

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8869</b> <b>Accredited to ISO 15189:2012</b>	<b>Royal Cornwall Hospitals NHS Trust</b>	
	<b>Issue No: 012   Issue date: 15 April 2025</b>	
	<b>Royal Cornwall Hospitals NHS Trust</b> <b>RCHT Pathology Service</b> <b>c/o Microbiology Department</b> <b>Royal Cornwall Hospital</b> <b>Truro</b> <b>Cornwall</b> <b>TR1 3LQ</b>	<b>Contact: Sarah Pointon</b> <b>Tel: +44 (0)1872 252582</b> <b>Fax: +44 (0)1872252440</b> <b>E-Mail: sarahpointon@nhs.net</b> <b>Website: www.rcht.nhs.uk</b>
<b>Testing performed at the above address only</b>		

### Site activities performed away from the location listed above:

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



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Location details	Activity
EBUS and EUS Endoscopy Suite Royal Cornwall Hospital Truro TR1 3QJ	Rapid on-Site evaluation of diagnostic cytology samples



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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 and tube techniques using procedure: BT-SOP-74 BT-SOP-39
Whole Blood	D variant investigation	Manual ABO and RhD grouping using Grifols DG Gel cards using procedure: BT-SOP-35
Whole Blood	Phenotype and RhK phenotype	Grifols Erytra blood grouping automated analyser using procedures: BT-SOP-75  Manual technique using Grifols DG Gel cards and tube technique 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



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion 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:
Whole Blood	DAT	Grifols Erytra blood grouping automated analyser using procedures: BT-SOP-75  Manual technique using Grifols DG Gel cards using procedure: BT-SOP-25
Whole Blood	Compatibility testing	Manual technique using Grifols DG Gel cards using procedure: BT-SOP-40 BT-SOP-33
Eluate prepared from patient's blood sample	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	Manual technique using Grifols DG Gel cards with the Immucor reagent kit: BT-SOP-27
Blood	Foetal Maternal Haemorrhage	Kleihauer Acid Elution Technique - BT-SOP-31



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
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	Alinity automated slide maker HA-AH-SOP-45, HA-TRAIN-4 Siemens Hematek Microscopes Light Microscopy HA-AH-SOP-14 HA-AH-SOP-15
Bone marrow	Morphology for the purpose of clinical diagnosis	Manual May Grunwald Giemsa and Perls staining using light microscopy HA-IMM-SOP-11
Blood	Glandular Fever Screen (Infectious Mononucleosis Heterophile Antibody)	Monogen Infectious Mononucleosis screening kit Latex agglutination method HA-AH-SOP-17



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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:
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
Body fluids (Ascitic, Pleural, peritoneal dialysis, synovial)	Body fluid cell counts Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	HA-AH-SOP-6,
CSF	CSF examination	HA AH SOP 11, HA-AH-INFO-2  Documented in-house methods to meet the requirements of the Sick Cell and Thalassemia screening programme(s) as defined in the July 2018 'NHS Sick Cell and thalassemia screening: Laboratory QA evidence requirements.
Blood	Sickle cell screening	Sickledex Hb S Screening Test kit Haemoglobin Solubility method HA-AH-SOP-16
Whole Blood	Identification and measurement of: HbA0 HbA2 HbF HbA1c	Sebia Capillarys Tera 3 using electrophoresis HA-CO-SOP-15 CH-MAN-SOP-30



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HUMAN BODY FLUIDS (cont'd)	<p><u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Haemostasis and thrombosis</u></p>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Plasma	PT/INR APTT Thrombin Time Normal Plasma correction	ACL TOP 550 Optical/Turbidimetric HA-AH-SOP-10 HA-AH-SOP-28
Plasma	Fibrinogen – Clauss	ACL TOP 550 Optical/Turbidimetric HA-AH-SOP-10 HA-AH-SOP-28 HA-AH-SOP-35
Plasma	D-Dimers	ACL TOP 550 Optical/Turbidimetric HA-AH-SOP-10 HA-AH-SOP-23 HA-AH-SOP-28
Plasma	PT/INR Thrombin	Manual tube technique clotting HA-CO-SOP-31 HA-AH-SOP-10
Plasma	APTT	Manual tube technique clotting HA-CO-SOP-21 HA-AH-SOP-10
Plasma	Fibrinogen – Clauss	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-26
Plasma	Normal plasma correction	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-31 HA-CO-SOP-21
Plasma	Reptilase time	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-32



