


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9210</p> <p>Accredited to ISO 15189:2012</p>	<h3>South Tees Hospitals NHS Foundation Trust</h3> <p>Issue Number: 005 Issue Date: 02 December 2021</p>	
	<p>South Tees Hospitals NHS Foundation Trust Pathology Services The James Cook University Hospital Marton Road Middlesbrough TS4 3BW United Kingdom</p>	<p>Contact: Ann Wallis Tel: +44 (0)1642 850850 Ext 55239 Fax: +44 (0)1642 282636 E-Mail: ann.wallis1@nhs.net Website: www.southtees.nhs.uk/services/pathology</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>Address Pathology Services The James Cook University Hospital Marton Road Middlesbrough TS4 3BW United Kingdom</p> <p>Local contact Dr Dianne Plews Tel: +44 (0)1642 854381</p>	<p>Haematology Blood transfusion including storage & issue of blood and blood products Special Haematology including Molecular Haematology Biochemistry Immunology Microbiology Virology Cellular Pathology</p>	JCUH
<p>Address Friarage Hospital Bullamoor Road Northallerton DL6 1JG United Kingdom</p> <p>Local contact Dr Dianne Plews Tel: +44 (0)1642 854381</p>	<p>Haematology Storage & issue of blood and blood products Biochemistry Cellular Pathology</p>	FHN



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
Sweat test clinic, Paediatric Outpatients Department, James Cook University Hospital	Sweat collection for diagnostic purposes	JCUH
Haematology Day Unit, James Cook University Hospital	Satellite blood fridge: storage of blood and products only	JCUH
Paediatric Resus Room, Accident and Emergency Department, James Cook University Hospital	Satellite blood fridge: storage of blood and products only	JCUH
Mortuary James Cook University Hospital Middlesbrough	Mortuary Services (body receipt, storage and release)	JCUH
Mortuary Friarage Hospital Northallerton	Mortuary Services (body receipt, storage and release)	FHN



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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>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u>	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated		Siemens ADVIA XPT S-BC-AUT-SOP0061 and procedures below:	
	Albumin	Photometry - End point S_BC_AUT_SOP0002	
	Bicarbonate	Photometry - Enzymatic S_BC_AUT_SOP0008	
Serum, Urine	Calcium	Photometry - End point S_BC_AUT_SOP0010	
Serum, Urine	Chloride	Ion Selective Electrode S_BC_AUT_SOP0012	
Serum, Urine	Creatinine	Photometry - Kinetic S_BC_AUT_SOP0016	
	C-Reactive Protein	Photometry - Turbidimetry S_BC_AUT_SOP0017	
Serum, CSF, Urine	Glucose	Photometry - End point S_BC_AUT_SOP0023	
Serum, Urine	Magnesium	Photometry - End point S_BC_AUT_SOP0034	
Serum, Urine	Phosphate	Photometry - End point S_BC_AUT_SOP0038	
Serum, Urine	Potassium	Ion Selective Electrode S_BC_AUT_SOP0039	
Serum, Urine	Sodium	Ion Selective Electrode S_BC_AUT_SOP0041	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated	Total Bilirubin	Siemens ADVIA XPT (cont'd) Photometry - End point S_BC_AUT_SOP0043	
Serum and CSF	Total Protein	Photometry - End point S_BC_AUT_SOP0044	
Serum, Urine	Urea	Photometry - Enzymatic S_BC_AUT_SOP0046	
Serum, Urine	Uric Acid	Photometry - End point S_BC_AUT_SOP0047	
	Creatinine (Enzymatic)	Photometry - Enzymatic S_BC_AUT_SOP0057	
	Angiotensin Converting Enzyme (ACE)	Photometry - Enzymatic S_BC_AUT_SOP0001	
	Alkaline Phosphatase (ALP)	Photometry - Enzymatic S_BC_AUT_SOP0003	
	Alanine Aminotransferase (ALT)	Photometry - Enzymatic S_BC_AUT_SOP0004	
Serum, Urine	Amylase	Photometry - Enzymatic S_BC_AUT_SOP0006	
	Aspartate Aminotransferase (AST)	Photometry - Enzymatic S_BC_AUT_SOP0007	
	Creatine Kinase (CK)	Photometry - Enzymatic S_BC_AUT_SOP0014	
	Gamma Glutamyl Transferase (GGT)	Photometry - Enzymatic S_BC_AUT_SOP0022	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated (cont'd)		Siemens ADVIA XPT (cont'd)	
	Lactate Dehydrogenase (LDH)	Photometry - Enzymatic S_BC_AUT_SOP0031	
	Cholesterol	Photometry - End point S_BC_AUT_SOP0013	
	HDL Cholesterol	Photometry - End point S_BC_AUT_SOP0024	
	Triglyceride	Photometry - End point S_BC_AUT_SOP0045	
	Carbamazepine	Photometry -EMIT S_BC_AUT_SOP0011	
	Lithium	Photometry - End point S_BC_AUT_SOP0033	
	Phenytoin	Photometry -EMIT S_BC_AUT_SOP0037	
	Theophylline	Photometry -EMIT S_BC_AUT_SOP0042	
	Valproate	Photometry -EMIT S_BC_AUT_SOP0050	
	Ethanol	Photometry - Enzymatic S_BC_AUT_SOP0021	
	Paracetamol	Photometry - End point S_BC_AUT_SOP0036	
	Salicylate	Photometry - End point S_BC_AUT_SOP0040	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated (cont'd)	Immunoglobulin A	Siemens ADVIA XPT (cont'd) Photometry - Turbidimetry S_BC_AUT_SOP0025	
	Immunoglobulin G	Photometry - Turbidimetry S_BC_AUT_SOP0026	
	Immunoglobulin M	Photometry - Turbidimetry S_BC_AUT_SOP0027	
	Ammonia	Photometry - End Point S_BC_AUT_SOP0005	
	Bile Acids	Photometry - Enzymatic S_BC_AUT_SOP0009	
	Direct Bilirubin	Photometry - End point S_BC_AUT_SOP0020	
	Lactate	Photometry - End point S_BC_AUT_SOP0030	
CSF and Urine	Protein	Photometry - End Point S_BC_AUT_SOP0048 Siemens Centaur XPT CLIA S_BC_END_SOP0065 and procedures below	
	Cortisol	S_BC_END_SOP0008	
	Digoxin	S_BC_END_SOP0053	
	Gentamicin	S_BC_END_SOP0052	
	Vancomycin	S_BC_END_SOP0051	
	Alpha-Fetoprotein (AFP)	S_BC_END_SOP0001	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated		Siemens Centaur XPT (cont'd)	
	CA-125	S_BC_END_SOP0003	
	CA 15-3	S_BC_END_SOP0004	
	CA19-9	S_BC_END_SOP0005	
	Carcino-Embryonic Antigen	S_BC_END_SOP0006	
	Procalcitonin	S_BC_END_SOP0062	
	Prostate Specific Antigen (PSA)	S_BC_END_SOP0024	
	Free T3 (FT3)	S_BC_END_SOP0012	
	Free T4 (FT4)	S_BC_END_SOP0013	
	Thyroid Stimulating Hormone (TSH)	S_BC_END_SOP0029	
	Brain Natriuretic Peptide (BNP)	S_BC_END_SOP0050	
	High Sensitivity Troponin-I	S_BC_END_SOP0046	
	Thyroid Peroxidase Antibody (TPO)	S_BC_END_SOP0054	
	Ferritin	S_BC_END_SOP0010	
	Folate	S_BC_END_SOP0011	
	Vitamin B12	S_BC_END_SOP0033	



