

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8869</p> <p>Accredited to ISO 15189:2012</p>	<h3>Royal Cornwall Hospitals NHS Trust</h3> <p>Issue No: 005 Issue date: 30 June 2021</p>	
	<p>Royal Cornwall Hospitals NHS Trust RCHT Pathology Service c/o Microbiology Department Royal Cornwall Hospital Truro Cornwall TR1 3LQ</p>	<p>Contact: Sarah Pointon Tel: +44 (0)1872 252582 Fax: +44 (0)1872252440 E-Mail: sarahpointon@nhs.net Website: www.rcht.nhs.uk</p>
<p>Testing performed at the above address only</p>		

Site activities performed away from the location listed above:

Location details	Activity
<p>Transfusion Laboratory, Trauma Theatre, Delivery Suite, Main Theatres Royal Cornwall Hospital Truro TR1 3QJ</p>	<p>Storage & issue of blood and blood products</p>
<p>West Cornwall Hospital Royal Cornwall Hospitals NHS Trust St Clare Street Penzance TR18 2PF</p>	<p>Mortuary and body storage Storage & issue of blood and blood products only</p>
<p>St Michael's Hospital Royal Cornwall Hospitals NHS Trust Trelissick Road Hayle TR27 4JA</p>	<p>Storage & issue of blood and blood products only</p>
<p>Duchy Hospital Penventinnie Lane Truro TR1 3UP</p>	<p>Storage & issue of blood and blood products only</p>
<p>Head and Neck Fine Needle Aspiration clinic ENT Department Royal Cornwall Hospital Truro TR1 3QJ</p>	<p>Rapid on-site evaluation of head and neck cytology samples.</p>
<p>EBUS and EUS Endoscopy Suite Royal Cornwall Hospital Truro TR1 3QJ</p>	<p>Rapid on-Site evaluation of diagnostic cytology samples</p>



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Blood Transfusion examinations to assist in clinical investigations</u>	In house documented methods incorporating manufacturers' instructions as required
Whole Blood	Blood grouping: A, B, O, Rh	Grifols Erytra blood grouping automated analyser using procedures: BT-SOP-75 BT-SOP-76 BT-SOP-77 Manual blood grouping using Grifols DG Gel cards using procedure: BT-SOP-74
Whole Blood	D variant investigation	Manual ABO and RhD grouping using Grifols DG Gel cards using procedure: BT-SOP-39
Whole Blood	Phenotype and RhK phenotype	Manual technique using Grifols DG Gel cards using procedure: BT-SOP-36
Whole Blood	Antibody screen identification of: D, C, c, E, e, Cw, K, k, Kpa, Jka, Jkab, Lea, Leb, M, N, S, s, P1, Lua, Fya, Fyb	Grifols Erytra blood grouping automated analyser using procedures: BT-SOP-75 BT-SOP-18 BT-SOP-24 Manual technique using Grifols DG Gel cards using procedure: BT-SOP-73 BT-SOP-18 BT-SOP-20
Whole Blood	DAT	Grifols Erytra blood grouping automated analyser using procedures: BT-SOP-27 Manual technique using Grifols DG Gel cards using procedure: BT-SOP-25



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<p>Whole Blood</p> <p>Eluate prepared from patient's blood sample</p> <p>Blood</p>	<p>Compatibility testing</p> <p>Elution for antibody investigation of: D, C, c, E, e, Cw, K, k, Kpa, Jka, Jkab, Lea, Leb, M, N, S, s, P1, Lua, Fya, Fyb</p> <p>Foetal Maternal Haemorrhage</p>	<p>Manual technique using Grifols DG Gel cards using procedure: BT-SOP-40 BT-SOP-33</p> <p>Manual technique using Grifols DG Gel cards with the Immucor reagent kit: BT-SOP-27</p> <p>Kleihauer Acid Elution Technique - BT-SOP-31</p>
<p>HUMAN BODY FLUIDS (cont'd)</p>	<p><u>Haematological examinations for the purpose of clinical diagnosis</u></p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p>



