT-SOP-116	
	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	
	Carbon Dioxide (CO <sub>2</sub> )	BIO-AUT-SOP-118	
	Cholesterol	BIO-AUT-SOP-117	
	Cholesterol HDL Ratio	Calculated result BIO-AUT-SOP-117 BIO-AUT SOP-122	
	Complement C3	BIO-AUT-SOP-154	A
	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</u> (cont'd)	Roche Cobas 8000 analyser (at site A) and Roche Cobas 6000 analyser (at site B) (multi assay photometry) with reference to:	
Serum/Plasma unless otherwise stated (cont'd)	Cortisol	BIO-AUT-SOP-320	A
Urine also	Creatinine	BIO-AUT-SOP-123 BIO-AUT-SOP-213	A, B
Urine also	Creatinine Clearance	Calculated Result BIO-AUT-SOP-123 BIO-AUT-SOP-213	
	Creatinine Kinase	BIO-AUT-SOP-119	
	Digoxin	BIO-AUT-SOP-308	
	Estimated Glomerular Filtration Rate	Calculated Result BIO-AUT-SOP-123 BIO-AUT-SOP-432	
	Ferritin	BIO-AUT-SOP-307	
	Folic Acid	BIO-AUT-SOP-305	
	Follicle Stimulating Hormone	BIO-AUT-SOP-316	A
	Free Thyroxine	BIO-AUT-SOP-302	A, B
	Free Tri-iodothyronine	BIO-AUT-SOP-311	A
	Gamma Glutamyl Transpeptidase	BIO-AUT-SOP-126	A, B
	Gentamicin	BIO-AUT-SOP-235	
	Globulin	Calculated Result BIO-AUT-SOP-111 BIO AUT-SOP-133	



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Serum/Plasma unless otherwise stated (cont'd)	Glucose	BIO-AUT-SOP-127	A	
	High Density Lipoprotein	Calculated Result BIO-AUT-SOP-122	A, B	
	Human Chorionic Gonadotrophin	BIO-AUT-SOP-318	A	
	Immunoglobulin A	BIO-AUT-SOP-151	A	
	Immunoglobulin G	BIO-AUT-SOP-152	A	
	Immunoglobulin M	BIO-AUT-SOP-153	A	
	Iron	BIO-AUT-SOP-130	A, B	
	Lactate Dehydrogenase	BIO-AUT-SOP-216		
	Lithium	BIO-AUT-SOP-205		
	Low Density Lipoprotein	Calculated Result BIO-AUT-SOP-117 BIO-AUT SOP-122 BIO-AUT-SOP-134		
	Lutinsing Hormone	BIO-AUT-SOP-315	A	
	Urine also	Magnesium	BIO-AUT-SOP-131	A, B
	Urine	Microalbumin	BIO-AUT-SOP-212	A
	NT Pro BNP	BIO-AUT-SOP-322	B	
	Oestradiol	BIO-AUT-SOP-317	A	
	Paracetamol	BIO-AUT-SOP-206	A, B	
	Parathyroid Hormone	BIO-AUT-SOP-319	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 (at site A) and Roche Cobas 6000 analyser (at site B) (multi assay photometry) with reference to:	
Serum/Plasma unless otherwise stated (cont'd)			
Urine also	Phosphate	BIO-AUT-SOP-132	A, B
	Progesterone	BIO-AUT-SOP-313	A
	Prolactin	BIO-AUT-SOP-314	A
	Prostate Specific Antigen	BIO-AUT-SOP-306	A, B
Cerebrospinal Fluid	Protein & Glucose	BIO-AUT-SOP-214	A
	Protein Total	BIO-AUT-SOP-133	A, B
Urine	Protein	BIO-AUT-SOP-214	
	Rheumatoid Factor	BIO-AUT-SOP-156	A
	Salicylate	BIO-AUT-SOP-208	A, B
	%Saturation of Ferritin	Calculated Result BIO-AUT-SOP-130 BIO-AUT-SOP-138	A, B
	Teicoplanin	BIO-AUT-SOP-237	B
	Theophylline	BIO-AUT-SOP-209	A, B
	Thyroid Peroxidase	BIO-AUT-SOP-312	B
	Thyroid Stimulating Hormone	BIO-AUT-SOP-310	A, B
	Transferrin	BIO-AUT-SOP-138	
	Triglyceride	BIO-AUT-SOP-134	
	Troponin T	BIO-AUT-SOP-303	
	Urea	BIO-AUT-SOP-137	