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Serum unless stated (cont'd)		Siemens Centaur XPT (cont'd)	
	Follicle Stimulating Hormone	S_BC_END_SOP0014	
	HCG (Pregnancy)	S_BC_END_SOP0016	
	Luteinising Hormone (LH)	S_BC_END_SOP0018	
	Oestradiol	S_BC_END_SOP0020	
	Progesterone	S_BC_END_SOP0022	
	Prolactin	S_BC_END_SOP0023	
	Sex hormone Binding Globulin	S_BC_END_SOP0026	
	Testosterone	S_BC_END_SOP0027	
		Beckman Access 2 ECLIA using procedures below	
	Thyroglobulin (Tg)	S_BC_END_SOP0028	
	Thyroglobulin Antibody (Tg Ab)	S_BC_END_SOP0030	
	Erythropoietin (EPO)	S_BC_END_SOP0009	
	Intrinsic Factor Antibody (IFA)	S_BC_END_SOP0017	
		Roche E411 ECLIA using procedures below	
	Cyclosporin	S_BC_END_SOP0061	
	Tacrolimus	S_BC_END_SOP0060	
	Anti Mullerian Hormone	S_BC_END_SOP0063	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated (cont'd)	Beta-Crosslaps	Roche E411 ECLIA (cont'd) S_BC_END_SOP0002	
	Parathyroid Hormone (PTH)	S_BC_END_SOP0025 IDS iSys CLIA using procedures below	
	25-Hydroxy Vitamin D	S_BC_SPC_SOP0027	
	IGF-1	S_BC_SPC_SOP0051	
	Growth Hormone	S_BC_SPC_SOP0050 Roche E411 ECLIA using procedures below	
	P1NP	S_BC_END_SOP0064	
	CK-MB Mass	S_BC_END_SOP0007	
Urine	Free Cortisol	S_BC_END_SOP0032	
	ACTH	S_BC_END_SOP0055	
	DHEAS	S_BC_END_SOP0058	
	Insulin	S_BC_END_SOP0057	
	C-Peptide	S_BC_END_SOP0056	
	HCG (Tumour Marker)	S_BC_END_SOP0038	
Serum and Urine	Osmolality	Advanced Instruments OSMO1 Freezing Point Depression S_BC_AUT_SOP0092 Advanced Instruments Osmometer Freezing Point Depression S_BC_AUT_SOP0035	JCUH FHN



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Whole Blood	Glycated Haemoglobin	Menarini Hb9210 Borate Affinity HPLC S_BC_SPC_SOP0052	
Faeces	Calprotectin	Alpha Labs Automated Siemens XPT Buhlmann Turbo S_BC_SPC_SOP0046	
Faeces	Elastase	Dynex DS2 ELISA J_BC_SPC_SOP0006	
Sweat	Chloride	Elicheck Chlorocheck 3500 chloride meter Coulometry J_BC_SPC_SOP0020	
Urine, Faeces	Reducing Substances	Fehling's reagent/Benedict's reaction J_BC_SPC_SOP0018	
Whole Blood	Carboxyhaemoglobin	IL GEM OPL Co-oximetry J_BC_SPC_SOP0008	
Whole Blood	Methaemoglobin	IL GEM OPL Co-oximetry J_BC_SPC_SOP0008	
Serum unless stated		Siemens Atellica Solution using S-BC-AUT-SOP0062 and procedures below:	FHN
	Alanine Aminotransferase (ALT)	Photometry – Enzymatic S_BC_AUT_SOP0004	
	Albumin (ALB)	Photometry - End point S_BC_AUT_SOP0002	
	Alkaline Phosphatase (ALP)	Photometry – Enzymatic S_BC_AUT_SOP0003	
Serum and Urine	Chloride (CL)	A-LYTE Integrated Multisensor S_BC_AUT_SOP0012	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	FHN
Serum unless stated		Siemens Atellica Solution cont'd S-BC-AUT-SOP0062	
Serum and Urine	Sodium	A-LYTE Integrated Multisensor S_BC_AUT_SOP0041	
Serum and Urine	Potassium	A-LYTE Integrated Multisensor S_BC_AUT_SOP0039	
Serum and Urine	Amylase	Photometry – Enzymatic S_BC_AUT_SOP0006	
	Aspartate Aminotransferase (AST)	Photometry – Enzymatic S_BC_AUT_SOP0007	
	B-Type Natriuretic Peptide (BNP)	Chemiluminescent Immunoassay (CLIA) S_BC_END_SOP0050	
Serum and Urine	Calcium (Ca)	Photometry - End point S_BC_AUT_SOP0010	
	Carbon Dioxide (CO2_c)	Photometry - Enzymatic	
	Cholestrol (CHOL_2)	Photometry - End point S_BC_AUT_SOP0013	
	C-Reactive Protein (CRP_2)	Photometry – Turbidimetry S_BC_AUT_SOP0017	
	Creatine Kinase (CK_L)	Photometry – Enzymatic S_BC_AUT_SOP0014	
Serum and Urine	Creatinine_2 (Crea_2)	Photometry - Kinetic S_BC_AUT_SOP0016	
	Digoxin (DIG)	CLIA S_BC_END_SOP0053	
	Direct Bilirubin (DBIL_2)	Photometry - End point S_BC_AUT_SOP0020	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	FHN
Serum unless stated	Enzymatic Creatinine (ECRE_2)	Siemens Atellica Solution cont'd S_BC-AUT-SOP0062 Photometry – Enzymatic S_BC_AUT_SOP0057	
	Ethanol (ETOH_2)	Photometry - Enzymatic S_BC_AUT_SOP0021	
	Ferritin (FER)	CLIA S_BC_END_SOP0010	
	Folate (FOL)	CLIA S_BC_END_SOP0011	
	Free T3 (FT3)	CLIA S_BC_END_SOP0013	
	Free T4 (FT4)	CLIA S_BC_END_SOP0014	
	Gamma-Glutamyl Transferase (GGT)	Photometry – Enzymatic S_BC_AUT_SOP0022	
Serum, CSF and Urine	Glucose (Glu)	Photometry - End point S_BC_AUT_SOP0023	
	High Density Lipoprotein (D-HDL)	Photometry - End point S_BC_AUT_SOP0024	
	High Sensitivity Troponin I (TnIH)	CLIA S_BC_END_SOP0066	
Serum and Urine	Inorganic Phosphate (IP)	Photometry - End point S_BC_AUT_SOP0038	
	Iron (IRON_2)	Photometry - End point F_BC_AUT_SOP0088	
	Lactate (LAC)	Photometry - End point S_BC_AUT_SOP0030	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	FHN
Serum unless stated	Lactate Dehydrogenase (LDH)	Siemens Atellica Solution cont'd S-BC-AUT-SOP0062 Photometry – Enzymatic S_BC_AUT_SOP0031	
	Lithium (LITH)	Photometry - End point S_BC_AUT_SOP0033	
Serum and Urine	Magnesium (MG)	Photometry - End point S_BC_AUT_SOP0034	
Urine	Microalbumin (uALB_2)	Photometry - End point F_BC_AUT_SOP0071	
	Paracetamol (ACET)	Photometry - End point S_BC_AUT_SOP0036	
	Prostate-Specific Antigen (PSA)	CLIA S_BC_END_SOP0024	
	Salicylate (SAL)	Photometry - End point S_BC_AUT_SOP0040	
	Theophylline (THEO_2)	Photometry -EMIT S_BC_AUT_SOP0042	
	Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)	CLIA S_BC_END_SOP0029	
	Total Bilirubin_2 (TBil_2)	Photometry - End point S_BC_AUT_SOP0043	
	Total hCG (ThCG)	CLIA S_BC_END_SOP0016	
Serum and CSF	Total Protein II (TP)	Photometry - End point S_BC_AUT_SOP0044	
	Transferrin (TRF)	CLIA F_BC_AUT_SOP0089	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	FHN
Serum unless stated		Siemens Atellica Solution cont'd S_BC_AUT_SOP0062	
	Triglycerides (TRIG)	Photometry - End point S_BC_AUT_SOP0045	
Serum and Urine	Urate (UA)	Photometry - End point S_BC_AUT_SOP0047	
Serum and Urine	Urea	Photometry – Enzymatic S_BC_AUT_SOP0046	
Urine	Protein (UPRO_2)	Photometry - End point S_BC_AUT_SOP0048	
	Vitamin B12 (VB12)	CLIA S_BC_END_SOP0033	