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Blood	Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT PLT volume Mean Platelet volume NEUT LYMPH MONO EOS BASO Reticulocytes	Abbott Alinity hq analyser using procedures: HA-AH-SOP-40 HA-AH-SOP-42 HA-AH-SOP-43 HA-AH-FORM-59 HA-TRAIN-2
Blood	Morphology for the purpose of clinical diagnosis	Siemens Hematak Microscopes Light Microscopy HA-AH-SOP-7 HA-AH-SOP-14 HA-AH-SOP-15 HA-AH-SOP-33
Bone marrow	Morphology for the purpose of clinical diagnosis	Manual May Grunwald Giemsa and Perls staining using light microscopy HA-IMM-SOP-11 HA-IMM-SOP-14



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Glandular Fever Screen (Infectious Mononucleosis Heterophile Antibody)	Monogen Infectious Mononucleosis screening kit Latex agglutination method HA-AH-SOP-17
Whole blood	Screening for Malaria parasites: <i>Plasmodium falciparum</i> <i>P. ovale</i> <i>P. vivax</i> <i>P. malariae</i> <i>P. knowlesi</i>	Manual Field's and Giemsa blood film staining method by Light Microscopy and rapid diagnostic test card. Antibody impregnated chromatography method HA-AH-SOP-18
Blood	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium falciparum</i> , <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	Rapid Diagnostic Test card, Antibody impregnated chromatography method and procedure: HA-AH-SOP-18



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Sickle cell screening	Documented in-house methods to meet the requirements of the Sickle Cell and Thalassemia screening programme(s) as defined in the July 2018 'NHS Sickle Cell and thalassemia screening: Laboratory QA evidence requirements. Sickledex Hb S Screening Test kit Haemoglobin Solubility method HA-AH-SOP-16
Plasma	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u>	
	PT/INR APTT Thrombin Time Normal Plasma correction	Werfen IL TOP 550 Optical/Turbidometric HA-AH-SOP-10 HA-AH-SOP-28
	Fibrinogen – Clauss	Werfen IL TOP 550 Optical/Turbidometric HA-AH-SOP-10 HA-AH-SOP-28 HA-AH-SOP-35
	D-Dimers	HA-AH-SOP-10 HA-AH-SOP-23 HA-AH-SOP-28
	PT/INR Thrombin	Manual tube technique clotting HA-CO-SOP-31 HA-AH-SOP-10
	APTT	Manual tube technique clotting HA-CO-SOP-21 HA-AH-SOP-10
	Fibrinogen – Clauss	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-26



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Plasma	Normal plasma correction	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-31 HA-CO-SOP-21
	Reptilase time	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-32
	Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII	Automated Werfen IL TOP 550 Optical/turbimetric HA-CO-SOP-7 Manual - Clotting HA-CO-SOP-6 HA-CO-SOP-9
	Inhibitor Screen	Manual dilutions Werfen IL TOP 550 Optical/turbimetric HA-CO-SOP-28 HA-CO-SOP-30
	Factor VIII Inhibitor Factor IX Inhibitor	Manual dilutions and assayed using Werfen IL TOP 550 Optical/turbimetric HA-CO-SOP-28 HA-CO-SOP-30
	VWF antigen VWF Ricof	Werfen IL TOP 550 Latex immunoassay HA-CO-SOP-12
	Antithrombin III functional Protein S	Werfen IL TOP 550 Chromogenic/Latex immunoassay HA-CO-SOP-40 HA-CO-SOP-45



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Plasma	Protein C functional	Werfen IL TOP 550 Optical/Turbimetric HA-CO-SOP-43 HA-CO-SOP-45
	Lupus anticoagulant	Manual tube technique Clotting HA-CO-SOP-42 HA-CO-SOP-44
	<u>Haemolytic examinations for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions as required
Blood	G6PD screen	Manual Technique Fluorescent spot HA-CO-SOP-13
	Detection of haemoglobins HbF HbA2 and abnormal haemoglobins (variants)	HPLC TOSOH G8 Analyser HA-CO-SOP-15 HA-CO-SOP-34



