

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 15189:2022</p>	<h3>Royal Cornwall Hospitals NHS Trust</h3> <p>Issue No: 019 Issue date: 24 April 2026</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 by the Organisation at the locations specified below</p>		

Laboratory locations:

Location details	Activity	Location code
<p>Royal Cornwall Hospitals NHS Trust Truro Cornwall TR1 3LQ</p> <p style="text-align: center;">Sarah Pointon</p>	<p>Haematology Blood Transfusion Biochemistry Microbiology Histopathology Cytology Andrology</p>	A

Site activities performed away from the location listed above:

Location details	Activity	
<p>Trauma Theatre, Delivery Suite, Main Theatres Royal Cornwall Hospital Truro TR1 3QJ</p>	<p>Storage & issue of blood and blood products</p>	B
<p>Royal Cornwall Hospitals NHS Trust Truro Cornwall TR1 3LQ</p>	<p>Mortuary and body storage</p>	C
<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>	D



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Location details	Activity	
St Michael's Hospital Royal Cornwall Hospitals NHS Trust Trelissick Road Hayle TR27 4JA	Storage & issue of blood and blood products only	E
Duchy Hospital Penventinnie Lane Truro TR1 3UP	Storage & issue of blood and blood products only	F
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.	G
EBUS and EUS Endoscopy Suite Royal Cornwall Hospital Truro TR1 3QJ	Rapid on-Site evaluation of diagnostic cytology samples	H
MOH's Laboratory, Dermatology Department, Royal Cornwall Hospital Truro TR1 3LJ	Moh's microscopical controlled excision of cutaneous tumours	I
Head and Neck Fine Needle Aspiration Clinic Ultrasound Outpatients department Camborne Redruth Community Hospital Redruth TR15 3ER	Rapid on-Site evaluation of diagnostic cytology samples	J
Bodmin Hospital CDC Boundary Road Bodmin PL31 2QT	Rapid on-Site evaluation of diagnostic cytology samples via Telecytology	K



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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>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	A
Whole Blood	D variant investigation	Manual ABO and RhD grouping using Grifols DG Gel cards using procedure: BT-SOP-35	A
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	A
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	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion 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:	A
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	A
Whole Blood	Compatibility testing	Manual technique using Grifols DG Gel cards using procedure: BT-SOP-40 BT-SOP-33	A
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	A
Blood	Foetal Maternal Haemorrhage	Kleihauer Acid Elution Technique - BT-SOP-31	A



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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 HA-AH-SOP-10	A
Blood	Morphology for the purpose of clinical diagnosis	Alinity automated slide maker HA-AH-SOP-45, HA-TRAIN-4 ELITech Group Aerospray Pro Haematology slide stainer Microscopes Light Microscopy HA-AH-SOP-14 HA-AH-SOP-15	A
Bone marrow	Morphology for the purpose of clinical diagnosis	Automated May Grunwald Giemsa staining using the ELITech Group Aerospray Pro Haematology slide stainer and manual Perls staining followed up light microscopy HA-IMM-SOP-11	A
Blood	Glandular Fever Screen (Infectious Mononucleosis Heterophile Antibody)	Monogen Infectious Mononucleosis screening kit Latex agglutination method HA-AH-SOP-17	A



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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:	
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	A
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	A
Body fluids (Ascitic, Pleural, peritoneal dialysis, synovial)	Body fluid cell counts Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	Automated May Grunwald staining using the Aerospray Pro Haematology slide stainer HA-AH-SOP-6, HA-AH-SOP-14	A
CSF	CSF examination	Automated May Grunwald staining using the Aerospray Pro Haematology slide stainer HA AH SOP 11, HA-AH-INFO-2, HA-AH-SOP-6, HA-AH-SOP-14	A