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HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis:</u>	Manufacturer's instructions and documented in-house methods using:	
EDTA Whole blood unless stated	Full blood count including the following parameters: White Blood Cells (WBC) Red Blood Cell Count (RBC) Haemoglobin (Hb) Platelets WBC Differential Mean corpuscular volume (MCV) Mean corpuscular haemoglobin (MCH) Mean corpuscular hemoglobin concentration (MCHC) % hypochromasia	Siemens Advia 2120, laser 2D light scatter S_HA_HAE_SOP001	JCUH/ FHN
	Reticulocyte count	S_HA_HAE_SOP002	JCUH/ FHN
	Blood film review	Siemens Hematek 3000 & Light Microscopy S_HA_HAE_SOP0018	JCUH
	WBC differential	Siemens Hematek 3000 & Light Microscopy S_HA_HAE_SOP0018	JCUH
Bone marrow (aspirate+trephine)	Morphological assessment	Siemens Hematek 3000 & Light Microscopy J_HA_HAE_SOP0023	JCUH



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HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	
EDTA Whole blood unless stated	Malaria Screen for detection of: <i>Plasmodium falciparum</i> <i>Plasmodium vivax</i> <i>Plasmodium ovale</i> <i>Plasmodium malariae</i>	Alere BinaxNOW rapid immunodiagnostic strip S_HA_HAE_SOP0024 Blood Film review using manual Giemsa (thin film) and Gurr Field's (thick film) stains S_HA_HAE_SOP0024	JCUH/ FHN
	Blood film for malaria detection		
	Blood film for assessment of morphology	Siemens Hematek 3000 & Light microscope, Microscopy S_HA_HAE_SOP0018	JCUH
	ESR	Starrsed Compact and Starrsed ST, Westergren sedimentation, J_HA_HAE_SOP0088	JCUH
	Plasma Viscosity	Benson Plasma viscometer J_HA_HAE_SOP0120	JCUH
Whole blood, serum, plasma	Infectious mononucleosis heterophile antibodies	Abbott Clearview IM, rapid immunodiagnostic strip, S_HA_HAE_SOP0010	JCUH/ FHN
	Haemoglobinopathy Screen: Hb A, C, E, F	Bio-Rad Variant II High performance liquid chromatography J_HA_HAE_SOP0013	JCUH
	Haemoglobin S	Sickledex qualitative solubility test J_HA_HAE_SOP0012	JCUH



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HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
CSF slides prepared as below	Identification of WBC	Wright Giemsa staining on Hematek J_HA_HAE_SOP0085	
HUMAN BODY FLUIDS	<u>Coagulation examination activities for the purpose of clinical diagnosis and monitoring</u>	Manufacturer's instructions and documented in-house methods using:	
Citrated whole blood unless stated	Coagulation screen including: Prothrombin Time/Ratio Activated Partial Prothrombin Time/Ratio Fibrinogen level Warfarin monitoring (INR) Thrombin Time Reptilase Time D-Dimer Anti Xa (Apixaban, Rivaroxaban, Edoxaban, UFH, Fondaparinux) Dabigatran	Stago Star Max Analyser Clot formation/ Chromogenic/ Immunoturbidometric using procedures below S_HA_CD_SOP0001 S_HA_CD_SOP0002 S_HA_CD_SOP0004 S_HA_CD_SOP0005 S_HA_CD_SOP0006 S_HA_CD_SOP0009 S_HA_CD_SOP0054	JCUH/ FHN



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HUMAN BODY FLUIDS Citrated whole blood unless stated (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis: (cont'd)</u> Factor assays: Factor II Factor V Factor VII Factor X Factor VIII Factor IX Factor XI Factor XII Factor XIII Thrombophilia screen including: ATIII Protein C Protein S Lupus anticoagulant screen Von Willebrand factor antigen Von Willebrand RICOF Thromboelastography (TEG)	Manufacturer's instructions and documented in-house methods using: Stago Star Max Analyser (cont'd) S_HA_CD_SOP0011 S_HA_CD_SOP0072 S_HA_CD_SOP0007 S_HA_CD_SOP0023 S_HA_CD_SOP0024 S_HA_CD_SOP0014 S_HA_CD_SOP0010 S_HA_CD_SOP0032 S_HA_CD_SOP0056 Haemonetics Haemoscope thromboelastography TEG6S_HA_CD_SOP0053	JCUH
Lithium Heparin Whole Blood	TEG Platelet Mapping	S_HA_CD_SOP0053	
Serum	Heparin Induced Thrombocytopenia (HIT) test	Biorad ID-PaGIA Heparin/PF4 Particle Gel agglutination assay S_HA_CD_SOP0015	



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HUMAN BODY FLUIDS EDTA Whole blood unless stated	<p><u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u></p> <p>Group and Screen ABO and RhD Blood group</p> <p>Red cell antibody screen: Rhesus blood group antibodies: anti-Cw anti-C anti-c anti-D anti-E anti-e</p> <p>Kell System blood group antibodies: anti-K anti-k anti-Kpa</p> <p>Kidd blood group antibodies: anti-JKa anti-JKb</p> <p>Duffy blood group antibodies: anti-Fya anti Fyb</p> <p>Lutheran blood group antibodies: anti-Lua anti-Lub</p> <p>MNS blood group antibodies: anti-M anti-N anti-S anti-s</p>	<p>Manufacturer's instructions and documented in-house methods using:</p> <p>Automated: Grifols Erytra Analyser - column agglutination J_HA_BT_SOP0011</p> <p>Manual: Grifols DG - Gel column agglutination S_HA_BT_SOP0004</p> <p>Automated: Grifols Erytra Analyser - column agglutination J_HA_BT_SOP0011</p> <p>Manual: Grifols DG-Gel - column agglutination J_HA_BT_SOP0001</p>	JCUH



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HUMAN BODY FLUIDS	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
EDTA Whole blood unless stated (cont'd)	Prophylactic anti D screen	Grifols Erytra column agglutination S_HA_BT_SOP0003	
	Serological Crossmatch	Grifols DG-Gel column agglutination J_HA_BT_SOP0010	
	Direct Antiglobulin Test (DAT)	Grifols DG-Gel column agglutination S_HA_BT_SOP0010	
	Antibody titre	Grifols DG-Gel column agglutination J_HA_BT_SOP0005	
	Red Cell Phenotyping – Rhesus and Kell	Grifols DG-Gel column agglutination S_HA_BT_SOP0040	
	Kleihauer (FMH)	CliniTech Shepard's Stain Kit acid elution S_HA_BT_SOP0027	
	Differentiation of foetal from maternal blood	Alkaline denaturation test S_HA_BT_SOP0070	