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HUMAN BODY FLUIDS (cont'd)	<u>Haemolytic examinations for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions as required
Ejaculate	<u>Andrology examinations for the purpose of clinical diagnosis</u>	Semen Analysis: In-house procedures following the guidelines below: WHO Laboratory Manual for the Examination and processing of Human Semen 5th Edition. 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons. P Hancock, B J Woodward, A Muneer, J C Kirkman-Brown: <i>J Clin Pathol</i> doi:10.1136/jclinpath-2016-203731
Ejaculate	Fertility screening: Semen liquefaction Semen viscosity Semen pH Semen volume Sperm concentration Sperm motility Sperm vitality Sperm morphology	Manual methods using in-house procedures: Phase contrast microscope, heated stage HA-AND-SOP-1
Ejaculate	Post-vasectomy semen analysis (PVSA): Detection of sperm	Manual Technique, centrifugation followed by Phase contrast microscopy using in-house procedure: HA-AND-SOP-2



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Body fluids: Cerebrospinal fluid (CSF) General body fluids, washings, Respiratory samples, Pericardial, Pleural, Peritoneal, Hydrocoele, cysts and Serous fluids, FNA, EBUS/EUS</p>	<p><u>Diagnostic Cytological examinations for the purpose of clinical diagnosis</u></p> <p>Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Preparation/centrifugation In-house procedures: CPC-SOP-112, DMP-CY-NG-SOP-9 Non-Gynae Preparation in conjunction with manufacturer's instructions using: Thermo Shandon Megafuge and cytocentrifuge Hologic T2000 processor</p> <p>Induced Clot formation Thermo Shandon Megafuge Recombinant Thrombin and Plasma Individual preparation stain and technical check Procedure: DMP-CY-NG-SOP-4 Clot formation from fluids for cytology</p> <p>Papanicolaou staining Automated using in-house procedures: DMP-CY-NG-SOP-12 in conjunction with manufacturer's instructions using: Leica Mini Linear staining machine</p> <p>Giemsa staining using Diff Quick And procedure DMP-CY-NG-SOP-12</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed tissues</p>	<p><u>Histopathology examinations for the purpose of clinical diagnosis</u></p> <p>Preparation and examination to identify or exclude morphological & structural abnormalities</p>	<p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Macroanalysis and dissection Manual method using: DMP-HI-SOP-47 Procedure for specimen dissection, Histology Cutting Regime – DMP-HI-SOP-46 Preparation of bowel screening specimens – DMP-HI-SOP-2, Instructions of Medical Liver Biopsies – DMP-HI-LI-169</p> <p>Decalcification Manual method using: Decalcification and softening SOP – DMP-IMM-SOP-5</p> <p>Tissue Processing Automated method using: Leica Peloris Tissue Processors and procedure for Operating Peloris Tissue Processor DMP-HI-SOP-47</p> <p>Embedding Manual method using: DMP-HI-SOP-47 Procedure for the embedding of tissue in paraffin wax</p> <p>Microtomy Manual method using: DMP-HI-SOP-46 and: Leica 2255 microtomes</p>
<p>Fresh tissue Frozen tissue</p>	<p>Intra-operative diagnosis</p>	<p>Rapid frozen section Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using: DMP-HI-SOP-3</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
Fresh tissue Frozen tissue	Intra-operative diagnosis	Fresh section service Leica CM1950 cryostat, Procedure DMP-HI-SOP-3
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin & Eosin (H&E) staining and coverslipping Automated method using: DMP-HI-SOP-46 and: Leica ST4020 linear staining machine and coverslipper
FFPE tissue	<u>Special staining for the detection of the following:</u>	Special staining Manual methods using SOP - DMP-HI-SOP-27 and the following stains:
	Acid and sulphated mucins	Alcian Blue
	Liberated aldehydes	Alcian Blue/PAS
	Amyloid	Congo Red
	Differentiating between haemopoetic cells, Helicobacter pylori	Giemsa
	Gram positive and gram-negative organisms	Gram
	Fungi and Pneumocystis	Grocott



