


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9724 Accredited to ISO 15189:2012</p>	<p>York and Scarborough Teaching Hospitals NHS Foundation Trust</p> <p>Issue No: 017 Issue date: 14 April 2025</p>	
	<p>York Hospital Wigginton Road York North Yorkshire YO31 8HE</p>	<p>Contact: Elizabeth Fox Tel: +44 (0) 1904 725163 E-Mail: Elizabeth.Fox14@nhs.net Website: www.yorkhospitals.nhs.uk/our-services/a-z-of-services/laboratory-medicine1</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
<p>Address York Hospital Wigginton Road York North Yorkshire YO31 8HE</p>	<p>Local contact Elizabeth Fox</p>	<p>Haematology and Blood Transfusion Biochemistry Cellular pathology Microbiology Virology/Serology Andrology Sickle cell and thalassaemia screening</p>	Y
<p>Address Scarborough Hospital Woodlands Drive Scarborough YO12 6QL</p>	<p>Local contact Elizabeth Fox</p>	<p>Haematology and Blood Transfusion Biochemistry</p>	S



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Site activities performed away from the locations listed above:

Location details		Activity
Address York Hospital Wigginton Rd York YO31 8HE	Local Contact Gemma Maxwell Gemma.maxwell8@nhs.net Tel: 0172385183	Blood Storage & Issue Management of Blood fridge at Ramsey Clifton Park Hospital, Management of Blood fridge in Main theatre York hospital.
Address Scarborough General Hospital Woodland's drive Scarborough YO12 6QL	Local Contact Gemma Maxwell Gemma.maxwell8@nhs.net Tel: 0172385183	Blood Storage & Issue Management of Blood fridges at Bridlington Hospital, Malton Hospital & Whitby Hospital. Management of Blood Fridge in Main theatre
Address Whitby Hospital Springhill Whitby YO21 1DP	Local Contact Gemma Maxwell Gemma.maxwell8@nhs.net Tel: 0172385183	Blood Storage
Address Malton Hospital Middlecave Road Malton YO17 7NG	Local Contact Gemma Maxwell Gemma.maxwell8@nhs.net Tel: 0172385183	Blood Storage
Address Nuffield Hospital York Haxby Road York YO31 8TA	Local Contact Gemma Maxwell Gemma.maxwell8@nhs.net Tel: 0172385183	Blood Storage
Address Bridlington Hospital Bessingby Road Bridlington YO16 4QP	Local Contact Gemma Maxwell Gemma.maxwell8@nhs.net Tel: 0172385183	Blood Storage and Remote Issue



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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 TISSUES AND FLUIDS	<u>Microbiological examinations for the purpose of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Whole Blood	Isolation of microorganisms of clinical significance	Becton Dickinson BACTEC FX continuous liquid culture monitoring system Gram film by light microscopy if positive Manual Subculture using pre-prepared media MB-SOP-BCULT	Y
Sputum, Pleural fluid, BAL	Isolation of microorganisms of clinical significance	Light Microscopy – Gram film as required Manual Culture using pre-prepared media MB-SOP-ROU-SPT	Y
Vaginal swabs Cervical swabs Urethral swabs	Isolation of microorganisms of clinical significance	Light microscopy - wet film only for T vaginalis Gram film for B. vaginalis Manual direct culture MB-SOP-GENITAL	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Sputum, Pleural fluid, BAL	Isolation of Mycobacteria sp of clinical significance	UV Fluorescent microscopy using Auramine-Phenol stain MGIT BD BACTEC™ MGIT™ 960 Mycobacterial continuous Liquid culture monitoring system. Solid culture using non-acidified pyruvate LJ slopes MB-SOP-AFB-CUL	Y
Swabs Ear, nose, throat, eye	Isolation of microorganisms of clinical significance	Light Microscopy of Gram film Manual Culture onto chromogenic agar MB-SOP-ROU-EAR MB-SOP-ROU-EYE MB-SOP-ROU-MOUTH MB-SOP-ROU-NOSE MB-SOP-ROU-THRO	Y
Swabs from wounds	Isolation of microorganisms of clinical significance	Microscopy Direct manual culture onto solid media and enrichment MB-SOP-AMC-ABS MB-SOP-AMC-ANID MB-SOP-AMC-SK&WS	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMLs) and incorporating relevant manufacturers' instructions	
CSF Ascetic fluid Bone Joint fluid CAPD fluid	Isolation of microorganisms of clinical significance	Microscopy Manual cell count via Fast Read 102 Disposable Counting Chambers. Gram film Direct manual culture and enrichment using solid culture media and enriched soybean-casein digest broth (BD Bactec Peds Plus) and nutrient broth MB-SOP-AMC-FLUID MB-SOP-AMC-PDF MB-SOP-CSF MB-SOP-CSFCS MB-SOP-AMC-TIS	Y
Faeces	Isolation of microorganisms of clinical significance	Manual direct culture and enrichment for enteric pathogens MB-SOP-FAE-PAR MB-SOP-FAE-SU	Y
Faeces	Detection of Rotavirus antigen	Rotavirus antigen detection using Meridian Biosciences ImmunoCARD STAT – immunogold based horizontal lateral flow technology. MB-SOP-FAE-ROT	Y



