


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	South Tees Hospitals NHS Foundation Trust	
	Issue Number: 008	Issue Date: 04 September 2024
	South Tees Hospitals NHS Foundation Trust Pathology Services The James Cook University Hospital Marton Road Middlesbrough TS4 3BW United Kingdom	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
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Pathology Services The James Cook University Hospital Marton Road Middlesbrough TS4 3BW United Kingdom Local contact Dr Dianne Plews Tel: +44 (0)1642 854381	Haematology Blood transfusion including storage & issue of blood and blood products Special Haematology including Molecular Haematology Biochemistry Immunology Microbiology Virology Cellular Pathology	JCUH
Address Friarage Hospital Bullamoor Road Northallerton DL6 1JG United Kingdom Local contact Dr Dianne Plews Tel: +44 (0)1642 854381	Haematology Storage & issue of blood and blood products Biochemistry Cellular Pathology	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:	
Serum unless stated		Siemens ADVIA XPT S-BC-AUT-SOP0061 and procedures below:	JCUH
	Albumin	Photometry - End point S_BC_AUT_SOP0002	JCUH
	Bicarbonate	Photometry - Enzymatic S_BC_AUT_SOP0008	JCUH
Serum, Urine	Calcium	Photometry - End point S_BC_AUT_SOP0010	JCUH
Serum, Urine	Chloride	Ion Selective Electrode S_BC_AUT_SOP0012	JCUH
Serum, Urine	Creatinine	Photometry - Kinetic S_BC_AUT_SOP0016	JCUH
	C-Reactive Protein	Photometry - Turbidimetry S_BC_AUT_SOP0017	JCUH
Serum, CSF, Urine	Glucose	Photometry - End point S_BC_AUT_SOP0023	JCUH
Serum, Urine	Magnesium	Photometry - End point S_BC_AUT_SOP0034	JCUH
Serum, Urine	Phosphate	Photometry - End point S_BC_AUT_SOP0038	JCUH
Serum, Urine	Potassium	Ion Selective Electrode S_BC_AUT_SOP0039	JCUH
Serum, Urine	Sodium	Ion Selective Electrode S_BC_AUT_SOP0041	JCUH



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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:	
Serum unless stated		Siemens ADVIA XPT (cont'd)	
	Total Bilirubin	Photometry - End point S_BC_AUT_SOP0043	JCUH
Serum	Total Protein	Photometry - End point S_BC_AUT_SOP0044	JCUH
Serum, Urine	Urea	Photometry - Enzymatic S_BC_AUT_SOP0046	JCUH
Serum, Urine	Uric Acid	Photometry - End point S_BC_AUT_SOP0047	JCUH
	Creatinine (Enzymatic)	Photometry - Enzymatic S_BC_AUT_SOP0057	JCUH
	Angiotensin Converting Enzyme (ACE)	Photometry - Enzymatic S_BC_AUT_SOP0001	JCUH
	Alkaline Phosphatase (ALP)	Photometry - Enzymatic S_BC_AUT_SOP0003	JCUH
	Alanine Aminotransferase (ALT)	Photometry - Enzymatic S_BC_AUT_SOP0004	JCUH
Serum, Urine	Amylase	Photometry - Enzymatic S_BC_AUT_SOP0006	JCUH
	Aspartate Aminotransferase (AST)	Photometry - Enzymatic S_BC_AUT_SOP0007	JCUH
	Creatine Kinase (CK)	Photometry - Enzymatic S_BC_AUT_SOP0014	JCUH
	Gamma Glutamyl Transferase (GGT)	Photometry - Enzymatic S_BC_AUT_SOP0022	JCUH