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE tissue (cont'd)	<u>Special staining for the detection of the following:</u> (cont'd)	Special staining Manual methods using SOP - DMP-HI-SOP-27 and the following stains:
	Basement membranes	Jones Hexamine Silver
	Bleach melanin pigment	Mallory Bleach
	5HT in melanin and lipofuscins	Masson Fontana
	Collagen and smooth muscle	Masson's Trichrome
	Elastic fibres & collagen	Miller's Elastin Van Gieson
	Chromophobe renal cell carcinoma and Haemosiderin	Mowry's Colloidal Iron
	Hydrophobic (neutral) lipids	Oil Red O
	Hepatitis B surface antigen and copper associated proteins	Orcein
	Liberated aldehydes	Periodic Acid Schiffs (PAS) with/without digestion (PASD)
	Haemosiderin	Perl's Prussian Blue
	Reticulin fibres	Reticulin
	Mast cell granules	Toluidine Blue
	Acid fast bacilli, e.g. <i>M. leprae</i>	Wade Fite
	Spirochetes	Warthin-Starry



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FFPE tissue (cont'd)	<u>Special staining for the detection of the following:</u> (cont'd) Acid fast bacilli, e.g. <i>M. tuberculosis</i>	Special staining Manual methods using SOP - DMP-HI-SOP-27 and the following stains: Ziehl Neelsen (ZN)
FFPE tissue	<u>Immunohistochemistry for the detection of the following:</u> Epithelial cell types Pan-keratin (Simple & complex epithelia) Sex chord stromal tumour cells Mast cells Embryonic cell in normal tissues and germ tumours Anaplastic lymphoma kinase (receptor CD246) ALK translocation for NSCLC B-catenin protein, binds to cytoplasmic tail of E-cadherin Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas Range of B-cell lymphocytes Compliment Cancer antigen 125	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies: 34BE12 (cytokeratin) AE1/AE3 (pan-cytokeratin) Alpha-Inhibin AA1 (mast cell tryptase) Alpha feto protein (AFP) ALK1 ALK-EML4 (NSCLC) Beta Catenin BCL2 and Bcl2 BOB1 C3 - Renal IPX CA125



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FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Sialyl-Lewis A, marker for the detection of pancreatic cancer	CA19-9
	Smooth muscle cells	H-Caldesmon
	Calcium binding protein structurally related to S100 and inhibin	Calretinin
	MHC class 1 related cell surface glycoprotein in cortical thymocytes; Langerhan's cells; interdigitating reticulum cells	CD1a
	Circulating T lymphocytes	CD2
	Renal transplant samples	CD3/PAS
	T-cells	CD3
	T-cells (helper and mature)	CD4
	Mature T-cells, T-cell lymphomas	CD5
	Suppressor/cytotoxic T lymphocytes	CD8
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10
	Hodgkin's & Reed-Sternberg cells	CD15
	B lymphocytes	CD 20 (L26)
	Follicular dendritic cells	CD21



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FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Key molecule for B cell activation and growth	CD23
	Hodgkin's & Reed-Sternberg cells	CD30
	Endothelial cells; plasma cells; activated B & T lymphocytes	CD31
	Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours	CD34
	Leukocyte common antigen	CD45 (LCA)
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56
	Identify platelets, megakaryocytes	CD61
	Macrophages; monocytes; granulocytes	CD68 (KP1)
	Normal & neoplastic B lymphocytes	CD79a
	C-kit oncoprotein – melanocytes, mast cells and glial cells	CD117
	Normal and neoplastic plasma cells	CD138
	Intestinal specific transcription factor	CDX2
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	CEA (MONOCLONAL)



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FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin
	Squamous epithelium	CK 5/6
	Simple, glandular & transitional epithelia	CK 7
	Simple and glandular epithelium	CK8/18
	Hair follicles, basal keratinocytes in stratified epithelium (various tissue/organs), myoepithelial cells (breast and salivary gland), thyroid oncocytes	CK 14
	Ductal and glandular Epithelia	CK19
	Gastric and intestinal epithelium	CK 20
	Cytomegalovirus viral inclusions	CMV IHC
	Mantle cell lymphoma and a variety of other tumours	CYD1 BMT
	Mantle cell lymphoma and a variety of other tumours	CYD1 tissue
	Lymphatic endothelium marker	D-240
	Smooth & striated muscle cells	Desmin
	Interstitial cells of Cajal in GI tract, GIST	DOG-1