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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:	
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.	A
Whole Blood	Identification and measurement of: HbA0 HbA2 HbF HbA1c	Sickledex Hb S Screening Test kit Haemoglobin Solubility method HA-AH-SOP-16	A
Plasma	<u>Haemostasis and thrombosis</u> <u>Haematological examinations for the purpose of clinical diagnosis</u> PT/INR APTT Thrombin Time Normal Plasma correction	Sebia Capillarys Tera 3 using electrophoresis HA-CO-SOP-15 CH-MAN-SOP-30	A
Plasma	Fibrinogen – Clauss	ACL TOP 550 Optical/Turbidimetric HA-AH-SOP-10 HA-AH-SOP-28 HA-AH-SOP-35	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis</u> <u>Haematological examinations</u> <u>for the purpose of clinical</u> <u>diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Plasma	D-Dimers	ACL TOP 550 Optical/Turbidimetric HA-AH-SOP-10 HA-AH-SOP-23 HA-AH-SOP-28	A
Plasma	PT/INR Thrombin	Manual tube technique clotting HA-CO-SOP-31 HA-AH-SOP-10	A
Plasma	APTT	Manual tube technique clotting HA-CO-SOP-21 HA-AH-SOP-10	A
Plasma	Fibrinogen – Clauss	Manual tube technique clotting HA-AH-SOP-10 HA-CO-SOP-26	A
Plasma	Normal plasma correction	Manual tube technique clotting HA-AH-SOP-10 HA-AH-SOP-31 HA-CO-SOP-21	A
Plasma	Reptilase time	Manual tube technique clotting HA-AH-SOP-10 HA-CO-SOP-32	A
Plasma	Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII	ACL TOP 550 Optical/turbidimetric HA-CO-SOP-7	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis</u> <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	Inhibitor Screen	Manual dilutions ACL TOP 550 Optical/turbidimetric HA-CO-SOP-30	A
Plasma	Factor VIII Inhibitor Factor IX Inhibitor	Manual dilutions and assayed using ACL TOP 550 Optical/turbidimetric HA-CO-SOP-30 HA-CO-SOP-36	A
Plasma	VWF antigen VWF Ricof	ACL TOP 550 Latex immunoassay HA-CO-SOP-12	A
Plasma	Antithrombin Protein S	ACL TOP 550 Chromogenic/Latex immunoassay HA-CO-SOP-40	A
Plasma	Protein C functional	ACL TOP 550 Optical/Turbidimetric HA-CO-SOP-40	A
Plasma	Lupus anticoagulant	Manual tube technique Clotting HA-CO-SOP-43	A
Plasma	Anti Xa for LMWH, RIV, APIX	ACL TOP 550 Optical/Turbidimetric HA-CO-SOP-39	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis</u> <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:	
Citrated plasma	Coagulation: Anti-xa for Heparin and LMWH Rivaroxaban Apixaban Edoxaban	ACL TOP 550 Optical/Turbidimetric HA-CO-SOP-39	A
Blood	<u>Haemolytic examinations for the purpose of clinical diagnosis</u> G6PD screen	Manual Technique Fluorescent spot HA-CO-SOP-13	A
Citrated plasma	ADAMTS13 Functional Assay	ADAMTS13 on the Acustar (HA-CO-SOP-54) Automated method on Acustar HA-CO-SOP-51	A
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. HA-CO-SOP-51	A
Citrated plasma	Collagen Binding Assay	Collagen Binding Assay on the Acustar (HA-CO-SOP-53) Automated method on Acustar HA-CO-SOP-51	A
Citrated plasma	Heparin Induced Thrombocytopaenia Screen (HIT)	Heparin Induced Thrombocytopaenia Screen (HIT) on the Acustar (HA-CO-SOP-52) HA-CO-SOP-51	A



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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	A
Semen	<u>Fertility testing</u>	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	A
	Volume	Volume/weight	A
	pH	Colorimetric strips	A
	Sperm morphology excluding TZI scoring	Automated Papanicolaou staining using the ELITech Aerospray Cytology Stainer Light Microscopy (Bright field)	A
	Sperm concentration	Microscopy (Phase contrast)	A
	Sperm motility	Microscopy (Phase contrast)	A