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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:
	<u>Haemostasis and thrombosis</u>	
Plasma	Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII	ACL TOP 550 Optical/turbidimetric HA-CO-SOP-7
Plasma	Inhibitor Screen	Manual dilutions ACL TOP 550 Optical/turbidimetric HA-CO-SOP-28 HA-CO-SOP-30
Plasma	Factor VIII Inhibitor Factor IX Inhibitor	Manual dilutions and assayed using ACL TOP 550 Optical/turbidimetric HA-CO-SOP-28 HA-CO-SOP-30 HA-CO-SOP-36
Plasma	VWF antigen VWF Ricof	ACL TOP 550 Latex immunoassay HA-CO-SOP-12
Plasma	Antithrombin III functional Protein S	ACL TOP 550 Chromogenic/Latex immunoassay HA-CO-SOP-40 HA-CO-SOP-45
Plasma	Protein C functional	ACL TOP 550 Optical/Turbidimetric HA-CO-SOP-43 HA-CO-SOP-45
Plasma	Lupus anticoagulant	Manual tube technique Clotting HA-CO-SOP-42 HA-CO-SOP-44





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HUMAN BODY FLUIDS (cont'd)	<u>Haematological 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	<u>Haemostasis and thrombosis</u>  Anti Xa for LMWH, RIV, APIX	ACL TOP 550 Optical/Turbidimetric HA-CO-SOP-39
Citrated plasma	Coagulation: Anti-xa for Heparin and LMWH Rivaroxaban Apixaban Edoxaban  <u>Haemolytic examinations for the purpose of clinical diagnosis</u>	ACL TOP 550 Optical/Turbidimetric HA-CO-SOP-39
Blood	G6PD screen	Manual Technique Fluorescent spot HA-CO-SOP-13
Citrated plasma	ADAMTS13 Functional Assay	ADAMTS13 on the Acustar (HA-CO-SOP-54) Automated method on Acustar
Citrated plasma	Anticardiolipin IgG Anticardiolipin IgM Anti-beta-2-glycoprotein 1 IgG Anti-beta-2-glycoprotein 1 IgM	Anticardiolipin and Anti-β2GP1 on Acustar (HA-CO-SOP-55) Automated method on Acustar.
Citrated plasma	Collagen Binding Assay	Collagen Binding Assay on the Acustar (HA-CO-SOP-53) Automated method on Acustar
Citrated plasma	Heparin Induced Thrombocytopaenia Screen (HIT)	Heparin Induced Thrombocytopaenia Screen (HIT) on the Acustar (HA-CO-SOP-52)



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HUMAN BODY FLUIDS (cont'd)	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy</u>  Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons; manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP HA-AND-SOP-2
Semen	<u>Fertility testing</u>  Volume  pH  Sperm morphology excluding TZI scoring  Sperm concentration  Sperm motility  Sperm vitality	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure SOP HA-AND-SOP-1  Volume/weight  Colorimetric strips  Stained slides (Romanowsky/Speedy-Diff) microscopy (Bright field)  Microscopy (Phase contrast)  Microscopy (Phase contrast)  Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)