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Latent EBV infection	EBER ISH Manual dewax
	Cell-cell boundaries or squamous epithelium	E-cadherin
	Epithelial membrane antigen (Glandular & ductal epithelia, perineurium; other cell types in various tumours)	EMA
	Cellular estrogen receptor expression	Estrogen receptor
	Epithelial cell types	ESA (BerEP4)
	Dermal dendritic cells	FXIIIa
	Neoplastic breast ductal cells	GATA3
	Human Chorionic Gonadotropin (Trophoblastic elements, e.g. in germ cell tumours)	HCG
	Expression of human epidermal growth factor receptor II	HER2 IHC
	Her2 region of chromosome 17	Her2 DDISH
	Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours)	HMB45



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Human papilloma virus subtypes 6 and 11	HPV low ISH Manual Dewax
	Human papilloma virus subtypes 16,18,31,33,51	HPV high ISH Manual Dewax
	Herpes simplex virus	HSV
	Plasma cells and related lymphoid cells containing IgA	IGA tissue IGA - Renal ipx IgA – BMT
	Plasma cells and related lymphoid cells containing IgD	IGD IgD BMT
	Plasma cells and related lymphoid cells containing IgG	IGG IGG - Renal ipx IgG- BMT
	Plasma cells and related lymphoid cells containing IgM	IGM IGM renal - ipx IgM - BMT



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa normal tissue Kappa BMT Kappa ISH BMT Manual Dewax Kappa ISH Manual Dewax
	Proliferating cells	KI67
	Dual stain	KI67/MELANA DUAL STAIN
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda normal tissue Lambda BMT Lambda ISH BMT Manual Dewax Lambda ISH Manual Dewax
	Melan A (MART-1) differentiation antigen (Normal, activated & neoplastic melanocytes)	MelanA
	MLH-1 mismatch repair protein	MLH-1 (mismatch repair)
	Pan-keratin (Simple & complex epithelia)	MNF116 (pan-cytokeratin)



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	MSH-2 mismatch repair protein	MSH-2 (mismatch repair)
	MSH6 mismatch repair protein in colorectal carcinomas	MSH-6 (mismatch repair)
	Multiple myeloma oncogene-1	MUM1
	Neutrophil granulocytes, monocytes	Myeloperoxidase
	B-lymphocyte transcription factor	OCT2
	Pluripotent germ cell tumours	OCT 3/4
	Atypical prostatic acinii	Prostatic acid phosphatase (PAP)
	Pre-B cells	PAX-5
	Mantle, germinal centre, interfollicular B-cells	PAX-8
	p16INK4a oncoprotein (Normal, activated and neoplastic)	P16
	Carcinomas; many neoplasms and normal cells	P53
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells	P63
	Expression of Alpha Methyl Acyl Coenzyme A Racemase	P504s



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue (cont'd)</p>	<p><u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Immunohistochemistry for the detection of the following:</u> (cont'd)</p> <p>Dual stain used on prostate cases</p> <p>Placental Alkaline Phosphatase in germ cell tumours</p> <p>PMS2 mismatch repair protein in colorectal carcinomas</p> <p>Cellular progesterone receptor expression</p> <p>Prostate specific antigen</p> <p>Non-small cell lung cancer</p> <p>Non-small cell lung cancer</p> <p>Melanocytic marker</p> <p>Melanocytes and langerhan cells</p> <p>Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types</p> <p>Smooth muscle, myoepithelial and other contractile cells</p> <p>Smooth muscle myosin heavy chain</p> <p>Synaptic vesicle protein (neurones; neuroendocrine cells)</p> <p>Terminal deoxynucleotidyl transferase in thymic and small number of bone marrow cortical lymphocytes</p>	<p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:</p> <p>P63/P504S cocktail</p> <p>PLAP</p> <p>PMS-2 (mismatch repair)</p> <p>Progesterone receptor</p> <p>Prostate specific antigen (PSA)</p> <p>PD-L1</p> <p>ROS-1</p> <p>SOX-10</p> <p>S100</p> <p>S100 red</p> <p>Smooth muscle actin (SMA)</p> <p>Smooth muscle myosin heavy chain (SMMHC)</p> <p>Synatophysin</p> <p>TdT</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE tissue (cont'd)	<u>Immunohistochemistry for the detection of the following:</u> (cont'd)	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Thyroid transcription factor-1 (Thyroid follicular & C cells)	TTF1
	Cytoplasm of melanocytes	Tyrosinase
	Vimentin intermediate filament	Vimentin
	Plasma cell marker	VS38
	Von Willebrand Factor (endothelial cells)	VWF
	WT1 expression	WT1
	Detection of:	Immunofluorescence using Roche Ventana BenchMark Ultra Platforms and procedure DMP-IMM-SOP-21 and the following antibodies:
Frozen sections	Identification of: antigens and antibodies in various auto-immune skin and renal diseases:	C1Q
	Polyclonal light chains of kappa type	Kappa
	Reacts with C3c fragment, native C3 and C3b	C3
	Characterising renal & cutaneous immune disorders	IGA, IGM. IGG