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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>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</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>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Diagnostic Cytological examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: DMP-GEN-SOP-25 Non-Gynae Screening using microscopes as follows: Nikon Eclipse E400 Olympus BX45 Leica DMLB	A
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	A G H
Fine needle aspirations (FNA)	Cellularity assessment	Manual material/slide preparation, Diff-Quik Romanowsky stain and telectology via Cellsens software using DMP-CY-NG-SOP-28 and microscopes: Olympus BX43	J, K
	<u>Histopathology examinations for the purpose of clinical diagnosis</u>	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
Formalin fixed tissues	Preparation and examination to identify or exclude morphological & structural abnormalities	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	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examinations for the purpose of clinical diagnosis</u>	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues	Preparation and examination to identify or exclude morphological & structural abnormalities	Decalcification Manual method using: Decalcification and softening SOP – DMP-IMM-SOP-5	A
Formalin fixed tissues		Tissue Processing Automated method using: Leica Peloris Tissue Processors and procedure for Operating Peloris Tissue Processor DMP-HI-SOP-47	A
Formalin fixed tissues		Embedding Manual method using: DMP-HI-SOP-47 Procedure for the embedding of tissue in paraffin wax	A
Formalin fixed tissues		Microtomy Manual method using: DMP-HI-SOP-46 and Leica RM2235, Leica RM2245, Leica Histocore Biocut and Leica Histocore Autocut	A
Fresh tissue Frozen tissue	Intra-operative diagnosis	Rapid frozen section Leica CM1950 cryostat & Leica ST4020 Mini linear staining machine DMP-HI-SOP-3	A
Fresh/Frozen tissue	MOHs microscopical controlled excision of cutaneous tumours	Manual cryotomy using Bright Instruments Cryostat cryostat - SOP: DMP-HI-SOP-45	I



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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	A
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:	A
	Acid and sulphated mucins	Alcian Blue	A
	Liberated aldehydes	Alcian Blue/PAS	A
	Amyloid	Congo Red	A
	Differentiating between haemopoetic cells	Giemsa	A
	<i>Helicobacter pylori</i>	Giemsa	A
	Gram positive and Gram-negative organisms	Gram	A
	Fungi and Pneumocystis	Grocott	A
	Basement membranes	Jones Hexamine Silver	A
	Collagen and smooth muscle	Masson's Trichrome	A
	Elastic fibres & collagen	Miller's Elastin Van Gieson	A
	Hydrophobic (neutral) lipids	Oil Red O	A
	Hepatitis B surface antigen and copper associated proteins	Orcein	A



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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:	A
	Liberated aldehydes	Periodic Acid Schiffs (PAS) with/without digestion (PASD)	A
	Haemosiderin	Perl's Prussian Blue	A
	Reticulin fibres	Reticulin	A
	Spirochetes	Warthin-Starry	A
	Acid fast bacilli, e.g. <i>M. tuberculosis</i>	Ziehl Neelsen (ZN)	A
	Pan-keratin (Simple & complex epithelia)	AE1/AE3 (pan-cytokeratin)	A
	<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:	
FFPE tissue	Sex chord stromal tumour cells	Alpha-Inhibin	A
	Mast cells	AA1 (mast cell tryptase)	A
	Embryonic cell in normal tissues and germ tumours	Alpha feto protein (AFP)	A
	Anaplastic lymphoma kinase (receptor CD246)	ALK1	A
	B-catenin protein, binds to cytoplasmic tail of E-cadherin	Beta Catenin	A



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FFPE tissue (cont'd)	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas	BCL2 and BCL6	A
	Range of B-cell lymphocytes	BOB1	A
	Cancer antigen 125	CA125	A
	Sialyl-Lewis A, marker for the detection of pancreatic cancer	CA19-9	A
	Smooth muscle cells	H-Caldesmon	A
	Calcium binding protein structurally related to S100 and inhibin	Calretinin	A
	MHC class 1 related cell surface glycoprotein in cortical thymocytes; Langerhan's cells; interdigitating reticulum cells	CD1a	A
	Circulating T lymphocytes	CD2	A
	T-cells	CD3	A
	T-cells (helper and mature)	CD4	A
	Mature T-cells, T-cell lymphomas	CD5	A
	Suppressor/cytotoxic T lymphocytes	CD8	A
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10	A
	Hodgkin's & Reed-Sternberg cells	CD15	A



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FFPE tissue (cont'd)	Suppressor/cytotoxic T lymphocytes	CD8	A
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10	A
	Hodgkin's & Reed-Sternberg cells	CD15	A
	B lymphocytes	CD 20 (L26)	A
	Follicular dendritic cells	CD21	A
	Key molecule for B cell activation and growth	CD23	A
	Hodgkin's & Reed-Sternberg cells	CD30	A
	Endothelial cells; plasma cells; activated B & T lymphocytes	CD31	A
	Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours	CD34	A
	Leukocyte common antigen	CD45 (LCA)	A
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56	A
	Identify platelets, megakaryocytes	CD61	A
	Macrophages; monocytes; granulocytes	CD68 (KP1)	A
	Normal & neoplastic B lymphocytes	CD79a	A