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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 (at site A) and Roche Cobas 6000 analyser (at site B) (multi assay photometry) with reference to:	
Serum/Plasma unless otherwise stated (cont'd)	Uric Acid	BIO-AUT-SOP-136	A, B
	Vancomycin	BIO-AUT-SOP-036	A
	Vitamin B12	BIO-AUT-SOP-304	A, B
Serum	Protein	Serum protein capillary electrophoresis using Helena Nexus 8 BIO-PRT-SOP-110	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	BIORAD VARIANT analyser (ion exchange chromatography) with specific reference to: BIO-GEN-SOP-033	A
Urine also	Osmolality	Advanced Instruments analyser (freezing point depression) with specific reference to: BIO-AUT-SOP-301	A, B
Cerebrospinal Fluid CSF	Xanthochromia	Spectrophotometry with specific reference to: BIO-GEN-SOP-011	A
Sweat	Sweat test: Chloride	Collection of sweat using WESTCOR / SHERWOOD system, Sherwood Chloride Analyser 926 with specific reference to: BIO-GEN-SOP-003 BIO-GEN SOP-002	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)		
Faeces	Faecal Occult Blood	GUAIAAC (02/08) (Card Methods) & FIT(O3) (Immunological) with specific reference to: CB10-BOW-SOP-008 CB10-BOW-SOP-002 CB10-BOW-SOP-003	B
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	Sysmex XE-2100 & XT analysers with specific reference to: HAE-AUT-SOP-002 CHAE-AUTO-SOP-003 Using iso-electric focusing, spectrophotometry	A, B A B
	Reticulocyte count (automated)	Sysmex XE-2100 & XT analysers with specific reference to: HAE-AUT-SOP-009 CHAE-AUT-SOP-005 Using iso-electric focusing, spectrophotometry	A, B A B



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HUMAN BODY FLUIDS Blood (unless otherwise stated – cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant.	
	Erythrocyte sedimentation rate (ESR)	Starrsed V8 interliner (Westergen reference method) and Compact analysers with specific reference to: HAE-AUT-SOP-003 HAE-AUT-SOP-004 CHAE-COA-SOP-007	A, B A A B
	Sickle Cell Screen	Clintech Sickle test (solubility) with specific reference to: HAE-SPE-SOP-006 CHAE-MISC-SOP-003	A, B A B
	Hb S	Sebia Hydrasys electrophoresis analyser with specific reference to: HAE-SPE-SOP-005	A
Urine / bone marrow	Haemosiderin – staining and morphology Iron containing granules- Urine	Iron stain and urinary Haemosiderin (Sigma Aldrich Kit) with specific reference to: HAE-SPE-SOP-001 HAE-SPE-SOP-002	A
	Haptoglobins	Radial Immunodiffusion with specific reference to HAE-SPE-SOP-007	A
	Infectious Mononucleosis Screening (IM heterophile antibodies)	Clearview IM kit (antibody/antigen reaction) with specific reference to: HAE-SPE-SOP-015 CHAE-MISC-SOP-001	A, B A 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	Wright-Giemsa stain using Hematek Stainer and blood film examination with specific reference to HAE-SPE-SOP-010 CHAE_MIS_SOP-008	A, B  A B
	Malarial antigens of:  <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	BINAX NOW ki (antibody/antigen) kit with specific reference to: HAE-SPE-SOP-011 CHAE-MIS-SOP-009 HAE-SPE-SOP-010	A, B  A B A
	Microfilariae screening	Manual staining using Giemsa stain with specific reference to HAE-SPE-SOP-019 HAE-SPE-SOP-019	A, B  A B
	Prothrombin time / INR	ACL TOP coagulation analysers with specific reference to:  HAE-COA-SOP-002 CHAE-COA-SOP-003 (turbidimetric)	  A B
	Activated Partial Thromboplastin Time (APTT)	HAE-COA-SOP-003 CHAE-COA-SOP-005 (turbidimetric)	A B
	Thrombin Time	HAE-COA-SOP-005 CHAE-COA-SOP-009 (turbidimetric)	A B
	Fibrinogen	HAE-COA-SOP-004 CHAE-COA-SOP-004 (turbidimetric)	A B