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<p><b>HUMAN TISSUES AND FLUIDS (cont'd)</b></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 &amp; 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>
<p>Synovial Fluid</p>	<p>Detection of Crystals</p>	<p>Thermo Shandon Megafuge In-house procedure DMP-CY-NG-SOP-5</p>
<p>Slides prepared in-house from sample types listed above</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Microscopy (qualitative analysis) In-house procedures: DMP-GEN-SOP-25 Non-Gynae Screening using microscopes as follows: Nikon Eclipse E400 Olympus BX45 Leica DMLB</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Diagnostic Cytological examinations for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions as required
Fine needle aspirations (FNA)	Cellularity assessment	Material/slide preparation followed by microscopy Manual methods using: DMP-CY-NG-SOP-11 And microscopes Nikon Eclipse E400 Olympus BX45 Leica DMLB
Formalin fixed tissues	<u>Histopathology examinations for the purpose of clinical diagnosis</u>  Preparation and examination to identify or exclude morphological & structural abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)  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  Decalcification Manual method using: Decalcification and softening SOP – DMP-IMM-SOP-5  Tissue Processing Automated method using: Leica Peloris Tissue Processors and procedure for Operating Peloris Tissue Processor DMP-HI-SOP-47  Embedding Manual method using: DMP-HI-SOP-47 Procedure for the embedding of tissue in paraffin wax



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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)
Formalin fixed tissues		Microtomy Manual method using: DMP-HI-SOP-46 and: Leica 2255 microtomes
Fresh tissue Frozen tissue	Intra-operative diagnosis	Rapid frozen section Leica CM1950 cryostat & Leica ST4020 Mini linear staining machine 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 Histocore Spectra ST 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 haemopoietic cells, Helicobacter pylori	Giemsa
	Gram positive and gram-negative organisms	Gram
	Fungi and Pneumocystis	Grocott
	Basement membranes	Jones Hexamine Silver
	Collagen and smooth muscle	Masson's Trichrome



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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:
	Elastic fibres & collagen	Miller's Elastin Van Gieson
	Hydrophobic (neutral) lipids	Oil Red O
	Hepatitis B surface antigen and copper associated proteins	Orcein
	Liberated aldehydes	Periodic Acid Schiff's (PAS) with/without digestion (PASD)
	Haemosiderin	Perl's Prussian Blue
	Reticulin fibres	Reticulin
	Spirochetes	Warthin-Starry
	Acid fast bacilli, e.g. <i>M. tuberculosis</i>	Ziehl Neelsen (ZN)
	Epithelial cell types	34BE12 (cytokeratin)
	Pan-keratin (Simple & complex epithelia)	AE1/AE3 (pan-cytokeratin)
FFPE tissue	<u>Immunohistochemistry for the detection of the following:</u>	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Sex chord stromal tumour cells	Alpha-Inhibin
	Mast cells	AA1 (mast cell tryptase)
	Embryonic cell in normal tissues and germ tumours	Alpha feto protein (AFP)



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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: (cont'd)</u>	Automated methods using Roche Ventana BenchMark Ultra Platforms, procedure DMP-IMM-SOP-21 and the following antibodies:
	Anaplastic lymphoma kinase (receptor CD246)	ALK1
	ALK translocation for NSCLC	ALK-EML4 (NSCLC)
	B-catenin protein, binds to cytoplasmic tail of E-cadherin	Beta Catenin
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas	BCL2 and BCL6
	Range of B-cell lymphocytes	BOB1
	Cancer antigen 125	CA125
	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
	T-cells	CD3
	T-cells (helper and mature)	CD4
	Mature T-cells, T-cell lymphomas	CD5



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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:
	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
	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





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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:
	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)
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin
	Squamous epithelium	CK 5/6
	Simple, glandular & transitional epithelia	CK 7
	Simple and glandular epithelium	CK8/18
	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



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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:
	Lymphatic endothelium marker	D-240
	Smooth & striated muscle cells	Desmin
	Interstitial cells of Cajal in GI tract, GIST	DOG-1
	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
	Expression of human epidermal growth factor receptor II	HER2 IHC (breast)
	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 IgD	IGD
	Plasma cells and related lymphoid cells containing IgG	IGG
	Plasma cells and related lymphoid cells containing IgM	IGM
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa normal tissue
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa BMT
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa ISH BMT Manual Dewax
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa ISH Manual Dewax
	Proliferating cells	KI67
	Dual stain	KI67/MELANA DUAL STAIN