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HUMAN TISSUES AND FLUIDS (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:	
FFPE tissue (cont'd)	C-kit oncoprotein – melanocytes, mast cells and glial cells	CD117	A
	Normal and neoplastic plasma cells	CD138	A
	Intestinal specific transcription factor	CDX2	A
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	CEA (MONOCLONAL)	A
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin	A
	Simple, glandular & transitional epithelia	CK 7	A
	Ductal and glandular Epithelia	CK19	A
	Gastric and intestinal epithelium	CK 20	A
	Cytomegalovirus viral inclusions	CMV IHC	A
	Mantle cell lymphoma and a variety of other tumours	CYD1	A
	Lymphatic endothelium marker	D-240	A
	Smooth & striated muscle cells	Desmin	A
	Interstitial cells of Cajal in GI tract, GIST	DOG-1	A
	Latent EBV infection	EBER ISH Manual dewax	A
	Cell-cell boundaries or squamous epithelium	E-cadherin	A



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FFPE tissue (cont'd)	Epithelial membrane antigen (Glandular & ductal epithelia, perineurium; other cell types in various tumours)	EMA	A
	Cellular estrogen receptor expression	Estrogen receptor	A
	Epithelial cell types	ESA (BerEP4)	A
	Dermal dendritic cells	FXIIIa	A
	Neoplastic breast ductal cells	GATA3	A
	Expression of human epidermal growth factor receptor II	HER2 IHC (breast)	A
	Her2 region of chromosome 17	Her2 DDISH	A
	Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours)	HMB45	A
	Herpes simplex virus	HSV	A
	Plasma cells and related lymphoid cells containing IgD	IGD	A
	Plasma cells and related lymphoid cells containing IgM	IGM	A
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa normal tissue	A
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa BMT	A



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HUMAN TISSUES AND FLUIDS (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:	
FFPE tissue (cont'd)	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa ISH BMT Manual Dewax	A
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa ISH Manual Dewax	A
	Proliferating cells	KI67	A
	Dual stain	KI67/MELANA DUAL STAIN	A
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda BMT	A
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda ISH BMT Manual Dewax	A
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda ISH Manual Dewax	A
	Melan A (MART-1) differentiation antigen (Normal, activated & neoplastic melanocytes)	MelanA	A
	MLH-1 mismatch repair protein	MLH-1 (mismatch repair)	A
	Pan-keratin (Simple & complex epithelia)	MNF116 (pan-cytokeratin)	A
	MSH-2 mismatch repair protein	MSH-2 (mismatch repair)	A
	MSH6 mismatch repair protein in colorectal carcinomas	MSH-6 (mismatch repair)	A
	Multiple myeloma oncogene-1	MUM1	A



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HUMAN TISSUES AND FLUIDS (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:	
FFPE tissue (cont'd)	Neutrophil granulocytes, monocytes	Myeloperoxidase	A
	B-lymphocyte transcription factor	OCT2	A
	Pluripotent germ cell tumours	OCT 3/4	A
	Atypical prostatic acini	Prostatic acid phosphatase (PAP)	A
	Pre-B cells	PAX-5	A
	Mantle, germinal centre, interfollicular B-cells	PAX-8	A
	p16INK4a oncoprotein (Normal, activated and neoplastic)	P16	A
	Carcinomas; many neoplasms and normal cells	P53	A
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells	P63	A
	Expression of Alpha Methyl Acyl		A
	Coenzyme A Racemase	P504s	A
	Dual stain used on prostate cases	P63/P504S cocktail	A
	PMS2 mismatch repair protein in colorectal carcinomas	PMS-2 (mismatch repair)	A
	Cellular progesterone receptor expression	Progesterone receptor	A
	Prostate specific antigen	Prostate specific antigen (PSA)	A
	Non-small cell lung cancer/SCC	PD-L1 (SP263)	A