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE Slides	<u>Molecular abnormalities for therapeutic application:</u> Detection of mutations for: RAS (including CRC) BRAF (including melanoma/CRC) EGFR (including NSCLC)	PCR using Biocartis Idylla analyser and procedure: DMP-IMM-SOP-31
HUMAN BODY FLUIDS	<u>Biochemistry examinations for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions as required
Whole Blood	Detection and quantification of: HBA1C HbF HbA2	TOSOH G11 & G8 High Pressure Liquid Chromatography CH-MAN-SOP-30 and CH-MAN-SOP-32
CSF	Detection of Xanthochromia	UVIKON XS Spectrophotometer CH-MAN-SOP-9
Serum/EDTA plasma	Visual detection of presumptive Cryoprotein	Visual inspection of cryoprotein precipitate formation: CH-MAN-SOP-1
Urine	5-Hydroxyindoleacetic Acid	WATERS High Pressure Liquid Chromatography CH-MAN-SOP-29
Urine, Blood	Osmolality	Micro-Osmomter model 3300 using freezing point methodology CH-AUTO-SOP-10



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required
Urine	Metanephrines	WATERS High Pressure Liquid Chromatography CH-MAN-SOP-27
Urine	Porphobilinogen	Spectrophotometry using UVIKON XS and Thermo Fisher Evolution 201 Extraction and chemical reaction using Recipe PGB kit.
Urine/faeces	Detection of: Glucose Sucrose Galactose	High Performance Liquid Chromatography Measurement of Urine and faecal sugar by chromatography CH-MAN-SOP-5
Faeces	Elastase	BIOSERV Enzyme Linked Immunoassay (ELISA) with extraction CH-MAN-SOP-11
Faeces	Calprotectin	Buhlmann Enzyme Linked Immunoassay (ELISA) with extraction CH-MAN-SOP-8
Sweat	Chloride	Sherwood 926 Chloride Meter Coulometry CH-MAN-SOP-28
Whole Blood – Serum/Plasma	Anti-Mullerian Hormone	Beckman Coulter Enzyme Linked Immunoassay (ELISA) CH-MAN-SOP-31