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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:	
Serum unless stated (cont'd)		Siemens ADVIA XPT (cont'd)	
	Lactate Dehydrogenase (LDH)	Photometry - Enzymatic S_BC_AUT_SOP0031	JCUH
	Cholesterol	Photometry - End point S_BC_AUT_SOP0013	JCUH
	HDL Cholesterol	Photometry - End point S_BC_AUT_SOP0024	JCUH
	Triglyceride	Photometry - End point S_BC_AUT_SOP0045	JCUH
	Carbamazepine	Photometry -EMIT S_BC_AUT_SOP0011	JCUH
	Lithium	Photometry - End point S_BC_AUT_SOP0033	JCUH
	Phenytoin	Photometry -EMIT S_BC_AUT_SOP0037	JCUH
	Theophylline	Photometry -EMIT S_BC_AUT_SOP0042	JCUH
	Valproate	Photometry -EMIT S_BC_AUT_SOP0050	JCUH
	Ethanol	Photometry - Enzymatic S_BC_AUT_SOP0021	JCUH
	Paracetamol	Photometry - End point S_BC_AUT_SOP0036	JCUH
	Salicylate	Photometry - End point S_BC_AUT_SOP0040	JCUH



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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:	
Serum unless stated (cont'd)		Siemens ADVIA XPT (cont'd)	
	Immunoglobulin A	Photometry - Turbidimetry S_BC_AUT_SOP0025	JCUH
	Immunoglobulin G	Photometry - Turbidimetry S_BC_AUT_SOP0026	JCUH
	Immunoglobulin M	Photometry - Turbidimetry S_BC_AUT_SOP0027	JCUH
	Ammonia	Photometry - End Point S_BC_AUT_SOP0005	JCUH
	Bile Acids	Photometry - Enzymatic S_BC_AUT_SOP0009	JCUH
	Direct Bilirubin	Photometry - End point S_BC_AUT_SOP0020	JCUH
	Lactate	Photometry - End point S_BC_AUT_SOP0030	JCUH
CSF and Urine	Protein	Photometry - End Point S_BC_AUT_SOP0048	JCUH
		Siemens Centaur XPT CLIA S_BC_END_SOP0065 and procedures below	JCUH
	Cortisol	S_BC_END_SOP0008	JCUH
	Digoxin	S_BC_END_SOP0053	JCUH
	Gentamicin	S_BC_END_SOP0052	JCUH
	Vancomycin	S_BC_END_SOP0051	JCUH
	Alpha-Fetoprotein (AFP)	S_BC_END_SOP0001	JCUH



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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:	
Serum unless stated		Siemens Centaur XPT (cont'd)	
	CA-125	S_BC_END_SOP0003	JCUH
	CA 15-3	S_BC_END_SOP0004	JCUH
	CA19-9	S_BC_END_SOP0005	JCUH
	Carcino-Embryonic Antigen	S_BC_END_SOP0006	JCUH
	Procalcitonin	S_BC_END_SOP0062	JCUH
	Prostate Specific Antigen (PSA)	S_BC_END_SOP0024	JCUH
	Free T3 (FT3)	S_BC_END_SOP0012	JCUH
	Free T4 (FT4)	S_BC_END_SOP0013	JCUH
	Thyroid Stimulating Hormone (TSH)	S_BC_END_SOP0029	JCUH
	Brain Natriuretic Peptide (BNP)	S_BC_END_SOP0050	JCUH
	High Sensitivity Troponin-I	S_BC_END_SOP0046	JCUH
	Thyroid Peroxidase Antibody (TPO)	S_BC_END_SOP0054	JCUH
	Ferritin	S_BC_END_SOP0010	JCUH
	Folate	S_BC_END_SOP0011	JCUH
	Vitamin B12	S_BC_END_SOP0033	JCUH