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Faeces	Detection of presence of Faecal Ova, Cysts and Parasites	Detection of faecal parasites using Apacor Midi Parasep faecal parasite concentrator and light microscopy MB-SOP-FAE-PAR	Y
Faeces	Detection of Clostridium difficile Toxin A and B and glutamate dehydrogenase antigen	Alere C.DIFF QUIK CHEK COMPLETE rapid membrane EIA MB-SOP-CDIF	Y
Faeces	Detection of Clostridium difficile toxin gene	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y
Tips IUCD Contact lens	Foreign objects Bacterial & fungal pathogens	Microscopy – gram film if required Direct manual culture and enrichment MB-SOP-ROU-TIPS	Y
Tissue	Isolation of microorganisms of clinical significance	Microscopy - Gram Direct manual culture and enrichment MB-SOP-AMC-TIS	Y
Bacterial cultures	Antimicrobial susceptibility testing (AST)	EUCAST methodology & interpretive breakpoints using: Manual disc diffusion Gradient MIC MB-SOP-TES-ABS E-TEST using concentration gradient strips manufactured by BioMerieux to provide measurement of MIC. MB-SOP-TES-ABS	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Bacterial cultures	Antibiotic resistance testing 1. Carbapenemase producing Enterobacteriaceae 2. Detection of bacteria with ESBL 3. Vancomycin Resistant Enterococci	1, 2, 3: Pre poured screening agar for CPE, ESBL, VRE testing MASTDISCS ID AmpC and ESBL detection discs. MB-SOP-TES-CARB MB-SOP-TES-ESBL MB-SOP-TES-VRE	Y
Skin Hair Nails	Isolation and presumptive identification of fungi of clinical significance	Microscopy following treatment with Potassium hydroxide. Fluorescent microscopy using Fluorescent Brightener Light microscopy of fungal cultures using Lactophenol Blue Manual inoculation and culture using solid agar MB-SOP-MYCOL	Y
Swabs	Screening for microorganisms of clinical significance - MRSA/MSSA screens	Manual inoculation and culture, single and bi-plate MB-SOP-MRSA/MSSA	Y
Nasopharyngeal aspiration and swabs	Detection of Respiratory Syncytial Virus	Meridian Bioscience Inc. TRU RSV-Rapid qualitative lateral flow for detection of RSV antigen MB-SOP-TRURSV	Y
Decontaminated Sputum and untreated sputum	Confirmation of presence of Mycobacterium tuberculosis	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Urine, endocervical swabs, Vaginal swabs in Roche PCR media	Confirmation of presence of Chlamydia trachomatis and Neisseria gonorrhoea	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y
Bacterial & fungal isolates cultured in-house from microbiology specimens as listed	Identification/ Biological classification	BioMerieux VITEK MS isolate ID system utilises Matrix-assisted laser desorption ionization–time of flight mass spectrometry (MALDI-TOF MS) technology - spectroscopy MB-SOP-MALDI	Y
Nasopharyngeal aspiration and swabs	Detection of Respiratory Syncytial Virus	Meridian Bioscience Inc. TRU RSV-Rapid qualitative lateral flow for detection of RSV antigen MB-SOP-TRURSV	Y
Decontaminated Sputum and untreated sputum	Confirmation of presence of Mycobacterium tuberculosis	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y
Urine, endocervical swabs, Vaginal swabs in Roche PCR media	Confirmation of presence of Chlamydia trachomatis and Neisseria gonorrhoea	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMLs) and incorporating relevant manufacturers' instructions	
Urine	Detection of Legionella pneumophila serogroup 1 antigen	Lateral flow membrane chromatographic test MB-SOP-UR-BINAX	Y
Urine	Detection of Streptococcus pneumoniae antigen	Lateral flow membrane chromatographic test MB-SOP-UR-BINAX	Y
Faeces	Detection of Helicobacter pylori antigens	Pro-Lab Diagnostics Proflow rapid membrane immunoassay MB-SOP-FAE-PYLORI	Y