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HUMAN TISSUES AND FLUIDS (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:	
FFPE tissue (cont'd)	Melanocytic marker	SOX-10	A
	Melanocytes and langerhan cells	S100	A
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types	S100 red	A
	Smooth muscle, myoepithelial and other contractile cells	Smooth muscle actin (SMA)	A
	Smooth muscle myosin heavy chain	Smooth muscle myosin heavy chain (SMMHC)	A
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synatophysin	A
	Terminal deoxynucleotidyl transferase in thymic and small number of bone marrow cortical lymphocytes	TdT	A
	Thyroid transcription factor-1 (Thyroid follicular & C cells)	TTF1 (Leica)	A
	Vimentin intermediate filament	Vimentin	A
	WT1 expression	WT1	A
	<i>Helicobacter pylori</i>	<i>H. pylori</i>	A
	DNA repair, loss observed in mesothelioma	BAP1	A
	Epithelial marker, isoform of P63	P40	A
	Epithelial marker, lateral and basement membrane	MOC-31	A



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HUMAN TISSUES AND FLUIDS (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:	
FFPE tissue (cont'd)	Prostatic hyperplasia and prostate adenocarcinoma	NKX3.1	A
	Red blood cell and precursor marker	Glycophorin C (RET 40)	A
	Squamous epithelium	CK5	A
Frozen sections	Identification of antigens and antibodies in various auto-immune skin and renal diseases:	C1Q	A
Frozen sections	Polyclonal light chains of kappa type	Kappa	A
	Detection of:	Immunofluorescence using Roche Ventana BenchMark Ultra Platforms and procedure DMP-IMM-SOP-21 and the following antibodies:	
Frozen sections	Characterising renal & cutaneous immune disorders	IgA, IgM, IgG	A
Fresh/Frozen Tissue	Detection of Polyclonal light chains of Lambda type	Direct Immunofluorescence for Polyclonal light chains using Lambda antibody	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular abnormalities for therapeutic application:</u>	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	A
Liquid Based Cytology	Detection of EGFR mutations (including NSCLC)	PCR using the Biocartis Idylla platform. DMP-IMM-SOP-31 for EGFR (LBC)	A
	<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	A
Serum/EDTA plasma	Visual detection of presumptive Cryoproteinsick	Visual inspection of cryoprotein precipitate formation: CH-MAN-SOP-1	A
Urine	5-Hydroxyindoleacetic Acid	WATERS High Pressure Liquid Chromatography CH-MAN-SOP-29	A
Urine, Blood	Osmolality	Micro-Osmomter Osmo1 using freezing point methodology CH-AUTO-SOP-10	A
		Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood Plasma	Ammonia		A
Blood- Serum SST and Plasma Lithium Heparin	Alpha-1-antitrypsin		A
Blood- Serum SST and Plasma Lithium Heparin. Fluid + CSF	Albumin		A



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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	
Blood- Serum SST and Plasma Lithium Heparin	Alkaline Phosphatase	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin	Apolipoprotein B		A
Blood- Serum SST and Plasma Lithium Heparin. CSF	Amylase		A
Blood- Serum SST and Plasma Lithium Heparin	Aspartate Aminotransferase		A
Blood- Serum SST and Plasma Lithium Heparin	Beta-2-microglobulin		A
Blood- Serum SST and Plasma Lithium Heparin	Bicarbonate		A
Blood- Serum SST and Plasma Lithium Heparin	Bile Acids		A
Blood- Serum SST and Plasma Lithium Heparin	Conjugated Bilirubin		A
Blood- Serum SST and Plasma Lithium Heparin, CSF	Total Bilirubin		A
Blood- Serum SST and Plasma Lithium Heparin	C3 (complement)		A
Blood- Serum SST and Plasma Lithium Heparin	C4 (complement)		A
Blood- Serum SST and Plasma Lithium Heparin	Caeruplasmin		A



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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	
Blood- Serum SST and Plasma Lithium Heparin. Urine	Calcium	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin	Carbamazapine		A
Blood- Serum SST and Plasma Lithium Heparin	Chloride		A
Blood- Serum SST and Plasma Lithium Heparin	Cholesterol		A
Blood- Serum SST and Plasma Lithium Heparin	Creatine Kinase		A
Blood- Serum SST and Plasma Lithium Heparin. Urine	Creatinine Enzymatic		A
Blood- Serum SST and Plasma Lithium Heparin	C-reactive protein		A
Blood- Serum SST and Plasma Lithium Heparin	Digoxin		A
Blood- Serum SST and Plasma Lithium Heparin	Ethanol		A
Blood- Serum SST and Plasma Lithium Heparin	Gentamicin		A
Blood- Serum SST and Plasma Lithium Heparin	Gamma-glutamyl transferase		A
Blood- Serum SST and Plasma Lithium Heparin. Fluid + CSF	Glucose		A