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



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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:	
Serum unless stated (cont'd)		Roche E411 ECLIA (cont'd)	
	Beta-Crosslaps	S_BC_END_SOP0002	JCUH
	Parathyroid Hormone (PTH)	S_BC_END_SOP0025	JCUH
		IDS iSys CLIA using procedures below	
	25-Hydroxy Vitamin D	S_BC_SPC_SOP0027	JCUH
	IGF-1	S_BC_SPC_SOP0051	JCUH
	Growth Hormone	S_BC_SPC_SOP0050	JCUH
		Roche E411 ECLIA using procedures below	
	P1NP	S_BC_END_SOP0064	JCUH
Urine	Free Cortisol	S_BC_END_SOP0032	JCUH
	ACTH	S_BC_END_SOP0055	JCUH
	DHEAS	S_BC_END_SOP0058	JCUH
	Insulin	S_BC_END_SOP0057	JCUH
	C-Peptide	S_BC_END_SOP0056	JCUH
	HCG (Tumour Marker)	S_BC_END_SOP0038	JCUH
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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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:	
Whole Blood	Glycated Haemoglobin	Menarini Hb9210 Borate Affinity HPLC S_BC_SPC_SOP0052	JCUH
Faeces	Calprotectin	Alpha Labs Automated Siemens XPT Buhlmann Turbo S_BC_SPC_SOP0046	JCUH
Sweat	Chloride	Elitech Chlorocheck 3500 chloride meter Coulometry J_BC_SPC_SOP0020	JCUH
Serum unless stated		Siemens Atellica Solution using S-BC-AUT-SOP0062 and procedures below:	
	Alanine Aminotransferase (ALT)	Photometry – Enzymatic S_BC_AUT_SOP0004	FHN
	Albumin (ALB)	Photometry - End point S_BC_AUT_SOP0002	FHN
	Alkaline Phosphatase (ALP)	Photometry – Enzymatic S_BC_AUT_SOP0003	FHN
Serum and Urine	Chloride (CL)	A-LYTE Integrated Multisensor S_BC_AUT_SOP0012	FHN



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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:	
Serum unless stated		Siemens Atellica Solution cont'd S-BC-AUT-SOP0062	
Serum and Urine	Sodium	A-LYTE Integrated Multisensor S_BC_AUT_SOP0041	FHN
Serum and Urine	Potassium	A-LYTE Integrated Multisensor S_BC_AUT_SOP0039	FHN
Serum and Urine	Amylase	Photometry – Enzymatic S_BC_AUT_SOP0006	FHN
	Aspartate Aminotransferase (AST)	Photometry – Enzymatic S_BC_AUT_SOP0007	FHN
Serum and Urine	Calcium (Ca)	Photometry - End point S_BC_AUT_SOP0010	FHN
	Carbon Dioxide (CO2_c)	Photometry - Enzymatic	FHN
	Cholesterol (CHOL_2)	Photometry - End point S_BC_AUT_SOP0013	FHN
	C-Reactive Protein (CRP_2)	Photometry – Turbidimetry S_BC_AUT_SOP0017	FHN
	Creatine Kinase (CK_L)	Photometry – Enzymatic S_BC_AUT_SOP0014	FHN
Serum and Urine	Creatinine_2 (Crea_2)	Photometry - Kinetic S_BC_AUT_SOP0016	FHN
	Direct Bilirubin (DBIL_2)	Photometry - End point S_BC_AUT_SOP0020	FHN



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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:	
Serum unless stated		Siemens Atellica Solution cont'd S-BC-AUT-SOP0062	FHN
	Enzymatic Creatinine (ECRE_2)	Photometry – Enzymatic S_BC_AUT_SOP0057	FHN
	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	FHN
	Free T4 (FT4)	CLIA S_BC_END_SOP0014	FHN
	Gamma-Glutamyl Transferase (GGT)	Photometry – Enzymatic S_BC_AUT_SOP0022	FHN
Serum and Urine	Glucose (Glu)	Photometry - End point S_BC_AUT_SOP0023	FHN
	High Density Lipoprotein (D-HDL)	Photometry - End point S_BC_AUT_SOP0024	FHN
	High Sensitivity Troponin I (TnIH)	CLIA S_BC_END_SOP0066	FHN
Serum and Urine	Inorganic Phosphate (IP)	Photometry - End point S_BC_AUT_SOP0038	FHN
	Iron (IRON_2)	Photometry - End point F_BC_AUT_SOP0088	FHN
	Lactate (LAC)	Photometry - End point S_BC_AUT_SOP0030	FHN