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HUMAN BODY FLUIDS	<u>Serological examinations for investigation for immunity and markers of infectious disease</u>	In-house documented methods following manufacturers' instructions	
Serum	Qualitative detection of Hep B surface antigen VZV IgG Toxoplasma IgG/IgM Measles IgG Lyme Disease IgG Lyme Disease IgM	BioMerieux VIDAS30, automated bench top immuno-analyser based on Enzyme Linked Fluorescent Assay (ELFA) presence technology. SE-SOP-HEPB SE-SOP-HBL SE-SOP-LYME SE-SOP-TOXGM SE-SOP-VZV SE-SOP-VIDAS	Y
Upper respiratory tract specimens from specimen types: - Nose swabs Throat swabs Nasopharyngeal secretions Nasopharyngeal aspirates	Syndromic Qualitative detection of winter respiratory viruses Adenovirus Corona Virus (229E, HKU1, NL63, OC43) Human Metapneumovirus Rhino/enterovirus Influenza virus A (H1, H1-2009, H3) Influenza virus B Parainfluenza virus 1-4 Respiratory Syncytial Virus A/B Chlamydia pneumoniae Mycoplasma pneumoniae Sars-CoV-2 RNA PCR	GenMark Eplex closed system Molecular Analyser (using multiplex rapid real-time PCR) MB-SOP-PCR-EPLEX	Y



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examinations for investigation for immunity and markers of infectious disease</u> (cont'd)	In-house documented methods following manufacturers' instructions (cont'd)	
Serum	Qualitative detection of: HIV Ag/Ab Combo - HIV p24 antigen and HIV-1 /HIV-2. Anti-HBc II Anti-HBc IgM HAVAb-IgM HBeAg HBsAg Qualitative II Anti-HCV HBeAg EBV EBNA-1 IgG EBV VCAG EBV VCAM CMVIgG CMVIgM Syphilis TP Quantitative detection of: AHBs Vancomycin Gentomycin Rubella IgG	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy screening programme: laboratory Quality Assurance evidence requirements for antenatal screening'. Architect i2000SR fully automated immunoassay system utilising Chemiluminescent microparticle immunoassay (CMIA) SE-SOP-HAVM SE-SOP-CMV SE-SOP-GENT SE-SOP-VANC SE-SOP-HBEAG SE-SOP-HEPB SE-SOP-HEPC SE-SOP-HIV SE-SOP-MEASLES SE-SOP-RUB SE-SOP-STS SE-SOP-EBV	Y Y