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HUMAN BODY FLUIDS	<u>Immunology examination activities for the purpose of clinical diagnosis:</u>	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated	Rheumatoid factor	BNII Nephelometer J_IMM_IC_SOP015	
Serum and CSF	Immunoglobulin G		
	Immunoglobulin A		
	Ceruloplasmin		
	Alpha 1 Antitrypsin		
	Haptoglobin		
	Beta 2 Microglobulin		
	Total Immunoglobulin E		
	Complement C3		
	Complement C4		
Serum and CSF	Albumin		
	Anti-streptolysin O		
	C1 inhibitor		
	Alpha 1 Acid Glycoprotein		
	Detection of allergen specific IgE	Phadia ImmunoCAP 250 Fluorezyme immunoassay (Immunocap) J_IMM_AA_SOP028	
	Detection of specific antibodies to:	Phadia ImmunoCAP 250 Fluorezyme immunoassay (ELiA) J_IMM_AA_SOP028	
	Myeloperoxidase		
	Proteinase 3		



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HUMAN BODY FLUIDS	<u>Immunology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated	Free light chains IgG subclasses	Binding Site Optilite J-IMM-VER0017	
	Cryoglobulins	Manual technique/ Cryocrit tube Immunoprecipitation J_IMM_IC_SOP016	
	Abnormalities of serum proteins including detection and quantitation of monoclonal bands	Serum Protein Capillary Zone Electrophoresis and Immunotyping using Sebia Capillarys J_IMM_IC_SOP026	
Urine	Detection of Bence-Jones protein and monoclonal band identification	Agarose gel electrophoresis using Sebia Hydrasys J_IMM_IC_SOP027	
	Detection and identification of monoclonal bands	Agarose gel electrophoresis using Sebia Hydrasys J_IMM_IC_SOP027	
	Detection of the following antibodies:	Menarini Zenit SP+ slide processor Indirect Immunofluorescence J_IMM_AA_SOP024	
	Anti-nuclear antibody (ANA)		
	Anti-mitochondrial antibody (AMA)		
	Anti-smooth muscle antibody (SMA)		
	Gastric parietal cell antibody (GPC)		
	Reticulin Antibody		



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HUMAN BODY FLUIDS Serum unless stated	Immunology examination activities for the purpose of clinical diagnosis: (cont'd)	Manufacturer's instructions and documented in-house methods using:	JCUH
	Liver kidney microsomal LKM	Zenit - Mouse LKS slides J_IMM_AA_SOP024	
	Endomysial Antibodies	Zenit - Primate Distal Oesophagus slides J_IMM_AA_SOP024	
	Autoantibody Indirect Immunofluorescence titres	Autoantibody slide interpretation by LED Microscopy J_IMM_AA_SOP025 Menarini Zenit SP+ slide processor Autoantibody J_IMM_AA_SOP024	
	Manual Autoantibody Indirect Immunofluorescence screens:	Autoantibody manual slide processing: Autoantibody Manual Slide Processing J_IMM_AA_SOP001	
	Anti-nuclear antibody ANA		
	Anti-mitochondrial antibody AMA		
	Anti-smooth muscle antibody SMA		
	Gastric parietal cell antibody GPC		
	Reticulin Antibody		
Liver kidney microsomal LKM			



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HUMAN BODY FLUIDS	<p><u>Immunology examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Manual Autoantibody Indirect Immunofluorescence titres:</p> <p>Anti-nuclear antibody ANA titre</p> <p>Anti-mitochondrial antibody AMA titre</p> <p>Anti-smooth muscle antibody SMA titre</p> <p>Liver kidney microsomal LKM titre</p> <p>Endomysial Antibodies</p> <p>Antibodies against specific liver antigens</p> <p>Skin Pemphigus/Pemphigoid Antibodies</p>	<p>Manufacturer's instructions and documented in-house methods using:</p> <p>Autoantibody Indirect Immunofluorescence titres manual slide processing Autoantibody Indirect Immunofluorescence Screen J_IMM_AA_SOP029</p> <p>Manual slide process- Primate distal J_IMM_AA_SOP030</p> <p>Euroimmun Euroline Profile Autoimmune Liver Diseases kit - Manual method Immunoblot J_IMM_AA_SOP031</p> <p>Manual slide process- Primate distal oesphagus autoantibody - Indirect Immunofluorescence Screen Manual Slide Processing J_IMM_AA_SOP030</p>	JCUH



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HUMAN BODY TISSUES	<u>Histopathological examination activities for the purpose of clinical diagnosis:</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Tissue: biopsy, excision, resection, neuropathology and post-mortem specimens	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection Based on RCPATH guidelines using Lexacom. Macropath, safety cabinet, downdraft benches. SOPs: F_CP_HCU_SOP0006; S_CP_H01_SOP0012; J_CP_H01_SOP0136; J_CP_H01_SOP0148; S_CP_H01_SOP0237; S_CP_H01_SOP0414 J_CP_H05_SOP0126	JCUH/ FHN
Formalin fixed tissue		Tissue processing using ThermoShandon Excelsior AS processor J_CP_H02_SOP0137	JCUH
		Embedding using Leica EG1160 and Sakura Tissue Tek embedding centres S_CP_H02_SOP0129	JCUH
Formalin fixed paraffin embedded tissue blocks		Tissue sectioning by Microtomy Leica Histocore Multicut S_CP_H02_SOP0282	JCUH



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HUMAN BODY TISSUES	<u>Histopathological examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	JCUH
Fresh frozen tissue Muscle biopsies	<u>Intra operative frozen section and neuropathology smears for rapid diagnosis to identify or exclude morphological and cytological abnormalities</u>	Preparation of frozen sections and smears: Leica CM 1850 Cryostat and rapid H&E staining protocol S_CP_H05_SOP0141 Neuropathology rapid diagnosis, including manual Toluidine blue staining protocol for smears J_CP_H05_SOP0126	JCUH
Muscle biopsies	<u>Confirmation of inflammatory myopathies</u>	Muscle biopsies J_CP_H05_SOP0184 Rapid manual Haematoxylin and Eosin stain protocol J_CP_H05_SOP0141.	JCUH
Formalin Fixed Paraffin Embedded (FFPE) wax blocks of processed tissue.	Routine morphological staining for the detection and identification of clinically abnormal and normal cells and tissue components	Automated Haematoxylin and Eosin staining and coverslipping using Sakura Tissue Tek Prisma J_CP_H02_SOP0406 J_CP_H02_SOP0399	JCUH
FFPE slides	Routine morphological staining for the detection of:	Interpretive/diagnostic microscopy Renal: J_CP_H05_SOP0146; Skin: J_CP_H05_SOP0147	JCUH/ FHN
FFPE slides and frozen sections and smears	Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues	Automated Sakura Tissue Tek stainer Haematoxylin & Eosin stain Manual Haematoxylin & Eosin stain J_CP_H02_SOP0406	JCUH