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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:	
Serum unless stated		Siemens Atellica Solution cont'd S-BC-AUT-SOP0062	FHN
	Lactate Dehydrogenase (LDH)	Photometry – Enzymatic S_BC_AUT_SOP0031	FHN
Serum and Urine	Magnesium (MG)	Photometry - End point S_BC_AUT_SOP0034	FHN
Urine	Microalbumin (uALB_2)	Photometry - End point F_BC_AUT_SOP0071	FHN
	Paracetamol (ACET)	Photometry - End point S_BC_AUT_SOP0036	FHN
	Prostate-Specific Antigen (PSA)	CLIA S_BC_END_SOP0024	FHN
	Salicylate (SAL)	Photometry - End point S_BC_AUT_SOP0040	FHN
	Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)	CLIA S_BC_END_SOP0029	FHN
	Total Bilirubin_2 (TBil_2)	Photometry - End point S_BC_AUT_SOP0043	FHN
	Total hCG (ThCG)	CLIA S_BC_END_SOP0016	FHN
Serum	Total Protein II (TP)	Photometry - End point S_BC_AUT_SOP0044	FHN
	Transferrin (TRF)	CLIA F_BC_AUT_SOP0089	FHN



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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:	
Serum unless stated		Siemens Atellica Solution cont'd S_BC-AUT-SOP0062	FHN
	Triglycerides (TRIG)	Photometry - End point S_BC_AUT_SOP0045	FHN
Serum and Urine	Urate (UA)	Photometry - End point S_BC_AUT_SOP0047	FHN
Serum and Urine	Urea	Photometry – Enzymatic S_BC_AUT_SOP0046	FHN
Urine	Protein (UCFP)	Photometry - End point S_BC_AUT_SOP0048	FHN
	Vitamin B12 (VB12)	CLIA S_BC_END_SOP0033	FHN
CSF	Xanthochromia analysis	Northstar Bio-UV spectrophotometer J_BC_SPC_SOP0028	JCHU
Faeces	Elastase analysis	Diasorin analyser immunoassay J_BC_SPC_SOP0006	JCHU



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HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis:</u>	Documented in-house methods to meet the requirements of the SCT screening programme as defined in the NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements. <i>An asterisk shall be used to identify the tests which form part of the ANNB programme</i>	
EDTA Whole blood unless stated	*Full blood count including the following parameters:	Siemens Advia 2120, laser 2D light scatter S_HA_HAE_SOP0001	JCUH/ FHN
	White Blood Cells (WBC)*		JCUH/ FHN
	Red Blood Cell Count (RBC)*		JCUH/ FHN
	Haemoglobin (Hb)*		JCUH/ FHN
	Platelets*		JCUH/ FHN
	WBC Differential*		JCUH/ FHN
	Mean corpuscular volume (MCV)*		JCUH/ FHN
	Mean corpuscular haemoglobin (MCH)*		JCUH/ FHN
	Mean corpuscular hemoglobin concentration (MCHC)*		JCUH/ FHN
	% hypochromasia*		JCUH/ FHN
	Reticulocyte count*	S_HA_HAE_SOP0002	JCUH/ FHN
	Blood film review*	Siemens Hematek 3000 & Light Microscopy S_HA_HAE_SOP0018	JCUH



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HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented in-house methods to meet the requirements of the SCT screening programme as defined in the NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements. <i>An asterisk shall be used to identify the tests which form part of the ANNB programme</i>	
EDTA Whole blood unless stated	*Full blood count including the following parameters:	Siemens Advia 2120, laser 2D light scatter S_HA_HAE_SOP0001	JCUH/ FHN
	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
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