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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 Lambda light chains	Lambda normal tissue
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda BMT
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda ISH BMT Manual Dewax
	Plasma cells and related lymphoid cells containing Lambda light chains	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)
	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



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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:
	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
	Dual stain used on prostate cases	P63/P504S cocktail
	PMS2 mismatch repair protein in colorectal carcinomas	PMS-2 (mismatch repair)
	Cellular progesterone receptor expression	Progesterone receptor
	Prostate specific antigen	Prostate specific antigen (PSA)
	Non-small cell lung cancer/SCC	PD-L1 (SP263)
	Non-small cell lung cancer	ROS-1
	Melanocytic marker	SOX-10



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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:
	Melanocytes and langerhan cells	S100
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types	S100 red
	Smooth muscle, myoepithelial and other contractile cells	Smooth muscle actin (SMA)
	Smooth muscle myosin heavy chain	Smooth muscle myosin heavy chain (SMMHC)
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synatophysin
	Terminal deoxynucleotidyl transferase in thymic and small number of bone marrow cortical lymphocytes	TdT
	Thyroid transcription factor-1 (Thyroid follicular & C cells)	TTF1 (Leica)
	Vimentin intermediate filament	Vimentin
	Plasma cell marker	VS38
	WT1 expression	WT1
Frozen sections	Identification of: antigens and antibodies in various auto-immune skin and renal diseases:	C1Q
Frozen sections	Polyclonal light chains of kappa type	Kappa



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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)
Frozen sections	Detection of:  Characterising renal & cutaneous immune disorders  <u>Molecular abnormalities for therapeutic application:</u>	Immunofluorescence using Roche Ventana BenchMark Ultra Platforms and procedure DMP-IMM-SOP-21 and the following antibodies:  IGA, IGM, IGG  Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
FFPE Tissue	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



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HUMAN BODY FLUIDS	<u>Biochemistry examinations for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions as required
CSF	Detection of Xanthochromia	UVIKON XS Spectrophotometer CH-MAN-SOP-9
Serum/EDTA plasma	Visual detection of presumptive Cryoproteinsick	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
	<u>Automated Biochemistry</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood Plasma	Ammonia	
Blood- Serum SST and Plasma Lithium Heparin	Alpha-1-antitrypsin	
Blood- Serum SST and Plasma Lithium Heparin. Fluid + CSF	Albumin	
Blood- Serum SST and Plasma Lithium Heparin	Alkaline Phosphatase	
Blood- Serum SST and Plasma Lithium Heparin	Apolipoprotein B	
Blood- Serum SST and Plasma Lithium Heparin. CSF	Amylase	
Blood- Serum SST and Plasma Lithium Heparin	Aspartate Aminotransferase	
Blood- Serum SST and Plasma Lithium Heparin	Beta-2-microglobulin	
Blood- Serum SST and Plasma Lithium Heparin	Bicarbonate	





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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
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Bile Acids	
Blood- Serum SST and Plasma Lithium Heparin	Conjugated Bilirubin	
Blood- Serum SST and Plasma Lithium Heparin, CSF	Total Bilirubin	
Blood- Serum SST and Plasma Lithium Heparin	C3 (complement)	
Blood- Serum SST and Plasma Lithium Heparin	C4 (complement)	
Blood- Serum SST and Plasma Lithium Heparin	Caeruplasmin	
Blood- Serum SST and Plasma Lithium Heparin. Urine	Calcium	
Blood- Serum SST and Plasma Lithium Heparin	Carbamazapine	
Blood- Serum SST and Plasma Lithium Heparin	Chloride	
Blood- Serum SST and Plasma Lithium Heparin	Cholesterol	
Blood- Serum SST and Plasma Lithium Heparin	Creatine Kinase	
Blood- Serum SST and Plasma Lithium Heparin. Urine	Creatinine Enzymatic	
Blood- Serum SST and Plasma Lithium Heparin	C-reactive protein	
Blood- Serum SST and Plasma Lithium Heparin	Digoxin	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions as required
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Ethanol	
Blood- Serum SST and Plasma Lithium Heparin	Gentamicin	
Blood- Serum SST and Plasma Lithium Heparin	Gamma-glutamyl transferase	
Blood- Serum SST and Plasma Lithium Heparin. Fluid + CSF	Glucose	
Blood- Serum SST and Plasma Lithium Heparin	Haptoglobin	
Blood- Serum SST and Plasma Lithium Heparin	High-density lipoprotein	
Blood- Serum SST and Plasma Lithium Heparin	Immunoglobulin A	
Blood- Serum SST and Plasma Lithium Heparin	Immunoglobulin G	
Blood- Serum SST and Plasma Lithium Heparin	Immunoglobulin M	
Blood- Serum SST and Plasma Lithium Heparin	Iron	
Blood- Serum SST and Plasma Lithium Heparin. CSF	Lactate	
Blood- Serum SST and Plasma Lithium Heparin. CSF	Lactate dehydrogenase	
Blood- Serum SST and Plasma Lithium Heparin	Lipoprotein A	
Blood- Serum SST and Plasma Lithium Heparin	Lithium	
Blood- Serum SST and Plasma Lithium Heparin	Magnesium	