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HUMAN BODY TISSUES	Histopathological examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	JCUH
FFPE tissue slides	Special Staining to identify suspected pathogens or demonstrate specific cellular components to aid the evaluation of disease states: :	Manual and Sakura Tissue Tek automated stainer J_CP_H02_SOP0406 See below - M=manual, A= Automated, B=Both	
	Acid mucins	Alcian blue (M) J_CP_H10_SOP0154	
	Fibrin, collagen, muscle	MSB (M) J_CP_H10_SOP0158	
	Basement membrane	PASilver (M) J_CP_H10_SOP0161	
	Haemosiderin	Perl's Prussian blue (M) J_CP_H10_SOP0162	
	Amyloid	Sirius red (M) J_CP_H10_SOP0165	
	Fibrin, collagen, muscle	Trichrome (M) J_CP_H10_SOP0166	
	Tubercle bacilli	Ziehl Nielson (M) J_CP_H10_SOP0168	
	Mycobacterium leprae	Wade Fite (M) J_CP_H10_SOP0170	
	Mast cells	Toluidene blue (M) J_CP_H10_SOP0175	
	Fungi	Grocott-Gomori (M) J_CP_H10_SOP0177	
	Melanin	Masson Fontana (M) J_CP_H10_SOP0178	
	Copper associated proteins	Shikata orcein (M) J_CP_H10_SOP0180	



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HUMAN BODY TISSUES	<u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	JCUH
FFPE tissue slides	Special Staining to identify suspected pathogens or demonstrate specific cellular components to aid the evaluation of disease states: : (cont'd)	Manual and Sakura Tissue Tek automated stainer J_CP_H02_SOP0406 See below - M=manual, A= Automated, B=Both	JCUH
	Reticulin fibres	Gordon & Sweet (M)J_CP_H10_SOP0208	
	Blood cells - plasma cells, megakaryocytes, mast cell granules, neutrophil granules, eosinophil granules	Giemsa for trephines (M)J_CP_H10_SOP0228	
	Elastic fibres	Millers S_CP_H10_SOP0156 (M)	
	Glycogen	PAS S_CP_H10_SOP0157 (M,A,B)	
	Acid mucins, neutral mucins	Alcian blue-PAS (M,A,B) S_CP_H10_SOP0163	
	Collagen	Van Gieson (M) S_CP_H10_SOP0167	
	Amyloid	Congo red (M) S_CP_H10_SOP0172	
	Helicobacter	Giemsa staining for helicobacter (M) S_CP_H10_SOP0173	
	Gram positive and negative organisms (bacteria)	Gram Twort staining (M) S_CP_H10_SOP0389	



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HUMAN BODY TISSUES	<u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	JCUH
Renal biopsies	Tissue morphology	Immunofluorescence, paraffin H&E and special stains J_CP_H05_SOP0146	
Skin	Tissue morphology	Immunofluorescence Microscopy, J_CP_H05_SOP0147	
FFPE tissue slides	Immunocytochemistry examination activities to detect the following (cont'd):	Ventana benchmark XT Immunocytochemistry using Ventana Ultraview kit J_CP_H11_SOP0236	
	Anaplastic large cell lymphoma	Alk1	
	Alpha-1-antitrypsin deficiency	a-1 antitrypsin	
	Yolk sac tumours, hepatocellular carcinoma	a-1-fetoprotein	
	Smooth, skeletal muscle differentiation: leiomyosarcoma, rhabdomyosarcoma, myofibroblasts, myoepithelium	Actin	



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FFPE tissue slides	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>Nodular lymphoma v. reactive hyperplasia, subset of lymphomas, carcinomas, and sarcomas</p> <p>Follicular lymphoma</p> <p>B-cell lymphoma</p> <p>(Epithelial glycoprotein) Subset of adenocarcinoma, negative on mesothelioma</p> <p>Alzheimer disease</p> <p>Nuclear localization in colorectal adenocarcinoma and abdominal fibromatosis</p> <p>Thyroid C cells, medullary carcinoma</p> <p>Mesothelioma</p> <p>Endometrial stromal tumours vs. smooth muscle tumours</p> <p>Ovarian epithelial tumours</p> <p>Langerhans cells, histiocytosis X</p> <p>Lymphoid malignancy, precursor and post-thymic lymphomas and leukemias</p> <p>T cell lymphoma</p> <p>Mature T cells, T cell lymphoma</p> <p>T cell subset</p> <p>T cells, mantle zone cells, small lymphocytic B cell lymphoma</p>	<p>Ventana benchmark XT (cont'd)</p> <p>BCL-2</p> <p>BCL-6</p> <p>BOB-1</p> <p>BerEP4</p> <p>Beta amyloid</p> <p>Beta catenin</p> <p>Calcitonin</p> <p>Calretinin</p> <p>Caldesmon</p> <p>CA125</p> <p>CD 1a</p> <p>CD2</p> <p>CD7</p> <p>CD3</p> <p>CD4</p> <p>CD5</p>	JCUH



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FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>T cell subset</p> <p>Subset of lymphomas and carcinomas</p> <p>Reed-Sternberg cells of Hodgkin lymphoma, neutrophils, some adenocarcinomas</p> <p>B cell and follicular dendritic cells and tumours</p> <p>Small lymphocytic (B cell) lymphoma</p> <p>Hodgkin lymphoma, anaplastic large cell lymphoma, embryonal carcinoma</p> <p>Endothelial cells and tumours</p> <p>Endothelium and endothelial tumours, leukaemia's, subset of mesenchymal tumours</p> <p>Hematopoietic neoplasms</p> <p>Natural killer cells (NK/T cell lymphoma), neural tumours</p> <p>Nerve sheath tumours, T cells in NLPHL</p> <p>Normal and abnormal megakaryocytes, haemopoetic malignancies</p> <p>Macrophage marker and histiocytic tumors</p> <p>B cell lymphomas</p> <p>PNET/Ewing tumours</p> <p>Gastrointestinal stromal tumours, mast cells</p>	<p>Ventana benchmark XT (cont'd)</p> <p>CD8</p> <p>CD10</p> <p>CD15</p> <p>CD21</p> <p>CD23</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD38</p> <p>CD56</p> <p>CD57</p> <p>CD61</p> <p>CD68</p> <p>CD79</p> <p>CD99</p> <p>CD117</p>	JCUH



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FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>B cell lymphoblastic leukaemia lymphoplasmocystoid leukaemia, plasma cells and myeloma</p> <p>Colorectal adenocarcinomas and subset of other GI adenocarcinomas</p> <p>Adenocarcinoma subset, negative on mesothelioma</p> <p>Adenocarcinoma subset, hepatocellular carcinoma (bile canalicular pattern), negative on mesothelioma</p> <p>Neuroendocrine differentiation</p> <p>Mesothelioma, squamous cell carcinoma, transitional cell carcinoma</p> <p>Pancreaticobiliary carcinomas, urothelial carcinoma, breast carcinoma, lung carcinoma, ovarian carcinoma</p> <p>Carcinoma subset</p> <p>GI tumours, transitional cell carcinoma, Merkel cell tumours</p> <p>Carcinoma subset; normal or hyperplastic prostate v. prostatic carcinomas</p> <p>Mantle cell lymphoma</p>	<p>Ventana benchmark XT (cont'd)</p> <p>CD138</p> <p>CDX2</p> <p>CEA (mono)</p> <p>CEA (poly)</p> <p>Chromogranin</p> <p>CK5</p> <p>CK7</p> <p>CK19</p> <p>CK20</p> <p>CK34 - 34BE12</p> <p>Cyclin D1 GM</p>	JCUH