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HUMAN BODY FLUIDS Blood (unless otherwise stated – cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant.	
	D-dimer	ACL TOP coagulation analysers cont'd with specific reference to:  HAE-COA-SOP-006 CHAE-COA-SOP-007 (Immunological measurements)	A B
	Factor Assays (VIII & IX only)	HAE-COA-SOP-007 HAE-COA-SOP-008	A A
	Thrombophilia testing:	ACL TOP coagulation analysers with specific reference to:	A
	Activated Protein C Resistance	HAE-COA-SOP-012 (turbidimetric)	A
	Antithrombin III	HAE-COA-SOP-009 (chromogenic absorbance)	A
	Protein C	HAE-COA-SOP-010 (chromogenic absorbance)	A
	Protein S	HAE-COA-SOP-011 (immunological measurements)	A
Bone Marrow and peripheral blood	film staining and Examination	Documented procedures & manufacturer's <i>instructions for Siemens Haematek Slide Stainer</i>	A, B
		Documented procedures with specific reference to: HAE-SPE-SOP-016 CHAE-MISC-SOP-006 CHAE-MISC-SOP-007	A, B A B 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</u>	In-house documented procedures based on equipment manuals as relevant.	
	Blood Grouping  ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative	Ortho Vision analyser with specific reference to:  Automated HAE-BB-FOR-12 CHAE-BB-SOP-025  Ortho Innova AutoVue CHAE-BB-FOR-068.	A B  B
	Seraclone Anti A, Anti B and Anti AB  Monoclonal Anti D1, Anti D2 and Anti D negative  Blood Grouping  ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative	Manual Biovue Gel Card HAE-BB-SOP-004 CHAE-BB-SOP-026	A B



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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 Red cells and plasma (unless otherwise stated – cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant.	
	Infant Grouping / Cord Bloods ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative	Automated Ortho Vision automated analyser with specific reference to  HAE-BB-FOR-12 CHAE-BB-SOP-017  Ortho Innova AutoVue CHAE-BB-FOR-068.	A B  B
	Antibody Screening	Ortho Vision analyser with specific reference to:	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 Anti-Chido/Rogers	Automated HAE-BB-SOP-12 CHAE-BB-SOP-025  Ortho Innova AutoVue CHAE-BB-FOR-068.	A B  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 Anti-Chido/Rogers	Manual Biovue Gel Card HAE-BB-SOP-004 CHAE-BB-SOP-026	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>	In-house documented procedures based on equipment manuals as relevant.	
	Cross matching	Ortho Vision analyser with specific reference to:  Automated HAE-BB-SOP-12 CHAE-BB-SOP-025	A, B  A B
		Ortho Innova AutoVue CHAE-BB-FOR-068.	B
		Manual Biovue Gel Card HAE-BB-SOP-004 CHAE-BB-SOP-026	A B
RBC Genotyping (Rh and Kell typing)		Ortho Visionanalyser with specific reference to:  Automated HAE-BB-SOP-12 CHAE-BB-SOP-025	A, B  A B
		Ortho Innova AutoVue CHAE-BB-FOR-068.	B
		Manual Biovue Gel Card HAE-BB-SOP-33 CHAE-BB-SOP-026	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>	In-house documented procedures based on equipment manuals as relevant.	
	Antibody Identification 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 Anti-Chido/Rogers	Ortho Vision analyser with specific reference to:  Automated HAE-BB-FOR-12 CHAE-BB-SOP-025  Ortho Innova AutoVue CHAE-BB-FOR-068.  Manual Biovue Gel Card HAE-BB-SOP-004 CHAE-BB-SOP-026	A, B  A B  B  A B
	Coombs test / monospecifics Detection of monospecific antiglobulins DAT	Ortho Visionanalyser with specific reference to:  Automated HAE-BB-SOP-13 CHAE-BB- SOP-026  Manual Biovue Gel Card HAE-BB-SOP-007 CHAE-BB-SOP-007	A, B  A B  A B
	Kleihauer test for the detection and estimation of foetal haemoglobin.	Fetal Red Cell Detection Kit (staining) with acid elution and morphology with specific reference to: HAE-BB-SOP-014 CHAE-BB-SOP-016	A B
		Manual tube technique	