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examinations for investigation for immunity and markers of infectious disease</u> (cont'd)	In-house documented methods following manufacturers' instructions (cont'd)	
Nose and Throat swabs, sputum, nasopharyngeal aspirates, tracheal aspirates and pleural aspirates in VTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, N2 and E gene targets	Cepheid Gene Xpert: using Real time Polymerase Chain Reaction (RT-PCR) SARS-CoV-2 RNA PCR (SMB-SOP-Covid-19)	Y
Nose and Throat swabs, sputum, nasopharyngeal aspirates, tracheal aspirates and pleural aspirates in VTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, Orf1a/b gene targets	Hologic Panther using TMA (target Mediated Amplification) and DKA (Dual Kinetic Assay) (MB-SOP-PCR-Panther -Covid19)	Y
Blood	Quantification of Chlamydia trachomatis rRNA Neisseria gonorrhoeae rRNA	Roche COBAS 4800 system for real-time PCR based amplification Roche COBAS X- 480 –fully automated multi-channel pipetting system for sample preparation extraction, purification and preparation of target nucleic acid for PCR analysis Roche COBAS Z-480 rapid thermal block cycler with integrated real-time detection capability. Simultaneous detection on 4 detection channels for multiplex real-time PCR assays PCR MB-SOP-PCR-CTNG MB-SOP-PCR-GX	Y



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HUMAN BODY FLUIDS (cont'd)	Biochemical examination <u>activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Serum/Heparinised plasma (unless stated)	Routine Biochemistry:	Roche Cobas 8000 c702 Module: Photometry	
	ACE	CB-SOP-ACE	S
	Albumin	CB-SOP-ALB	Y, S
	Alanine Aminotransferase	CB-SOP-ALT	Y, S
	Alkaline Phosphatase	CB-SOP-ALP	Y, S
	Alpha-1-Antitrypsin	CB-SOP-AAT	S
	Amylase	CB-SOP-AMYLASE	Y, S
	Aspartate Amino Transferase	CB-SOP-AST	Y, S
	Beta-2-Microglobulin	CB-SOP-B2M	Y
	Bicarbonate	CB-SOP-BIC	Y, S
	Bile Acids	CB-SOP-BILEACIDS	Y, S
	Bilirubin (Total)	CB-SOP-TBIL	Y, S
	Bilirubin (Direct/Indirect)	CB-SOP-DBIL	Y, S
	C3 Complement	CB-SOP-C3	S
	C4 Complement	CB-SOP-C4	S
	Caeruloplasmin	CB-SOP-CAE	S
	Cholesterol (Total)	CB-SOP-CHOLEST	Y, S
	Creatine Kinase	CB-SOP-CK	Y, S
	CRP	CB-SOP-CRP	Y, S
	Creatinine	CB-SOP-CREAT	Y, S
	Calcium	CB-SOP-CALCIUM	Y, S
	Gamma GT	CB-SOP-GGT	Y, S
	Haptoglobin	CB-SOP-HAP	S
	HDL	CB-SOP-HDL	Y, S
	Immunoglobulins (IGG,IGA,IGM)	CB-SOP-IGG, -IGA, -IGM	Y, S
	Iron	CB-SOP-IRON	Y, S
	Lactate Dehydrogenase	CB-SOP-LDH	Y, S
	Magnesium	CB-SOP-MAG	Y, S
	Phosphate	CB-SOP-PHOSPHATE	Y, S
	Protein (Total)	CB-SOP-TOTALPROT	Y, S
	Transferrin	CB-SOP-TRF	Y, S
	Triglyceride	CB-SOP-TRIG	Y, S
	Urate	CB-SOP-URA	Y, S
	Urea	CB-SOP-URE	Y, S