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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
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Paracetamol	
Blood- Serum SST and Plasma Lithium Heparin	Phenobarbitone	
Blood- Serum SST and Plasma Lithium Heparin	Phentoin	
Blood- Serum SST and Plasma Lithium Heparin	Phosphate	
Blood- Serum SST and Plasma Lithium Heparin	Potassium	
Blood- Serum SST and Plasma Lithium Heparin	Rheumatoid factor	
Blood- Serum SST and Plasma Lithium Heparin	Salicylate	
Blood- Serum SST and Plasma Lithium Heparin. Urine	Sodium	
Blood- Serum SST and Plasma Lithium Heparin	Theophylline	
Blood- Serum SST and Plasma Lithium Heparin	Tobramycin	
Blood- Serum SST and Plasma Lithium Heparin	Transferrin	



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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
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Triglyceride	
Blood- Serum SST and Plasma Lithium Heparin. Urine	Urate	
Blood- Serum SST and Plasma Lithium Heparin. Fluid + CSF. Urine	Total Protein	
	Automated Biochemistry (cont'd)	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin. Urine	Urea	
Blood- Serum SST and Plasma Lithium Heparin	Vancomycin	
Urine	Microalbumin	
	Automated Biochemistry (cont'd)	Abbott Alinity - chemiluminescent microparticle immunoassay (CMIA) technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Alpha-feta Protein	
Blood- Serum SST and Plasma Lithium Heparin	CA-125	
Blood- Serum SST and Plasma Lithium Heparin	Carcinoembryonic Antigen	
Blood- Serum SST and Plasma Lithium Heparin	Cortisol	
Blood- Serum SST and Plasma Lithium Heparin	DHEA-Sulfate	



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Estradiol	
Blood- Serum SST and Plasma Lithium Heparin	Ferritin	
Blood- Serum SST and Plasma Lithium Heparin	Folate	
Blood- Serum SST and Plasma Lithium Heparin	Follicle Stimulating Hormone	
Blood- Serum SST and Plasma Lithium Heparin	Luteinizing Hormone	
Blood- Serum SST and Plasma Lithium Heparin	Human chorionic gonadotropin (hCG)	
Blood- Serum SST and Plasma Lithium Heparin	Progesterone	
Blood- Serum SST and Plasma Lithium Heparin	Prolactin	
Blood- Serum SST and Plasma Lithium Heparin	Prostate specific antigen	
Blood- Serum SST and Plasma Lithium Heparin	Prostate specific antigen	
Blood- Serum SST and Plasma Lithium Heparin	Free triiodothyronine (FT3)	
Blood- Serum SST and Plasma Lithium Heparin	Free thyroxine (FT4)	
Blood- Serum SST and Plasma Lithium Heparin	Testosterone	