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HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented in-house methods to meet the requirements of the SCT screening programme as defined in the NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements. <i>An asterisk shall be used to identify the tests which form part of the ANNB programme</i>	
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> Blood film for malaria detection	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
	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: (cont'd)</u>	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	JCUH
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		Stago Star Max Analyser Clot formation/ Chromogenic/ Immunoturbidometric using procedures below	JCUH/ FHN
	Coagulation screen including:	S_HA_CD_SOP0001	JCUH/ FHN
	Prothrombin Time/Ratio		JCUH/ FHN
	Activated Partial Prothrombin Time/Ratio		JCUH/ FHN
	Fibrinogen level		JCUH/ FHN
	Warfarin monitoring (INR)	S_HA_CD_SOP0002	JCUH/ FHN
	Thrombin Time	S_HA_CD_SOP0004	JCUH/ FHN
	Reptilase Time	S_HA_CD_SOP0005	JCUH/ FHN
	D-Dimer	S_HA_CD_SOP0006	JCUH/ FHN
	Anti Xa (Apixaban, Rivaroxaban, Edoxaban, UFH, Fondaparinux)	S_HA_CD_SOP0009	JCUH/ FHN
	Dabigatran	S_HA_CD_SOP0054	



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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>	Manufacturer's instructions and documented in-house methods using: Stago Star Max Analyser (cont'd)	JCUH
	Factor assays: Factor II Factor V Factor VII Factor X Factor VIII Factor IX Factor XI Factor XII	S_HA_CD_SOP0011	JCUH
	Factor XIII	S_HA_CD_SOP0072	
	Thrombophillia screen including:	S_HA_CD_SOP0007	JCUH
	ATIII	S_HA_CD_SOP0023	JCUH
	Protein C	S_HA_CD_SOP0024	JCUH
	Protein S	S_HA_CD_SOP0014	JCUH
	Lupus anticoagulant screen	S_HA_CD_SOP0010	JCUH
	Von Willebrand factor antigen	S_HA_CD_SOP0032	JCUH
	Von Willebrand RICO	S_HA_CD_SOP0056	JCUH
	Thromboelastography (TEG)	Haemonetics Haemoscope thromboelastography TEG6S_HA_CD_SOP0053	JCUH
Lithium Heparin Whole Blood	TEG Platelet Mapping	S_HA_CD_SOP0053	JCUH
Serum	Heparin Induced Thrombocytopenia (HIT) test	Biorad ID-PaGIA Heparin/PF4 Particle Gel agglutination assay S_HA_CD_SOP0015	JCUH



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HUMAN BODY FLUIDS	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u>	Manufacturer's instructions and documented in-house methods using:	JCUH
EDTA Whole blood unless stated	Group and Screen ABO and RhD Blood group	Automated: Grifols Erytra Analyser - column agglutination J_HA_BT_SOP0011 Manual: Grifols DG - Gel column agglutination S_HA_BT_SOP0004	JCUH
	Red cell antibody screen: Rhesus blood group antibodies: anti-Cw anti-C anti-c anti-D anti-E anti-e Kell System blood group antibodies: anti-K anti-k anti-Kpa Kidd blood group antibodies: anti-JKa anti-JKb Duffy blood group antibodies: anti-Fya anti Fyb Lutheran blood group antibodies: anti-Lua anti-Lub MNS blood group antibodies: anti-M anti-N anti-S anti-s	Automated: Grifols Erytra Analyser - column agglutination J_HA_BT_SOP0011 Manual: Grifols DG-Gel - column agglutination J_HA_BT_SOP0001	JCUH
			JCUH
			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	JCUH
	Serological Crossmatch	Grifols DG-Gel column agglutination J_HA_BT_SOP0010	JCUH
	Direct Antiglobulin Test (DAT)	Grifols DG-Gel column agglutination S_HA_BT_SOP0010	JCUH
	Antibody titre	Grifols DG-Gel column agglutination J_HA_BT_SOP0005	JCUH
	Red Cell Phenotyping – Rhesus and Kell	Grifols DG-Gel column agglutination S_HA_BT_SOP0040	JCUH
	Kleihauer (FMH)	CliniTech Shepard's Stain Kit acid elution S_HA_BT_SOP0027	JCUH