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Faeces and rectal swabs Tissues and biopsies Bile Throat related specimens Intravascular cannulae and associated specimens Sterile fluids Bronchoalveolar lavage, sputum and associated specimens Skin and superficial soft tissue swabs Pus and exudate specimens from deep-seated infections Mouth swabs Specimens from bacterial eye infections Ear swabs Nasal samples Per-nasal swabs MRSA screening swabs Cerebrospinal fluid CAPD fluid Genital tract swabs and associated specimens</p>	<p><u>Microbiological – General Bacteriology examinations for the purpose of clinical diagnosis</u></p> <p>Isolation and identification of significant microorganisms for the purposes of clinical diagnosis.</p>	<p>In-house documented procedure based on Public Health England UK Standards for Microbiology Investigations and incorporating manufacturer's instructions as relevant:</p> <p>Manual culture and microscopy; identification using commercial kits and bioMerieux Vitek2. Faeces: CMB-BAC-BSOP-30 Tissues and biopsies: CMB-BAC-BSOP-17 Bile: CMB-BAC-BSOP-15 Throat swabs: CMB-BAC-BSOP-9 Intravascular cannulae and associated specimens: CMB-BAC-BSOP-20 Sterile fluids: CMB-BAC-BSOP-26 Bronchoalveolar lavage, sputum and associated specimens: CMB-BAC-BSOP-57 Skin and superficial soft tissue swabs: CMB-BAC-BSOP-11 Pus and exudate specimens from deep-seated infections: CMB-BAC-BSOP-14 Mouth swabs: CMB-BAC-BSOP-4 Eye infections: CMB-BAC-BSOP-2 Ear swabs: CMB-BAC-BSOP-1 Nasal samples: CMB-BAC-BSOP-5 Samples for Bordetella pertussis and Bordetella parapertussis: CMB-BAC-BSOP-6 MRSA screening swabs: CMB-BAC-BSOP-29 Cerebrospinal fluid: CMB-BAC-BSOP-27 CAPD fluid: CMB-BAC-BSOP-25 Genital tract swabs and associated specimens: CMB-BAC-BSOP-28</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Bacterial isolates from samples indicated above.</p> <p>Urine</p> <p>Whole blood Sterile fluids</p>	<p><u>Microbiological – General Bacteriology examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Antimicrobial susceptibility testing of microorganisms.</p> <p>Isolation and identification of significant microorganisms for the purposes of clinical diagnosis</p> <p>Isolation and identification of significant microorganisms for the purposes of clinical diagnosis.</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Manual disc or strip diffusion method (EUCAST) and Automated Susceptibility testing with BioMerieux Vitek 2. CMB-BAC-EX-14 CMB-BAC-SOP-21 CMB-BAC-SOP-17</p> <p>Automated and/or Manual methods Automated microscopy CMB-BAC-BSOP-41 CMB-BAC-SOP-23 using: Equipment: Beckmann Coulter iQ200</p> <p>Manual culture: identification using commercial kits and bioMerieux Vitek 2</p> <p>Continuous automated monitoring for microbial growth In-house documented procedure based on Public Health England UK Standards for Microbiology Investigations and incorporating manufacturers instructions: CMB-BAC-BSOP-37 CMB-BAC-SOP-24</p> <p>Equipment: Beckton Dickinson BACTEC FX</p> <p>Manual culture: identification using commercial kits and bioMerieux Vitek 2</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiological – General Bacteriology examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedure based on Public Health England UK Standards for Microbiology Investigations and incorporating manufacturers instructions:
Bronchoalveolar lavage Sputum and associated specimens Tissues Urines Sterile fluids Pus (including swabs)	Isolation and preliminary identification of significant microorganisms for the purposes of clinical diagnosis	Continuous automated Mycobacterium liquid culture monitoring CMB-BAC-BSOP-40 CMB-BAC-SOP-14 Equipment: BioMerieux BacT/ALERT MB 3D
Faeces	Detection of antigen: GDH C difficile toxin A and B	Manual culture, manual staining and fluorescent microscopy for preliminary identification In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-9CMB-VIR-SOP-10 Enzyme Linked Fluorescent Assay (ELFA)Equipment: BioMerieux Vidas
Faeces	Detection of Giardia and Cryptosporidium antigen	In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-21 Equipment: Launch Diagnostics DS2



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<p><u>Microbiological – General Bacteriology examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Mycology examinations for the purpose of clinical diagnosis</u></p>	In house documented procedure based on Public Health England UK Standards for Microbiology Investigations and incorporating manufacturers instructions:
Nail Skin Hair	Isolation and identification of dermatophytes, non-dermatophytes and yeasts	CMB-BAC-BSOP-39 Manual staining using calcofluor white and fluorescent microscopy Manual plate culture
Faeces Duodenal/jejunal aspirates Urine Peri-anal swabs	<p><u>Parasitology examinations for the purpose of clinical diagnosis</u></p> <p>Examination for the presence of parasites (ova, cysts, trophozoites and worms)</p>	CMB-BAC-BSOP-31 Direct microscopy and modified formol-ether concentration
Serum	<p><u>Virology and Serological examinations for the purpose of clinical diagnosis</u></p> <p>Detection of: Helicobacter IgG</p>	In-house documented method incorporating manufacturer's instructions: ELISA method using Siemens BEP 2000 and procedure: CMB-VIR-SOP-22