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Thyroid Stimulating Hormone (TSH)	
Blood- Serum SST and Plasma Lithium Heparin	Vitamin B12	
Blood- Serum SST and Plasma Lithium Heparin	Vitamin D	
Blood- Serum SST and Plasma Lithium Heparin	Troponin I	
Blood- Serum SST and Plasma Lithium Heparin	NT-PRO BNP	
Blood- Serum SST and Plasma Lithium Heparin	Pro-Calcitonin	
Blood- Serum SST and Plasma Lithium Heparin	Parathyroid Hormone	
Blood- Serum SST and Plasma Lithium Heparin	SARS-COV2-IgG	
Blood- Serum SST and Plasma Lithium Heparin	SARS-COV2-IgG	
Blood- Serum SST and Plasma Lithium Heparin	Tacrolimus	
Blood- Serum SST and Plasma Lithium Heparin	Thyroid peroxidase antibodies	



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required
	<u>Automated Biochemistry (cont'd)</u>	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32
Blood- Serum SST and Plasma Lithium Heparin	Macro Prolactin	Abbott Alinity using chemiluminescent microparticle immunoassay (CMIA) technology. PEG precipitation completed before sample run to allow for determination of macro prolactin if present
Urine	Metanephrines	WATERS High Pressure Liquid Chromatography CH-MAN-SOP-27
Urine/faeces	Detection of: Glucose Sucrose Galactose	High Performance Liquid Chromatography Measurement of Urine and faecal sugar by chromatography CH-MAN-SOP-5
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><b>HUMAN BODY FLUIDS AND TISSUES</b></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 UKHSA Standards for Microbiology Investigations and incorporating manufacturer's instructions as relevant:</p> <p>Manual culture and microscopy; identification using commercial kits and bioMerieux Vitek2 or Bruker MALDI-ToF</p> <p>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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiological – General <u>Bacteriology examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedure based on UKHSA Standards for Microbiology Investigations and incorporating manufacturer's instructions as relevant:
Bacterial isolates from samples indicated above.	Antimicrobial susceptibility testing of microorganisms.	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
Urine	Isolation and identification of significant microorganisms for the purposes of clinical diagnosis	Automated and/or Manual methods Automated microscopy CMB-BAC-BSOP-41 CMB-BAC-SOP-23 using: Equipment: Beckmann Coulter iQ200  Manual culture: identification using commercial kits and bioMerieux Vitek 2 or Bruker MALDI-ToF
Whole blood Sterile fluids	Isolation and identification of significant microorganisms for the purposes of clinical diagnosis.	Continuous automated monitoring for microbial growth In-house documented procedure based on UKHSA Standards for Microbiology Investigations and incorporating manufacturers instructions: CMB-BAC-BSOP-37 CMB-BAC-SOP-24  Equipment: Beckton Dickinson BACTEC FX  Manual culture: identification using commercial kits and bioMerieux Vitek 2 or Bruker MALDI-ToF
Bacteria or yeast isolates	Identification of microorganisms for the purpose of clinical diagnosis	Bruker MALDI Biotyper MBT smart CMB-BAC-SOP-25



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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 methods incorporating manufacturers' instructions as required
Faeces	Detection of antigen: GDH C difficile toxin A and B	In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-9CMB-VIR-SOP-10 Enzyme Linked Fluorescent Assay (ELFA)Equipment: BioMerieux Vidas
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
Nail Skin Hair	<u>Mycology examinations for the purpose of clinical diagnosis</u>  Isolation and identification of dermatophytes, non-dermatophytes and yeasts	Manual culture, manual staining and fluorescent microscopy for preliminary identification  CMB-BAC-BSOP-39 Manual staining using calcofluor white and fluorescent microscopy Manual plate culture
Faeces Duodenal/jejunal aspirates Urine Peri-anal swabs	<u>Parasitology examinations for the purpose of clinical diagnosis</u>  Examination for the presence of parasites (ova, cysts, trophozoites and worms)	CMB-BAC-BSOP-31 Direct microscopy and modified formol-ether concentration



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Virology and Serological examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturer's instructions:
Serum	Detection of: HBsAg Ultra HIV DUO RUBELLA IgG II Toxoplasma total Ab 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	Manual Rapid immunochromatographic test using procedure CMB-VIR-SOP-5