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
	Routine Biochemistry:	Roche Cobas 8000 c702 Module: Photometry	
CSF	Protein	CB-SOP-UPRO	Y, S
	Lactate	CB-SOP-LAC	Y, S
EDTA Plasma	Ammonia	CB-SOP-AMMONIA	Y
FI-Oxalate plasma:	Alcohol	CB-SOP-ALCOHOL	Y
	Glucose	CB-SOP-GLUCOSE	Y, S
	Lactate	CB-SOP-LAC	Y, S
FI-Oxalate CSF:	Glucose	CB-SOP-GLUCOSE	Y, S
Urine	Urine Albumin	CB-SOP-UALB	Y, S
	Urine Amylase	CB-SOP-AMYLASE	Y, S
	Urine Calcium	CB-SOP-CALCIUM	Y, S
	Urine Creatinine	CB-SOP-CREAT	Y, S
	Urine Magnesium	CB-SOP-MAG	Y, S
	Urine Phosphate	CB-SOP-PHOSPHATE	Y, S
	Urine Protein	CB-SOP-UPRO	Y, S
	Urine Urate	CB-SOP-URA	Y, S
	Urine Urea	CB-SOP-UREA	Y, S
	Routine Biochemistry:	Roche Cobas 8000 c702 Module: Using Indirect ISE:	
Serum/Heparinised plasma	Chloride	CB-SOP-ISE	Y, S
	Potassium	CB-SOP-ISE	Y, S
	Sodium	CB-SOP-ISE	Y, S
Urine	Chloride	CB-SOP-ISE	Y, S
	Urine Potassium	CB-SOP-ISE	Y, S
	Urine Sodium	CB-SOP-ISE	Y, S
	<u>Routine Biochemistry:</u>	Roche Cobas 8000 c702 Module: Using: particle enhanced turbidimetric Immunoassay	
	Faecal calprotectin	Buhlmann fCAL turbo kit CB-SOP-FCAL and CB-SOP-8000FAECAL	Y
	Faecal Elastase	Buhlmann fPELA turbo kit - CB-SOP-FELA	Y
Serum	Lipoprotein (a)	CB-SOP-LPA	Y



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HUMAN BODY FLUIDS (cont'd)	Biochemical examination <u>activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
	Therapeutic Drug Monitoring:	Roche Cobas 8000 c702 Module: Using kinetic interaction of micro-particles in a solution (KIMS) Immunoassay:	
Serum/Heparinised Plasma	Carbamazepine Phenytoin Theophylline Valproic Acid	CB-SOP-CARBAMAZ CB-SOP-PHT CB-SOP-THEO CB-SOP-VAL	Y Y Y, S Y
Serum/Heparinised Plasma	Paracetamol Salicylate Lithium	Roche Cobas 8000 c702 Module: Photometry CB-SOP-PAR CB-SOP-SAL CB-SOP-LITHIUM	Y, S Y, S Y, S
Serum only		Roche Cobas 8000 e801 Module: Using Electrochemiluminescence immunoassay analyser (ECLIA):	
Serum/Heparinised Plasma EDTA: Whole Blood	Digoxin Tacrolimus	CB-SOP-DIG CB-SOP-TAC	Y, S Y



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Serum	Endocrine Biochemistry:	Roche Cobas 8000 e801 Module: Using Electrochemiluminescence immunoassay analyser (ECLIA):	
	AFP	CB-SOP-AFP	Y
	Anti-TSH	CB-SOP-TRAB	Y
	CA125	CB-SOP-CA125	Y, S
	CA15-3	CB-SOP-CA15-3	Y
	CA19-9	CB-SOP-CA19-9	Y, S
	CEA	CB-SOP-CEA	Y, S
	Cortisol	CB-SOP-COR	Y, S
	Ferritin	CB-SOP-FERRITIN	Y, S
	FSH	CB-SOP-FSH	Y, S
	Folate	CB-SOP-FOL	Y, S
	FT3	CB-SOP-FT3	Y, S
	FT4	CB-SOP-FT4	Y, S
	Growth Hormone	CB-SOP-GH	Y
	HCG	CB-SOP-HCG	Y, S
	Insulin Like Growth Factor 1 (IGF-1)	CB-SOP-IGF1	Y
	LH	CB-SOP-LH	Y, S
	Oestradiol	CB-SOP-E2	Y, S
	Progesterone	CB-SOP-PRG	Y
	Prolactin	CB-SOP-PRL	Y
	Prostate Specific Antigen (PSA)	CB-SOP-PSA	Y, S
	SHBG	CB-SOP-SHBG	Y
	Testosterone	CB-SOP-TES	Y
	Thyroid Antibodies (TPO)	CB-SOP-TPO	Y
	Troponin T	CB-SOP-TPT	Y, S
	TSH	CB-SOP-TSH	Y, S
	Vitamin B12	CB-SOP-B12	Y, S
	Vitamin D	CB-SOP-VITD	Y, S
	sFLT-1/PIGF	CB-SOP-sFLT-1PLGF	Y
	NT-ProBNP	CB-SOP-BNP	Y, S
EDTA: Heparinised Plasma	PTH	CB-SOP-PTH	Y, S
EDTA: whole blood	Cyclosporin	CB-SOP-CYC	Y