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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 &amp; neck, skin, urinary tract &amp; testis, bone &amp; 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> <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Dissection Fisher Scientific 150mm / 6" Steel Rule, 300MM / 12" Steel Rule Afos Dissection Table HIS-REC-DOC-009 HIS-DIS-DOC-005</p> <p>Tissue processing <b>Sakura</b> Sakura TTEExpressX120 VIP 5 &amp; 6 Tissue processor HIS-PMS-SOP-007 HIS-PMS-SOP-005</p> <p>Tissue embedding Sakura Tissue Tek Embedding Centre HIS-SPC-SOP-049</p> <p>Tissue sectioning Lieca Microtomes HIS-SPC-SOP-041 HIS-SPC-SOP-042</p> <p>Cryotomy Lieca Cryostat HIS-GEN-SOP-003</p>	<p>A</p>



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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 in bone marrow</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&amp;E Staining using HE600 and procedures: HIS-SPC-SOP-039 HIS-SPC-SOP-015 HIS-SPC-SOP-002</p> <p>Special Staining using manual and/or automated methods: Manual staining procedure SOP- Manual Histochemical Staining and/or Automated Staining using: Roche Ventana Special Stains stainer and Benchmark Special Stains in conjunction with manufacturer's instructions</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>	A





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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>Automated Staining (cont'd).</u>	
	Reticular fibres	Reticulum II Staining Kit	
	Acid Mucopolysaccharides	Alcian Blue Kit	
	Differentiate collagen from muscle tissue	Trichrome Staining Kit	
	Gram +ve & -ve microorganisms	Gram Staining Kit	
	Warthin Starry	Steiner II Staining Kit	
	Elastic fibres	Elastic Staining Kit	
	Acid fast bacilli	AFBII	
	Amyloid	Congo red	
	Haemopoietic cells	Giemsa	
		<u>Manual staining:</u>	A
	Amyloid	Congo Red HIS-SPC-SOP-010	
	Differentiate between collagen and muscle	Haematoxylin & Van Gieson CMP-STN-020	
	Connective tissue and fibrin	Martius Scarlet Blue HIS-SPC-SOP-018	
	Copper	Rhodanine CMP-SPC-004	
	Tubercle bacilli	AFB III Staining Kit / Auramine O	