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FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following: (cont'd)</u></p> <p>All epithelial cells and all carcinomas</p> <p>Epithelial cells, most carcinomas, adenomatoid tumor</p> <p>Epithelial cells, most carcinomas, mesothelioma</p> <p>Skeletal, smooth muscle tumours</p> <p>Gastrointestinal stromal tumors (GIST)</p> <p>Epstein Barr Virus latent membrane protein</p> <p>Epithelial membrane antigen Some carcinomas, meningioma, anaplastic large cell lymphoma</p> <p>Prostate adenocarcinomas</p> <p>Prognostic and predictive marker in breast and other carcinomas</p> <p>Positive on ductal, negative on lobular breast carcinomas</p> <p>Dermal dendrocytes, dermatofibroma</p> <p>Breast carcinomas and urothelial carcinomas</p> <p>Glioma</p> <p>Breast, salivary, sweat gland tumours</p>	<p>Ventana benchmark XT (cont'd)</p> <p>Cytokeratin AE1/AE3</p> <p>Cytokeratin CAM5.2</p> <p>Cytokeratin MNF</p> <p>Desmin</p> <p>DOG-1</p> <p>EBV</p> <p>EMA</p> <p>ERG</p> <p>Estrogen receptor</p> <p>E-Cadherin</p> <p>Factor 13a</p> <p>GATA 3</p> <p>GFAP</p> <p>GCDFP</p>	JCUH



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FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>Trophoblasts and choriocarcinoma</p> <p>melanoma</p> <p>Subset of myeloma</p> <p>Subset of myeloma</p> <p>Subset of myeloma</p> <p>Granulosa cell tumours, adrenal cortical tumours</p> <p>Myeloma, some B cell lymphomas</p> <p>Hodgkin lymphoma, anaplastic large cell lymphoma, embryonal carcinoma</p> <p>Cell proliferation marker</p> <p>B cell lymphomas, target of immunotherapy</p> <p>Myeloma, some B cell lymphomas</p> <p>Common leukocyte antigen, T200 antigen) Marker of lymphocytes, hematolymphoid processes</p>	<p>Ventana benchmark XT (cont'd)</p> <p>HCG</p> <p>HMB45</p> <p>IgD</p> <p>IgG</p> <p>IgM</p> <p>Inhibin</p> <p>Kappa</p> <p>CD30</p> <p>Ki67</p> <p>L26 (CD20)</p> <p>Lambda</p> <p>LCA (CD45)</p>	JCUH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>Reed-Sternberg cells of Hodgkin lymphoma, neutrophils, some adenocarcinomas</p> <p>Epstein Barr Virus</p> <p>Melanoma, adrenal cortical and ovarian stromal tumours</p> <p>T cells, leukemias, macrophages, often coexpressed in B cell lymphomas</p> <p>B cell Lymphomas</p> <p>Granulocytes and histocytes, marker of leukaemia</p> <p>Rhabdomyosarcoma</p> <p>Smooth muscle and skeletal muscle</p> <p>Lung adenocarcinomas</p> <p>Neurons and neuronal tumours</p> <p>B cell Lymphomas</p> <p>Carcinoma including ovarian serous carcinoma, clear cell renal cell carcinoma, and papillary thyroid carcinoma</p>	<p>Ventana benchmark XT (cont'd)</p> <p>CD15</p> <p>LMP</p> <p>Melan A</p> <p>MT1 (CD43)</p> <p>MUM-1</p> <p>Myeloperoxidase</p> <p>Myogenin</p> <p>Myosin</p> <p>Napsin A</p> <p>Neurofilament protein</p> <p>PAX5</p> <p>PAX8</p>	JCUH



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FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>Placental alkaline phosphatase Seminoma</p> <p>Lymphatic endothelium</p> <p>Breast (prognostic and predictive marker) meningiomas</p> <p>Prostate carcinoma</p> <p>Prostate carcinoma</p> <p>Prostate carcinoma</p> <p>Cervical cancers, high grade cervical intraepithelial neoplasia, serous carcinomas, squamous cell carcinoma in oral pharynx.</p> <p>Tumour suppressor gene product over expressed in subset of malignancies - marker of p53 mutation and poor prognosis</p> <p>Distinction between complete and partial hydatidiform moles</p> <p>Myoepithelial marker, in situ v. infiltrating breast carcinoma; squamous, transitional cell marker; lost in prostatic adenocarcinomas</p> <p>Prostate carcinoma marker</p> <p>Primary renal cell carcinoma</p> <p>Germ cell tumours</p> <p>Melanoma</p> <p>Melanoma, Schwann cells, neural support cells, Langerhans histiocytes</p>	<p>Ventana benchmark X (cont'd)</p> <p>PLAP</p> <p>Podoplanin</p> <p>Progesterone</p> <p>PSA</p> <p>PSAP</p> <p>PSMA</p> <p>P16</p> <p>P53</p> <p>P57</p> <p>P63</p> <p>P504s</p> <p>Renal cell carcinoma</p> <p>SALL 4</p> <p>SOX 10</p> <p>S100</p>	JCUH



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FFPE tissue slides (cont'd)	<p><u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)</p> <p>Neuroendocrine differentiation (e.g., sm. cell CA), neuroblastoma</p> <p>Progressive supranuclear palsy</p> <p>Acute lymphoblastic lymphomas and leukaemias.</p> <p>Mesothelioma</p> <p>Thyroid follicular tumours</p> <p>Lung and thyroid carcinomas</p> <p>Sarcomas, lymphomas, co-expressed with cytokeratin in some carcinomas</p> <p>Wilm's tumour gene product - desmoplastic small round cell tumour, mesothelioma, ovarian surface epithelial tumours</p>	<p>Ventana benchmark XT (cont'd)</p> <p>Synaptophysin</p> <p>Tau</p> <p>TDT</p> <p>Thrombomodulin</p> <p>Thyroglobulin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT1</p>	JCUH



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HUMAN BODY TISSUES	<u>Immunocytochemistry examination activities to detect the following:</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	JCUH
Frozen tissue sections	FITC IgA FITC IgG FITC IgM FITC IgLambda FITC IgKappa FITC IgC3 FITC IgC1q	Manual slide preparation and Fluorescent microscope J_CP_H05_SOP0147	
HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis:</u>	Based on In-house Royal College of Pathologists guidelines, British Society for Clinical Cytology: Codes of Practice, documented procedures using manual methods and analysers in conjunction with manufacturers' instructions as specified:	JCUH
Biological material - slides, Needle rinse fluid		Diff-Quick staining S_CP_CNG_SOP0019 Thinprep T2000 processor J_CP_CTP_SOP0001	
Fine Needle Aspirates: Breast, Thyroid, Lung, Head and Neck, Lymph nodes, skin, other lesions/tissue.	Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities	Safety cabinet, staining machine, coverslipper: J_CP_CNG_SOP0029 J_CP_CNG_SOP0057	



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HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Based on In-house Royal College of Pathologists guidelines, British Society for Clinical Cytology: Codes of Practice, documented procedures using manual methods and analysers in conjunction with manufacturers' instructions as specified:	JCUH
Epithelial cells & non-epithelial cells from: Urine, Sputum, Serous fluid, peritoneal washings, bladder washings, CSF, cyst aspirates, synovial fluid, endometrial aspirate, needle rinse fluids and other human tissues/fluids	Determination of presence/absence of malignant and inflammatory cells	Safety cabinet, centrifuge, cytospin, T2000 staining machine, coverslipper S_CP_CNG_SOP0034 J_CP_CNG_SOP0049 S_CP_CNG_SOP0041 J_CP_CNG_SOP0011 S_CP_CNG_SOP0009J_CP_CNG_SOP0015 J_CP_CNG_SOP0029	
Endoscopic Washings/Brushings Aspirated fluid	Determination of presence/absence of malignant cells	S_CP_CNG_SOP0012	
Brush in transport medium	Determination of presence/absence of malignant cells	S_CP_CNG_SOP0013	
Nipple discharge	Determination of presence/absence of malignant cells	J_CP_CNG_SOP0029	
Biological material - slides	Eosinophil staining in non-gynae specimens	Safety cabinet, centrifuge J_CP_CNG_SOP0020	
Cell suspension/fluid	Cell block preparation (+/- ICC)	Safety cabinet, centrifuge - histology processing S_CP_CNG_SOP0002	
Previously stained PAP slides	Immunocytochemistry on previously stained PAP slides	ICC processing S_CP_CNG_SOP0055	