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Faeces	Faecal Haemaglobin	Faecal Immunological Test (FIT) - HM-JACKarc (Alpha Laboratories) using latex turbidometry	
	Allergy Testing:	Thermo Fisher Scientific Phadia 250 Immunoassay analyser: Fluorescence enzyme immunoassay (FEIA):	
Serum	IgE (Total)	CB-SOP-TIGE & SIGE	Y
	Spe (Almond)	CB-SOP-TIGE & SIGE	Y
	Spe (Asp. Fumig.)	CB-SOP-TIGE & SIGE	Y
	Spe (Asp. Niger)	CB-SOP-TIGE & SIGE	Y
	Spe (Brazil Nut)	CB-SOP-TIGE & SIGE	Y
	Spe (Cashew Nut)	CB-SOP-TIGE & SIGE	Y
	Spe (Cat)	CB-SOP-TIGE & SIGE	Y
	Spe (Coconut)	CB-SOP-TIGE & SIGE	Y
	Spe (Cheese)	CB-SOP-TIGE & SIGE	Y
	Spe (Cheese Mould)	CB-SOP-TIGE & SIGE	Y
	Spe (Cod)	CB-SOP-TIGE & SIGE	Y
	Spe (Cow's Milk)	CB-SOP-TIGE & SIGE	Y
	Spe (Dog)	CB-SOP-TIGE & SIGE	Y
	Spe (Egg)	CB-SOP-TIGE & SIGE	Y
	Spe (Feathers Panel)	CB-SOP-TIGE & SIGE	Y
	Spe (Fish Panel)	CB-SOP-TIGE & SIGE	Y
	Spe (Food Mix)	CB-SOP-TIGE & SIGE	Y
	Spe (Grass)	CB-SOP-TIGE & SIGE	Y
	Spe (Hazelnut)	CB-SOP-TIGE & SIGE	Y
	Spe (HDM)	CB-SOP-TIGE & SIGE	Y
	Spe (Horse)	CB-SOP-TIGE & SIGE	Y
	Spe (Inhalent Panel)	CB-SOP-TIGE & SIGE	Y
	Spe (Latex)	CB-SOP-TIGE & SIGE	Y
	Spe (Mould Panel)	CB-SOP-TIGE & SIGE	Y
	Spe (Nut Panel)	CB-SOP-TIGE & SIGE	Y
	Spe (Peanut)	CB-SOP-TIGE & SIGE	Y
	Spe (Rodent Panel)	CB-SOP-TIGE & SIGE	Y
	Spe (Soya)	CB-SOP-TIGE & SIGE	Y
	Spe (Tree)	CB-SOP-TIGE & SIGE	Y
	Spe (Walnut)	CB-SOP-TIGE & SIGE	Y
	Spe (Weed Mix)	CB-SOP-TIGE & SIGE	Y
	Spe (Wheat)	CB-SOP-TIGE & SIGE	Y



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
Whole Blood: EDTA	Special Biochemistry: Haemoglobin A1c IFCC	TOSOH G11 HPLC CB-SOP-TOSOHG11	Y, S
Serum, Urine	Osmolality	Vitech Scientific Model OSMO1 Osmometer (freezing point depression method) CB-SOP-OSMO	Y, S
Serum	Serum Protein Electrophoresis: Monoclonal protein band detection and quantitation	SEBIA Capillarys Octa 3, Supplier method by capillary electrophoresis CB-SOP-CAPPROT	Y
Serum	Immunotyping	SEBIA Capillarys Octa 3, Supplier method by capillary electrophoresis CB-SOP-CAPIMM	Y
Serum, Urine	Serum Immunofixation Urine Immunofixation Urine Bence Jones Protein	Sebia Hydrasis 2, supplier method by gel electrophoresis and immunofixation CB-SOP-SIGFIX CB-SOP-UIGFIX CB-SOP-URINEBJP	Y
Serum	Alkaline Phosphatase Isoenzymes	Sebia Hydrasys 2 Phoresis System, supplier method by electrophoresis/I Lectin binding CB-SOP-ALPISOENZ	
Sweat	Sweat Test	Sherwood Model 926MK2 Chloride Meter CB-SOP-SWEAT	Y
CSF	Xanthochromia	Uvikon XS Spectrophotometer - spectrophotometric scanning CB-SOP-SPECTRO	Y
Serum	Free Light Chains (kappa and lambda)	Binding Site Optilite using immunoturbidimetric assay CB-SOP-OPTILITE	Y
	IgG4 subclasses	CB-SOP-GSUBG4	Y