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HUMAN BODY FLUIDS (cont'd)	<u>Virology and Serological examinations for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions as required
Faeces	Rotavirus Adenovirus	Manual Rapid immunochromatographic test using procedure CMB-BAC-BSOP-30
Combined nose and throat swab in viral transport medium Nasopharyngeal Aspirate (NPA)	Rapid SARS-CoV-2 detection of: E gene N2 gene	PCR using Cepheid GeneXpert using SARS-CoV-2 Xpert Xpress assay CMB-VIR-SOP-36
Combined nose and throat swab in viral transport medium Nasopharyngeal Aspirate (NPA)	Rapid detection of: SARS-CoV-2 combined N2 & E gene Influenza A Influenza B RSV	PCR using Cepheid GeneXpert using SARS-CoV-2 combined Xpert Xpress assay CMB-VIR-SOP-36
Faeces	Rapid detection of <i>Clostridium difficile</i> : tcdB (toxin B gene) cdt (binary toxin gene) nucleotide position 117 of the tcdC gene	PCR using Cepheid GeneXpert and Xpert C.difficile BT assay CMB-VIR-SOP-33
Combined nose and throat swab in viral transport medium Nasopharyngeal Aspirate (NPA)	Rapid SARS-CoV-2 detection of: ORF1 gene	Hologic Panther using Transcription mediated amplification (TMA) technology and Hologic Aptima SARS-CoV-2 assay CMB-VIR-SOP-35
Combined nose and throat swab in viral transport medium Nasopharyngeal Aspirate (NPA) Bronchial Alveolar Lavage (BAL) Sputum	Detection of SARS-CoV-2: ORF1 gene N gene	Extraction of viral RNA using Qiagen QIAcube and Qiagen QIAamp viral RNA mini (manual and automated on the QIAcube) followed by Real time PCR testing on Thermo Scientific ABI 7500 using CerTest Viasure SARS-CoV-2 assay CMB-VIR-SOP-17 CMB-VIR-SOP-39



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Virology and Serological examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required
Combined nose and throat swab in viral transport medium Nasopharyngeal Aspirate (NPA) Bronchial Alveolar Lavage (BAL) Sputum	Detection of: SARS-CoV-2 combined N1 & N2 gene Influenza A Influenza B RSV	Extraction of viral RNA using Qiagen QIAcube and Qiagen QIAamp viral RNA mini (manual and automated on the QIAcube) followed by Real time PCR testing on Thermo Scientific ABI 7500 using combined CerTest Viasure SARS-CoV-2/Flu/RSV assay CMB-VIR-SOP-17 CMB-VIR-SOP-40
Faeces	Detection of Helicobacter pylori antigen	Premier Platinum Hp SA PLU enzyme Immunoassay on Dynex DS2 automated ELISA CMB-VIR-SOP-38
	<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	Determination and quantification of nucleic acid for: HCV	Reverse transcription PCR Equipment: Cepheid GeneXpert In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-29
EDTA Plasma	Determination and quantification of nucleic acid for: HIV	Reverse transcription PCR Equipment: Cepheid GeneXpert In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-28
Faeces	Detection of: Norovirus I Norovirus II	Reverse transcriptase PCR using CMB-VIR-SOP-27 Equipment: : Cepheid GeneXpert



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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:
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
CSF	HSV-1 HSV-2 VZV Enterovirus Parechovirus	Nucleic acid extraction followed by PCR amplification using QIAGEN QIAcube, ABI 7500 Fast PCR system: CMB-VIR-SOP-17 CMB-VIR-SOP-20
Faeces	Investigation for Gastro-intestinal pathogens: Salmonella enterica spp Shigella spp Enteroinvasive E.coli Campylobacter jejuni/coli/lari Cryptosporidium parvum/hominis Giardia duodenalis Verotoxin-producing E.coli	EntericBio real-time Gastro Panel 2 PCR assay using EntericBio workstation and Roche Lightcycler 480 II CMB-BAC-BSOP-30
END		