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HUMAN BODY FLUIDS	<u>Virology and Serological examinations for the purpose of clinical diagnosis (cont'd)</u>	
Serum	Detection of: HBsAg Ultra HIV DUO RUBELLA IgG II Toxoplasma total Ab Anti-HBc Total II VZV IgG HAV IgM Measles IgG HAV Total CMV IgM CMV IgG EBV VCA IgG EBV VCA IgM EBV EBNA antibody CMV IgG Avidity Borellia bergdorferi (Lyme) IgM Borellia bergdorferi (Lyme) IgG Anti-HCV	Enzyme Linked Fluorescent Assay (ELFA), Equipment: bioMerieux Vidas and procedure: CMB-VIR-SOP-9
Serum	HBsAg* HCV Ab HIV 1+2 Ab and HIV 1 p24 antigen* Syphilis Total Ab* Anti HBS	Documented in-house methods to meet the requirements of the IDPS screening programme(s) as defined in the July 2018 'Infectious diseases in pregnancy screening: Laboratory QC evidence requirements (relevant tests marked with *)' CMIA based examination for the serological detection Equipment: Abbott Architect In-house documented method incorporating manufacturers instructions: CMB-VIR-SOP-30
Urine	Detection of: Streptococcus pneumoniae antigen Legionella pneumophila antigen	Manual Rapid immunochromatographic test using procedure CMB-VIR-SOP-5
Serum	HEV IgM	
Faeces	Rotavirus Adenovirus	Manual Rapid immunochromatographic test using procedure CMB-BAC-BSOP-30



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturers instructions:
GU swabs Urine	Detection of antigens for: C.trachomatis N.gonorrhoeae	PCR amplification using Hologic Panther and procedure: CMB-VIR-SOP-24
Serum EDTA Plasma	Determination and quantification of nucleic acid for: HCV HIV	Reverse transcription PCR Equipment: Cepheid GeneXpert In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-29 CMB-VIR-SOP-28
Faeces	Detection of: Norovirus I Norovirus II	Reverse transcriptase PCR using CMB-VIR-SOP-27 Equipment: : Cepheid GeneXpert
Nasal swabs in viral transport medium	Detection of: Influenza A Influenza B RSV	Reverse transcriptase PCR using CMB-VIR-SOP-26 Equipment: : Cepheid GeneXpert
Respiratory samples	Detection of: Influenza A and Swine Lineage Influenza B Adenovirus RSV Enterovirus Rhinovirus hMPV Parainfluenza 1,2,3,4	Nucleic acid extraction followed by PCR amplification using QIAGEN QIAcube and AusDiagnostics Easy-Plex™ (High-Plex) robot and analyser and procedures CMB-VIR-SOP-17 and CMB-VIR-SOP-23
Swabs	Detection of: HSV-1 HSV-2 VZV Adenovirus Enterovirus	Nucleic acid extraction followed by PCR amplification using QIAGEN QIAcube and AusDiagnostics Easy-Plex™ (High-Plex) robot and analyser and procedures CMB-VIR-SOP-17 and CMB-VIR-SOP-23
Swabs	Detection of presence of nucleic acid for: HSV-1 HSV-2 VZV	PCR amplification CMB-VIR-SOP-23 Equipment: AusDiagnostics Easy-Plex™ (High-Plex) robot and analyser



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HUMAN BODY FLUIDS (cont'd) CSF	<u>Molecular examinations for the purpose of clinical diagnosis</u> HSV-1 HSV-2 VZV Enterovirus Parechovirus	In-house documented method incorporating manufacturers instructions: Nucleic acid extraction followed by PCR amplification using QIAGEN QIAcube, ABI 7500 Fast PCR system: CMB-VIR-SOP-17 CMB-VIR-SOP-20
END		