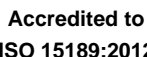
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HUMAN BODY FLUIDS	<u>Immunology examination activities for the purpose of clinical diagnosis:</u>	Manufacturer's instructions and documented in-house methods using:	JCUH
Serum unless stated	Rheumatoid factor	BNII Nephelometer J_IMM_IC_SOP015	JCUH
Serum 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		JCUH
	Anti-streptolysin O		
	C1 inhibitor		
	Alpha 1 Acid Glycoprotein		JCUH
	Detection of allergen specific IgE	Phadia ImmunoCAP 250 Fluorezyme immunoassay (Immunocap) J_IMM_AA_SOP028	JCUH
	Detection of specific antibodies to:	Phadia ImmunoCAP 250 Fluorezyme immunoassay (ELiA) J_IMM_AA_SOP028	JCUH
	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	Binding Site Optilite	JCUH
	IgG subclasses	J-IMM-VER0017	JCUH
Urine	Cryoglobulins	Manual technique/ Cryocrit tube Immunoprecipitation J_IMM_IC_SOP016	JCUH
	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	JCUH
	Detection of Bence-Jones protein and monoclonal band identification	Agarose gel electrophoresis using Sebia Hydrasys J_IMM_IC_SOP027	JCUH
	Detection and identification of monoclonal bands	Agarose gel electrophoresis using Sebia Hydrasys J_IMM_IC_SOP027	JCUH
	Detection of the following antibodies:	Menarini Zenit SP+ slide processor Indirect Immunofluorescence J_IMM_AA_SOP024	JCUH
	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	JCUH
	Endomysial Antibodies	Zenit - Primate Distal Oesophagus slides J_IMM_AA_SOP024	JCUH
		Autoantibody slide interpretation by LED Microscopy J_IMM_AA_SOP025	JCUH
	Autoantibody Indirect Immunofluorescence titres	Menarini Zenit SP+ slide processor Autoantibody J_IMM_AA_SOP024	JCUH
	Manual Autoantibody Indirect Immunofluorescence screens:	Autoantibody manual slide processing: Autoantibody Manual Slide Processing J_IMM_AA_SOP001	JCUH
	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	<u>Immunology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Manufacturer's instructions and documented in-house methods using:	JCUH
	Manual Autoantibody Indirect Immunofluorescence titres:	Autoantibody Indirect Immunofluorescence titres manual slide processing Autoantibody Indirect Immunofluorescence Screen J_IMM_AA_SOP029	JCUH
	Anti-nuclear antibody ANA titre		
	Anti-mitochondrial antibody AMA titre		
	Anti-smooth muscle antibody SMA titre		
	Liver kidney microsomal LKM titre		
	Endomysial Antibodies	Manual slide process- Primate distal J_IMM_AA_SOP030	JCUH
	Antibodies against specific liver antigens	Euroimmun Euroline Profile Autoimmune Liver Diseases kit - Manual method Immunoblot J_IMM_AA_SOP031	JCUH
	Skin Pemphigus/Pemphigoid Antibodies	Manual slide process- Primate distal oesophagus autoantibody - Indirect Immunofluorescence Screen Manual Slide Processing J_IMM_AA_SOP030	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 Leica Histocore arcadia embedding system and Sakura Tissue Tek embedding centre S_CP_H02_SOP0129	JCUH
Formalin fixed paraffin embedded tissue blocks		Tissue sectioning by Microtomy Leica Histocore Multicut S_CP_H02_SOP0282	JCUH, FHN