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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 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 (GI191E/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 - Thyroid 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 procedure: 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>	Roche Ventana stainer Benchmark Ultra (cont'd)	
	CD61 - Platelets, megakaryocytes, monocytes, macrophages, endothelial cells	CD61, CELL MARQUE	
	CD68 - Macrophages, monocytes, neutrophils, basophils, large lymphocytes	CD68 (KP-1)	
	CD79a - B cells	CD79a (SP18)	
	CD8 - or identification of cytotoxic/suppressor T cells	CD8 (SP57)	
	CDX-2 - Intestinal epithelial cells	CDX-2 (EPR2764Y)	
	Chromogranin A - Neuroendocrine cells and tumours	Chromogranin A (LK2H10)	
	CINtec p16 - P16 protein overexpression	CINtec p16	
	CMV - Cytomegalovirus infection in human tissues	CMV Blend (8B1.2, 1G5.2 & 2D4.2)	
	Cyclin D1 - Mantle cell lymphomas, myelomas	Cyclin D1 (SP4-R)	
	CAM5.2 - Secretory epithelia	Cytokeratin (CAM 5.2)	
	CK 14 - Neoplasms of squamous cell origin	Cytokeratin 14 (SP53)	
	CK 19 - Ductal and glandular epithelial	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 etc	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 CYT-NGN-005  FNA preparation at Breast Clinics CYT-LAB-SOP-058  FNA Aspiration and Needle wash procurement CYT-LAB-POL-002  Light microscopy using in-house procedure CYT-LAB-SOP-Microscopy  Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting cont'd  Manual Romanowsky stain SOP-- Manual Histochemical Staining	A, B
Sputum	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Sputum SOP – Diagnostic Sputum Cytopathology	A
Bronchial Brushing Bronchial Lavage Bronchial Washings		SOP – Diagnostic Bronchoscopic Cytopathology	
Urine		SOP – Diagnostic Urine Cytopathology	



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HUMAN BODY FLUIDS (cont'd)	<u>Cytopathology (Non-Gynae) 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
Fluids: Pleural Fluid, Peritoneal Fluid, Pericardial Fluid, Peritoneal Washings, Cyst Fluids, Hydrocoele	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)	SOP – Diagnostic Fluid Cytopathology	
		Hologic ThinPrep 5000 (T5/T5000) Processor S/N 90681F13DO Hologic ThinPrep 5000 (T5/T5000) Autoloader S/N C0144113D0 and <u>SOPs:</u> 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 Gynaecological Cytopathology: CMP-CYT-006	
CSF	Tinctorial stains for the demonstration of:	SOP – Diagnostic Cerebrospinal fluid Cytopathology	
	Cells (nuclei and cytoplasm) and micro organisms	Papanicolaou (Manual) Staining CYT-STN-022	A
Liquid Based Cervical Cell Samples	Cells (nuclei and cytoplasm) and micro organisms	Clin-Tech Speedy-Diff Kit CMP-STn-024	
		Automated Papanicolaou Staining & coverslipping Tissue-Tek Prisma /Glas g2 CMP-CYT-007	A
		Light microscopy using in-house procedure CYT-LAB-SOP-Microscopy	



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Liquid Based Cervical Cell Samples	<p><u>Molecular Techniques</u></p> <p>Detection of high risk Human Papillomavirus DNA</p> <p>Detection of genotypes of both low and high risk Human Papillomavirus</p>	<p>High- Risk HPV testing with the Roche cobas 4800 CMP-MOL-022</p> <p>HPV Linear Array: Testing CMP-MOL-020</p>	



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Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Northern Health & Social Care Trust**

**Issue No: 004 Issue date: 23 April 2021**

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Cytopathological (Gynae) 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	<u>Molecular Techniques (cont'd)</u>  Detection of mutations in tumour DNA to identify:  Skin Cancer BRAF NRAS  LUNG CANCER EGFR KRAS BRAF ALK  COLORECTAL CANCER KRAS BRAF NRAS	Morphological Assessment for tissue / material supplied for Pathology Review and suitability for tissue for molecular testing.  The extraction of tumour DNA from supplied tissue, using whole and macrodissected sections of the tissue.  The quantification of extracted DNA / NAs for quality control and sample processing.  cobas BRAF Mutation Test CMP-MOL-061  cobas EGFR mutation Testing CMP-MOL-036  cobas KRAS Mutation Testing CMP-MOL-032	A
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	<u>Microscopy (qualitative analysis)</u> Using procedures: CMP-CLR-052, CMP-CYT-006, HIS-GEN-POL-003 and microscopes listed above	A
END			