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HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Based on In-house Royal College of Pathologists guidelines, British Society for Clinical Cytology: Codes of Practice, documented procedures using manual methods and analysers in conjunction with manufacturers' instructions as specified:	JCUH
Cell suspension	Treatment of ThinPrep halo's, or those containing much blood, protein or non-cellular debris	Safety cabinet, centrifuge, T2000, staining machine, coverslipper Hologic T2 Operator's Manual J_CP_CNG_SOP0010	
CSF	Smear preparation for the purposes of staining/slide reading for identification of WBC (see above)	Cytocentrifugation J_CP_CNG_SOP0015	
Stained prepared slides		Microscope S_CP_CSC_SOP0014	
Stained prepared slides	BMS reporting of negative non-gynae specimens including urine, bronchial and serous effusion samples	Microscope J_CP_CMA_SOP0012	
Fine needle aspirates from ENT clinic - head and neck lumps and bumps	Determination of presence/absence of malignant cells	Safety cabinet, hair-dryer, centrifuge, cytospin, T2000, staining machine, coverslipper J_CP_CNG_SOP0029	
Fine needle aspirates from Breast clinic	Determination of presence/absence of malignant cells	J_CP_CNG_SOP0029 J_CP_CNG_SOP0011	
Slides prepared as above	Morphological assessments and interpretation/diagnosis	Using light microscopy	



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis:</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Blood	Isolation and characterisation of microorganisms of clinical significance	Using in-house procedures listed below:	
Bone, tissue, prosthetics, joints	Isolation and characterisation of microorganisms of clinical significance	Biomerieux BacTAlert automated continuous monitoring blood culture system and standard bacteriological culture, identification and microscopy methods S_B_SPE0006	
CSF	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods and enrichment culture S_B_SPE0057	
CSF shunts	Quantitative cell counts, Isolation and characterisation of microorganisms of clinical significance	Quantitative cell counts using KOVA slides S_B_SPE0044 Standard bacteriological culture, identification and microscopy methods S_B_SPE0007	
CAPD fluid	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods S_B_SPE0007	
	Quantitative cell counts, isolation and characterisation of microorganisms of clinical significance	Quantitative cell counts using KOVA slides S_B_SPE0044 Standard bacteriological culture, identification and microscopy methods J_B_SPE0001	



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HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Corneal scrape/intraocular fluid/contact lens	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods S_B_SPE0014	
Ear/Eye/Nose/Throat/Oral swabs and Antral washout	Isolation and characterisation of microorganisms of clinical significance	Automated sample inoculation using the Copan Walk Away Specimen Processor (WASP) S_B_EQU0013 Standard bacteriological culture, identification and microscopy methods S_B_SPE0010 , S_B_SPE0014, S_B_SPE0020, S_B_SPE0022	
Faeces	Isolation of bacterial enteric pathogens including: <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp. <i>Escherichia coli</i> O157 <i>Campylobacter</i> spp.	Standard bacteriological culture, identification and microscopy methods S_B_SPE0003	



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HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Faeces	Detection of Clostridium difficile glutamate dehydrogenase and Toxins A & B	Techlab C.diff QuikChek Complete for GDH and Toxins A & B, with confirmation of positives by PCR using Cepheid GeneXpert® C.difficile kit S_M_SPE0001	
Faeces, Urine	Detection of Ova, Cysts and Parasites (OCP)	Microscopic examination for ova and cysts of human parasites either direct and/or faecal concentration using the Diasys Parasep system S_B_SPE0035	
Faeces	<i>Cryptosporidium</i> oocysts	Auramine phenol/UV microscopic examination S_B_SPE0045, S_B_SPE0003	
Genital/HVS/cervical/penile/ urethral swabs and IUCD	Isolation and characterisation of microorganisms of clinical significance, including microscopy for the presence of bacterial vaginosis and Trichomonas vaginalis when clinically indicated	Automated sample inoculation using the Copan Walk Away Specimen Processor (WASP) S_B_EQU0013 Standard bacteriological culture, identification and microscopy methods using the Hayes methodology and an inverted microscope when indicated S_B_SPE0009	
Nose/throat and groin/perineum swabs	Methicillin-Resistant Staphylococcus aureus (MRSA) screening	Bacteriological culture using Biomerieux ChromID MRSA agar and PCR using Cepheid GeneXpert MRSA NxG kit S_B_SPE0024	
Pernasal swab	Isolation and characterisation of Pertussis spp	Standard bacteriological culture, identification and microscopy methods S_B_SPE0026	



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HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Pus/sterile/non-sterile fluids, including bile and pleural fluid	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods and enrichment culture S_B_SPE0008 Quantitative cell counts using KOVA slides (sterile fluids) S_B_SPE0044	
Rectal swabs/faeces	Carbapenemase screening	Bacteriological culture using Biomerieux CarbaSmartChromID Bi-plate S_B_ANT0011 PCR using the Cepheid GeneXpert Carba-R kit S_B_ANT0013	
Skin/hair/nails/sputum	Isolation and characterisation of fungi of clinical significance	Fungal culture, macroscopic analysis and microscopic analysis using Calcofluor white reagent/UV microscope and Lactophenol Cotton Blue/light microscope S_B_SOP0004, S_B_SPE0049, S_B_SPE0050	
Sputum/pus/fluid	Identification of Acid and Alcohol Fast Bacilli (AAFB)	Auramine phenol stain using fluorescent microscopy S_B_SOP0004	
Sputum/respiratory secretions/bronchoalveolar lavage	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods S_B_SPE0004	
Respiratory samples from patients with Cystic Fibrosis	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods S_B_SPE0055	



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HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Urine	Cell counts, culture and characterisation of microorganisms of clinical significance	Automated cell counts using Beckman Coulter iQ200 IRIS Sprint analyser S_B_EQU0005 Bacteriological culture using Biomerieux CPSE Chromogenic agar S_B_SPE0001	
Wound/skin/ulcer/abscess swabs/IV line tips	Isolation and characterisation of microorganisms of clinical significance	Automated sample inoculation using the Copan Walk Away Specimen Processor (WASP) S_B_EQU0013	
Bacterial & fungal isolates cultured in-house from the above	Identification/ classification of clinically significant bacteria and fungi	Automated identification using: Bruker MALDI-TOF-MS S_B_EQU0010	
Bacterial & fungal isolates cultured in-house from the above	Identification/classification of clinically significant bacteria and fungi	Biomerieux Analytical Profile Index (API) test kits S_B_SOP0060	