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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	
Blood- Serum SST and Plasma Lithium Heparin	Haptoglobin	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin	High-density lipoprotein		A
Blood- Serum SST and Plasma Lithium Heparin	Immunoglobulin A		A
Blood- Serum SST and Plasma Lithium Heparin	Immunoglobulin G		A
Blood- Serum SST and Plasma Lithium Heparin	Immunoglobulin M		A
Blood- Serum SST and Plasma Lithium Heparin	Iron		A
Blood- Serum SST and Plasma Lithium Heparin. CSF	Lactate		A
Blood- Serum SST and Plasma Lithium Heparin. CSF	Lactate dehydrogenase		A
Blood- Serum SST and Plasma Lithium Heparin	Lipoprotein A		A
Blood- Serum SST and Plasma Lithium Heparin	Lithium		A
Blood- Serum SST and Plasma Lithium Heparin	Magnesium		A
Blood- Serum SST and Plasma Lithium Heparin	Paracetamol		A



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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	
Blood- Serum SST and Plasma Lithium Heparin	Phenobarbitone	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin	Phentoin		A
Blood- Serum SST and Plasma Lithium Heparin	Phosphate		A
Blood- Serum SST and Plasma Lithium Heparin	Potassium		A
Blood- Serum SST and Plasma Lithium Heparin	Rheumatoid factor		A
Blood- Serum SST and Plasma Lithium Heparin	Salicylate		A
Blood- Serum SST and Plasma Lithium Heparin. Urine	Sodium		A
Blood- Serum SST and Plasma Lithium Heparin	Theophylline		A
Blood- Serum SST and Plasma Lithium Heparin	Tobramycin		A
Blood- Serum SST and Plasma Lithium Heparin	Transferrin		A
Blood- Serum SST and Plasma Lithium Heparin	Triglyceride		A
Blood- Serum SST and Plasma Lithium Heparin. Urine	Urate		A



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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	
Blood- Serum SST and Plasma Lithium Heparin. Fluid + CSF. Urine	Total Protein	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin. Urine	Urea		A
Blood- Serum SST and Plasma Lithium Heparin	Vancomycin		A
Urine	Microalbumin		A
Blood- Serum SST and Plasma Lithium Heparin	Alpha-feta Protein		A
Blood- Serum SST and Plasma Lithium Heparin	CA-125		A
Blood- Serum SST and Plasma Lithium Heparin	Carcinoembryonic Antigen		A
Blood- Serum SST and Plasma Lithium Heparin	Cortisol		A
Blood- Serum SST and Plasma Lithium Heparin	DHEA-Sulfate		A
Blood- Serum SST and Plasma Lithium Heparin	Estradiol		A
Blood- Serum SST and Plasma Lithium Heparin	Ferritin		A
Blood- Serum SST and Plasma Lithium Heparin	Folate		A
Blood- Serum SST and Plasma Lithium Heparin	Follicle Stimulating Hormone		A



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Blood- Serum SST and Plasma Lithium Heparin	Luteinizing Hormone	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin	Human chorionic gonadotropin (hCG)		A
Blood- Serum SST and Plasma Lithium Heparin	Progesterone		A
Blood- Serum SST and Plasma Lithium Heparin	Prolactin		A
Blood- Serum SST and Plasma Lithium Heparin	Prostate specific antigen		A
Blood- Serum SST and Plasma Lithium Heparin	Prostate specific antigen		A
Blood- Serum SST and Plasma Lithium Heparin	Free triiodothyronine (FT3)		A
Blood- Serum SST and Plasma Lithium Heparin	Free thyroxine (FT4)		A
Blood- Serum SST and Plasma Lithium Heparin	Testosterone		A
Blood- Serum SST and Plasma Lithium Heparin	Thyroid Stimulating Hormone (TSH)		A
Blood- Serum SST and Plasma Lithium Heparin	Vitamin B12		A
Blood- Serum SST and Plasma Lithium Heparin	Vitamin D		A
Blood- Serum SST and Plasma Lithium Heparin	Troponin I		A