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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 1950 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		Interpretive/diagnostic microscopy Renal: J_CP_H05_SOP0146; Skin: J_CP_H05_SOP0147	JCUH/ FHN
FFPE slides and frozen sections and smears	Routine morphological staining for the detection of: 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	JCUH
	Acid mucins	Alcian blue (M) J_CP_H10_SOP0154	JCUH
	Fibrin, collagen, muscle	MSB (M) J_CP_H10_SOP0158	JCUH
	Basement membrane	PASilver (M) J_CP_H10_SOP0161	JCUH
	Haemosiderin	Perl's Prussian blue (M) J_CP_H10_SOP0162	JCUH
	Amyloid	Sirius red (M) J_CP_H10_SOP0165	JCUH
	Fibrin, collagen, muscle	Trichrome (M) J_CP_H10_SOP0166	JCUH
	Tubercle bacilli	Ziehl Nielson (M) J_CP_H10_SOP0168	JCUH
	Mast cells	Toluidene blue (M) J_CP_H10_SOP0175	JCUH
	Fungi	Grocott-Gomori (M) J_CP_H10_SOP0177	JCUH
	Melanin	Masson Fontana (M) J_CP_H10_SOP0178	JCUH
	Copper associated proteins	Shikata orcein (M) J_CP_H10_SOP0180	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
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	JCUH
	Blood cells - plasma cells, megakaryocytes, mast cell granules, neutrophil granules, eosinophil granules	Giemsa for trephines (M)J_CP_H10_SOP0228	JCUH
	Elastic fibres	Millers S_CP_H10_SOP0156 (M)	JCUH
	Glycogen	PAS S_CP_H10_SOP0157 (M,A,B)	JCUH
	Acid mucins, neutral mucins	Alcian blue-PAS (M,A,B) S_CP_H10_SOP0163	JCUH
	Collagen	Van Gieson (M) S_CP_H10_SOP0167	JCUH
	Amyloid	Congo red (M) S_CP_H10_SOP0172	JCUH
	Helicobacter	Giemsa staining for helicobacter (M) S_CP_H10_SOP0173	JCUH
	Gram positive and negative organisms (bacteria)	Gram Twort staining (M) S_CP_H10_SOP0389	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
Renal biopsies	Tissue morphology	Immunofluorescence, paraffin H&E and special stains J_CP_H05_SOP0146	JCUH
FFPE tissue slides	Immunocytochemistry examination activities to detect the following (cont'd):	Ventana Benchmark Ultra immunostainers Immunocytochemistry using Ventana Ultraview kit J_CP_H11_SOP0236	JCUH
	Anaplastic large cell lymphoma	Alk1	JCUH
	Alpha-1-antitrypsin deficiency	a-1 antitrypsin	JCUH
	Yolk sac tumours, hepatocellular carcinoma	a-1-fetoprotein	JCUH
	Smooth, skeletal muscle differentiation: leiomyosarcoma, rhabdomyosarcoma, myofibroblasts, myoepithelium	Actin	JCUH



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



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



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



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



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



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



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



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



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HUMAN BODY TISSUES	<u>Immunocytochemistry examination activities to detect the following: (cont'd)</u>	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	JCUH



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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	<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	JCUH
		Thinprep T2000 processor J_CP_CTP_SOP0001	JCUH
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	JCUH



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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, , endometrial aspirate, needle rinse fluids and other human tissues/fluids	Determination of presence/absence of malignant cells, benign changes and associated inflammatory conditions	HologicThinPrep® 5000 automated bench top processing system J_CP_CTP_SOP0002	JCUH
Endoscopic Washings/Brushings Aspirated fluid	Determination of presence/absence of malignant cells	S_CP_CNG_SOP0012	JCUH
Brush in transport medium	Determination of presence/absence of malignant cells	S_CP_CNG_SOP0013	JCUH
Nipple discharge	Determination of presence/absence of malignant cells	J_CP_CNG_SOP0029	JCUH
Cell suspension/fluid	Cell block preparation (+/- ICC)	Safety cabinet, centrifuge - histology processing S_CP_CNG_SOP0002	JCUH