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Bacterial isolates cultured in-house from the above	Antibiotic susceptibility testing	EUCAST methodology by disc diffusion using zone size templates S_B_ANT0009 EUCAST MICs E tests S_B_ANT0002 Micro broth dilution using the Merlin kit S_B_ANT0015	
Yeast isolates cultured in-house from the above	Antifungal susceptibility testing	Micro broth dilution using Sensititre YeastOne kit S_B_ORG0001	
	Extended Spectrum Beta-Lactamases /AmpC	MAST 4-disc D68C S_B_ANT0009	
	Extended Spectrum Beta-Lactamases	MAST 6-disc D52C S_B_ANT0009	
	AmpC	MAST 3-disc D69C S_B_ANT0009	
Bacterial isolates cultured in-house from the above	Rapid Carbapenem detection by PCR	Meropenem 10ug disc S_B_ANT0014	
Bacterial isolates cultured in-house from the above	Rapid Carbapenemase detection	Bio-Rad Rapid β Carba kit S_B_ANT0012	
Bacterial isolates cultured in-house from the above	Carbapenemase confirmation/detection	Carba-R Kit PCR using the Cepheid GeneXpert® S_B_ANT0013	
Bacterial isolates cultured in-house from the above	Salmonella confirmation	Remel Salmonella anti sera S_B_ORG0015	



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	JCUH
Bacterial isolates cultured in-house from the above	Meningitis confirmation	Bio Rad Meningitis antisera kit S_B_SPE0007	
Bacterial isolates cultured in-house from the above	Identification of Streptococcal Groups A, B, C, D, F and G	Prolab streptococcal grouping kit S_B_ORG0028	
Staphylococcal isolates cultured in-house from the above	Detection of the fibrinogen affinity (clumping factor), protein A, and capsular polysaccharides of Staphylococcus aureus	Pastorex Staph-plus kit S_B_ORG0032	
Bacterial isolates cultured in-house from the above	Identification/classification of clinically significant microorganisms	Gram staining S_B_SPE0040	
Serum unless stated	<u>Serological examination activities for the purpose of clinical diagnosis:</u>	In-house documented procedures using the following equipment and SOPs: Siemens Advia Centaur XP Direct Chemiluminescence using Acridinium Ester Technology J_BC_END_SOP0065 and procedures below	
	Hepatitis A IgM	S_V_SOP0065	
	Hepatitis A total antibody	S_V_SOP0065	
	Hepatitis B surface antigen	S_V_SOP0029	
	Hepatitis B core total antibody	S_V_SOP0029	
	Hepatitis B surface antibody	S_V_SOP0066	
	Hepatitis C antibody	S_V_SOP0067	
	HIV antibody/antigen	S_V_SOP0064	
	Syphilis total antibody	S_V_SOP0045	
	Rubella IgG	S_V_SOP0068	
	Rubella IgM	S_V_SOP0068	
	Toxoplasma IgG	S_V_SOP000069	
	Toxoplasma IgM	S_V_SOP0065	



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HUMAN TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures using the following equipment and SOPs:	JCUH
Serum unless stated (cont'd)		Biomerieux Vidas 3 Enzyme linked fluorescent assay S_V_EQU0017 and procedures below	
	Hepatitis B core IgM	S_V_SOP0080	
	Hepatitis B 'e' antigen	S_V_SOP0077	
	Hepatitis B 'e' antibody	S_V_SOP0078	
	HIV antibody/antigen	S_V_SOP0080	
	HIV p24 antigen	S_V_SOP0080	
	Rubella IgG	S_V_SOP0072	
	Cytomegalovirus IgG	S_V_SOP0076	
	Cytomegalovirus avidity	S_V_SOP0076	
	Epstein Barr Virus (EBV) IgM	S_V_SOP0075	
	Epstein Barr Virus (EBV) IgG	S_V_SOP0075	
	Epstein Barr Virus Nuclear Antibody (EBNA) IgG	S_V_SOP0075	
	Measles IgG	S_V_SOP0074	
	Varicella zoster IgG	S_V_SOP0073	
	Borrelia IgG	S_V_SOP0070	
	Borrelia IgM	S_V_SOP0071	
	Mumps IgG	S_V_SOP0071	



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HUMAN TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures using the following equipment and SOPs:	JCUH
Serum unless stated (cont'd)		Dynex DS2 Enzyme linked immunosorbent assay S_V_EQU0001 and procedures below	
	Hepatitis C antibody/antigen	S_V_SOP0012	
	Cytomegalovirus IgG	S_V_SOP0013	
	Cytomegalovirus IgM	S_V_SOP0082	
	Parvovirus B19 IgM	S_V_SOP0052	
	Parvovirus B19 IgG	S_V_SOP0052	
	Hepatitis E IgG	S_V_SOP0056	
	Hepatitis E IgM	S_V_SOP0056	
	Measles IgM	S_V_SOP0042	
	Mumps IgM	S_V_SOP0043	
	Mycoplasma IgM	S_V_SOP0044	
Stool	<i>Helicobacter pylori</i> antigen	S_V_SOP0016	
Serum	HIV typing I/II	BioRad Geenius HIV 1/2 Confirmatory assay J_V_SOP0062	
Urine	Legionella antigen	TRU Legionella lateral flow immunoassay S_V_SOP0101	
	Pneumococcal antigen	TRU Strep pneumo lateral flow immunoassay S_V_SOP0100	



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HUMAN TISSUES AND FLUIDS	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis:</u>	Extraction, PCR amplification and detection using equipment and procedures stated below	JCUH
CSF, skin swab, genital swab, conjunctival swab, EDTA whole blood, oral swab	<i>Herpes simplex I&II DNA</i> Varicella zoster virus DNA	Applied Biosystems ABI 7500 RT-PCR J_V_EQU0015 and procedures below S_V_SOP0049	
CSF	Enterovirus RNA	S_V_SOP0085	
CSF	Parechovirus RNA	S_V_SOP0085	
Conjunctival swab, Stool, EDTA Whole Blood	Adenovirus DNA	S_V_SOP0051	
EDTA whole blood, BAL, Urine	Cytomegalovirus DNA	S_V_SOP0050	
Nasopharyngeal aspirate/secretions, throat swab, BAL	Respiratory syncytial virus RNA	S_V_SOP0039	
Nasopharyngeal aspirate/secretions, throat swab, BAL	Influenza A RNA	S_V_SOP0039	
Nasopharyngeal aspirate/secretions, throat swab, BAL	Influenza B RNA	S_V_SOP0039	
Nasopharyngeal aspirate/secretions, throat swab, BAL	Parainfluenza 1,2,3 and 4	S_V_SOP0039	
Nasopharyngeal swabs	Influenza A RNA	Cepheid GeneXpert RT-PCR / PCR / qualitative genotyping S_V_EQU0015 and procedures below S_V_SOP0059	
Nasopharyngeal swabs	Influenza B RNA	S_V_SOP0059	



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ISO 15189:2012

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

South Tees Hospitals NHS Foundation Trust

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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 TISSUES AND FLUIDS	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Extraction, PCR amplification and detection using equipment and procedures stated below	JCUH
Nasopharyngeal swab	RSV	Cepheid GeneXpert (cont'd) S_V_SOP0059	
EDTA whole blood	BCR ABL	S_V_SOP0057	
EDTA whole blood	Factor II &Factor V	S_V_SOP0054	
Endocervical swab, vaginal swab, urethral swab, urine, rectal swab, throat swab, eye swab, penile swab, vulval swab	<i>Chlamydia trachomatis</i> DNA	Hologic Panther RT-PCR/PCR S_V_EQU0018 and procedures below: S_V_SOP0093	
Endocervical swab, vaginal swab, urethral swab, urine, rectal swab, throat swab, eye swab, penile swab, vulval swab	<i>Neisseria gonorrhoea</i> DNA	S_V_SOP0093	
EDTA whole blood, serum	HIV-1 RNA	S_V_SOP0095	
	Hepatitis C RNA	S_V_SOP0094	
	Hepatitis B DNA	S_SOP0099	

END