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Blood- Serum SST and Plasma Lithium Heparin	NT-PRO BNP	Abbott Alinity - photometric detection technology CH-AUTO-SOP-32	A
Blood- Serum SST and Plasma Lithium Heparin	Pro-Calcitonin		A
Blood- Serum SST and Plasma Lithium Heparin	Parathyroid Hormone		A
Blood- Serum SST and Plasma Lithium Heparin	SARS-COV2-IgG		A
Blood- Serum SST and Plasma Lithium Heparin	SARS-COV2-IgG		A
Blood- Serum SST and Plasma Lithium Heparin	Tacrolimus		A
Blood- Serum SST and Plasma Lithium Heparin	Tyroid peroxidase antibodies		A
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	A
Urine	Total Metadrenaline Total Normetadrenaline 3-methoxytyramine	WATERS High Pressure Liquid Chromatography with electrochemical detection CH-MAN-SOP-27	A
Urine/faeces	Detection of: Glucose Sucrose Galactose	High Performance Liquid Chromatography Measurement of Urine and faecal sugar by chromatography CH-MAN-SOP-5	A



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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	A
Faeces	Calprotectin	Buhlmann Enzyme Linked Immunoassay (ELISA) with extraction CH-MAN-SOP-8	A
Sweat	Chloride	Sherwood 926 Chloride Meter Coulometry CH-MAN-SOP-28	A
Faeces	Faecal elastase	Alpha Laboratories BUHLMANN FPELA TURBO™ kit CH-MAN-SOP-37	A



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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 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>	<p>A</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 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	A
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	A
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	A



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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	
Bacteria or yeast isolates	Identification of microorganisms for the purpose of clinical diagnosis	Bruker MALDI Biotyper MBT smart CMB-BAC-SOP-25	A
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	A
Rectal swabs Faeces	Detection of bacteria with carbapenem-hydrolysing B-lactamases (carbapenemases) in screening samples	ThermoFisher Scientific Brilliance CRE selective medium CMB-BAC-BSOP-60 Resist-5	A
Urine	Detection of: <i>Streptococcus pneumoniae</i> antigen <i>Legionella pneumophila</i> antigen	Manual Rapid immunochromatographic test using procedure CMB-VIR-SOP-5	A
Faeces	Rotavirus Adenovirus	Manual Rapid immunochromatographic test using Coris Bioconcept Combi-strip CMB-BAC-BSOP-30	A
Faeces	Detection of <i>Helicobacter pylori</i> antigen	Premier Platinum Hp SA PLUS enzyme Immunoassay on Dynex DS2 automated ELISA CMB-VIR-SOP-38	A
Nail Skin Hair	Mycology examinations for the purpose of clinical diagnosis Isolation and identification of dermatophytes, non-dermatophytes and yeasts	CMB-BAC-BSOP-39 Manual staining using calcofluor white and fluorescent microscopy Manual plate culture	A