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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	JCUH
CSF	Smear preparation for the purposes of staining/slide reading for identification of WBC (see above)	Cytocentrifugation J_CP_CNG_SOP0015	JCUH
Stained prepared slides		Microscope S_CP_CSC_SOP0014	JCUH
Stained prepared slides	BMS reporting of negative non-gynae specimens including urine, bronchial and serous effusion samples	Microscope J_CP_CMA_SOP0012	JCUH
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	JCUH
Fine needle aspirates from Breast clinic	Determination of presence/absence of malignant cells	J_CP_CNG_SOP0029 J_CP_CNG_SOP0011	JCUH
Slides prepared as above	Morphological assessments and interpretation/diagnosis	Using light microscopy	JCUH
Biopsy, excision, resection and post-mortem specimens	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Tissue processing using EpreDia™ Revos™ Tissue Processor	JCUH



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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 UK Health Security Agency (UKHSA) 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:	JCUH
	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	JCUH
Bone, tissue, prosthetics, joints	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods and enrichment culture S_B_SPE0057	JCUH
CSF	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	JCUH
CSF shunts	Isolation and characterisation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods S_B_SPE0007	JCUH
CAPD fluid	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	JCUH



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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 UK Health Security Agency (UKHSA) 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	JCUH
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	JCUH
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	JCUH



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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 UK Health Security Agency (UKHSA) 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	JCUH
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	JCUH
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 UK Health Security Agency (UKHSA) 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 UK Health Security Agency (UKHSA) 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 UK Health Security Agency (UKHSA) 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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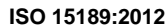
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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs) 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	





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HUMAN TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the NHS Infectious diseases in pregnancy screening: laboratory quality assurance evidence requirements'. <i>An asterisk shall be used to identify the tests which form part of the ANNB programme</i>	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_SOP0079	
	Hepatitis B 'e' antigen*	S_V_SOP0077	
	Hepatitis B 'e' antibody*	S_V_SOP0078	
	Hepatitis B surface antigen*	S_V_SOP0078	
	HIV antibody/antigen*	S_V_SOP0080	
	HIV p24 antigen	S_V_SOP0080	
	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>	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the NHS Infectious diseases in pregnancy screening: laboratory quality assurance evidence requirements'. <i>An asterisk shall be used to identify the tests which form part of the ANNB programme</i>	JCUH
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</i> DNA Varicella zoster virus DNA	Applied Biosystems ABI 7500 RT-PCR J_V_EQU0015 and procedures below S_V_SOP0049	
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 Cepheid GeneXpert RT-PCR / PCR / qualitative genotyping S_V_EQU0015 and procedures below	
Nasopharyngeal swabs	Influenza A RNA	S_V_SOP0059	
Nasopharyngeal swabs	Influenza B RNA	S_V_SOP0059	



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Accredited to
ISO 15189:2012

Schedule of Accreditation
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United Kingdom Accreditation Service
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	
Nasopharyngeal, nasal and oropharyngeal swabs, nasopharyngeal wash/aspirate, nasal aspirate	SARS-CoV-2	Hologic Panther target capture, Transcription Mediated Amplification (TMA), and Dual Kinetic Assay (DKA using the Aptima® SARS-CoV-2 assay S_V_SOP0102	JCUH
Nasopharyngeal swab	SARS-CoV-2	Cepheid GeneXpert Xpress SARS-CoV-2 RT-PCR assay S_V_SOP0059	JCUH
		SAMBA II SARS-CoV-2	JCUH
Nose and throat swabs	SARS-CoV-2	S_V_SOP0104	
Nasopharyngeal swab	FA/FB/RSV/SARS-CoV-2	Cepheid GeneXpert Xpress RT-PCR Assay	JCUH
END			