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Faeces Duodenal/jejunal aspirates Urine Peri-anal swabs	<u>Parasitology examinations for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions as required	A
	Examination for the presence of parasites (ova, cysts, trophozoites and worms)	CMB-BAC-BSOP-31 Direct microscopy and modified formol-ether concentration	
Serum	<u>Virology and Serological examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturer's instructions:	A
	Detection of:	Enzyme Linked Fluorescent Assay (ELFA), Equipment: bioMerieux Vidas and procedure: CMB-VIR-SOP-9	
	Hepatitis B surface antigen	HBsAg Ultra	
	HIV 1 and 2 antibodies	HIV Duo	
	Anti - HCV	Anti-HCV	
	Toxoplasma total Antibody	Toxoplasma total Ab	
	Varicella Zoster Virus IgG	VZV IgG	
	Measles IgG	Measles IgG	
	<i>Borellia burgdorferi</i> (Lyme) IgM	<i>Borellia burgdorferi</i> (Lyme) IgM	
<i>Borellia burgdorferi</i> (Lyme) IgG	<i>Borellia burgdorferi</i> (Lyme) IgG		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology and Serological examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturer's instructions:	
Serum	Serological detection of:	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 *)	A
	Hepatitis B surface antibody (anti-HBs)	CMIA based examination for the serological detection Equipment: Abbott Architect i2000SR In-house documented method incorporating manufacturers instructions: CMB-VIR-SOP-30	A
	Hepatitis B surface antigen*	Anti-HBs	A
	HIV 1+2 Ab and HIV 1 p24 antigen*	HBsAg	A
	Syphilis Total Antibody*	HIV Ag/Ab Combo	A
	Rubella IgG	Syphilis TP	A
	Hepatitis A IgG	Rubella IgG	A
	Hepatitis A IgM	Anti-HAV IgG	A
	Cytomegalovirus IgG	Anti-HAV IgM	A
	Cytomegalovirus IgM	CMV IgG	A
	Cytomegalovirus IgG Avidity	CMV IgM	A
	Epstein Barr Virus VCA IgG	CMV IgG Avidity	A
	Epstein Barr Virus VCA IGM	EBV VCA IgG	A
		EBV VCA IGM	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology and Serological examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturer's instructions:	
Serum	Serological detection of:	CMIA based examination for the serological detection Equipment: Abbott Architect i2000SR In-house documented method incorporating manufacturers instructions: CMB-VIR-SOP-30	A
	Epstein Barr Virus EBNA IgG	EBV EBNA IgG	A
	Hepatitis C virus antibody	Anti-HCV	A
	Hepatitis B core total	Anti-HBc	A
Serum	Hepatitis E Virus IgM	Manual Rapid immunochromatographic test using MP Biomedical Assure HEV IgM Test CMB-VIR-SOP-5	A
	<u>Molecular examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturers instructions:	
GU swabs Urine	Detection of : <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	PCR amplification using Hologic Panther and procedure: CMB-VIR-SOP-24	A
Serum	Determination and quantification of nucleic acid for: Hepatitis C virus	Reverse transcription PCR Equipment: Cepheid GeneXpert In-house documented method incorporating manufacturer's instructions: CMB-VIR-SOP-29	A
Faeces	Rapid detection of <i>Clostridioides 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	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturers instructions:	
Combined nose and throat swab in viral transport medium Nasopharangeal 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	A
Combined nose and throat swab in viral transport medium Nasopharangeal Aspirate (NPA)	Rapid detection of: SARS-CoV-2 combined N2 & E gene Influenza A Influenza B Respiratory Syncytial Virus	PCR using Cepheid GeneXpert using SARS-CoV-2 combined Xpert Xpress assay CMB-VIR-SOP-36	A
Faeces	Detection of: Norovirus I Norovirus II	Reverse transcriptase PCR using CMB-VIR-SOP-27 Cepheid GeneXpert Xpert Norovirus assay CMB-VIR-SOP-36	A
Respiratory samples	Detection of: Influenza A and Swine Lineage Influenza B Adenovirus Respiratory Syncytial Virus Enterovirus Rhinovirus hMPV Parainfluenza 1,2,3,4 <i>Mycoplasma pneumoniae</i> SARS-CoV-2 ORF 1 and ORF-8	Nucleic acid extraction followed by PCR amplification using NucliSENS EMAG and AusDiagnostics High-Plex Alliance™ robot and analyser and procedures CMB-VIR-SOP-23 and CMB-VIR-SOP-43	A
Swabs	Detection of presence of nucleic acid for: Herpes Simplex Virus-1 Herpes Simplex Virus-2 Varicella Zoster Virus Enterovirus Adenovirus	Nucleic acid extraction followed by PCR amplification using NucliSENS EMAG and AusDiagnostics High-Plex Alliance™ robot and analyser, AusDiagnosis Herpes, Enterovirus and Adenovirus 8-well Panel and procedures CMB-VIR-SOP-23 and CMB-VIR-SOP-43	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purpose of clinical diagnosis</u>	In-house documented method incorporating manufacturers instructions:	
Faeces	Investigation for Gastro-intestinal pathogens: <i>Salmonella enterica</i> spp <i>Shigella</i> spp Enteroinvasive <i>E. coli</i> <i>Campylobacter jejuni/coli/lari</i> <i>Cryptosporidium parvum/hominis</i> <i>Giardia duodenalis</i> Shiga-like toxin producing <i>E. coli</i> <i>Yersinia enterocolitica</i> spp. <i>Vibrio cholerae/parahemolyticus</i> <i>Entamoeba histolytica</i>	Serosep Enteric Dx PCR using EntericBio workstation and Roche Lightcycler 480 II CMB-BAC-BSOP-30	A
END			