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HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
	Calculated Tests	Calculations referenced in accordance with published papers and methods according to Teitz	
Urine	ACR	CB-INF-CALC	Y, S
Serum	Adjusted Calcium	CB-INF-CALC	Y, S
Serum	Anion Gap	CB-INF-CALC	Y, S
Serum	AKI (ACB Algorithm)	CB-INF-CALC	Y, S
Serum	Cholesterol: HDL ratio	CB-INF-CALC	Y, S
Serum and Urine	Creatinine Clearance	CB-INF-CALC	Y, S
Serum	eGFR	CB-INF-CALC	Y, S
Serum	Free Androgen Index	CB-INF-CALC	Y
Serum	Free Testosterone (vermeulen equation)	CB-INF-CALC	Y
Serum	Globulin (total protein – albumin)	CB-INF-CALC	Y, S
Serum	Indirect Bilirubin	CB-INF-CALC	Y, S
Serum	Non-HDL Cholesterol	CB-INF-CALC	Y, S
Serum	LDL Cholesterol	CB-INF-CALC	Y, S
Serum	Free Light Chains (kappa and lambda)	CB-INF-CALC	Y
Serum	Monomeric Prolactin	CB-INF-CALC	Y
Urine	PCR (Urine protein/urine creatinine)	CB-INF-CALC	Y, S
Serum	% Iron Saturation	CB-INF-CALC	Y, S
Serum	sFLT-1/PIGF Ratio	CB-INF-CALC	Y



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HUMAN BODY FLUIDS and TISSUES	<u>Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue samples	<u>Histopathology</u>	Specimen dissection: Leica IPC cassette printers (2) HI-SOP-CUT-UP HI-SOP-CYTOGENT HI-SOP-HMDS HI-SOP-TESTES	Y
		Decalcification using HI-SOP-DECAL	Y
		Tissue processing: Leica Peloris III processor HI-SOP-PROCESSOR	Y
		Embedding: Thermofisher Scientific HistoStar embedding centre x 2	Y
	Automated Staining for Identification of basophilic and eosinophilic structures	Haematoxylin and eosin stain automated: Leica HistoCore Spectra Workstation automated stainer and film coverslipper HI-SOP-MOUNT HI-SOP-STAINER	Y
	Manual Identification of basophilic and eosinophilic structures	Haematoxylin and eosin stain HI-SOP-Rapid-H&E	Y



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Formalin fixed paraffin embedded tissue samples (unless stated)	Special staining to identify the following:	Manual staining with reference to documented procedures listed below	Y
	Collagen, muscle	Weigert's van Gieson (HI-SOP-WVG)	Y
	Connective tissue	Masson Trichrome with Aniline Blue (HI-SOP-MT)	Y
	Fibrin, muscle, collagen	Martius Scarlet Blue (HI-SOP-MSB)	Y
	Elastic fibres/muscle	Miller's Elastic Stain (HI-SOP-EVG)	Y
	Reticulin fibres	Gordon and Sweet's Reticulin (HI-SOP-RETIC)	Y
	Amyloid	Highman's Congo Red (HI-SOP-CONGO RED)	Y
	Acid and neutral mucins	Alcian Blue pH 2.5/Alcian Blue pH 2.5+/- with PAS (HI-SOP-AB)	Y
	Fungi, mucins and lack of glycogen	Periodic Acid Schiff (PAS)/ PAS + digestion (HI-SOP-PAS)	Y
	Ferric iron	Perls' Prussian Blue (HI-SOP-PERLS)	Y
	Melanin	Masson Fontana (HI_SOP-MF)	Y
	Melanin	Melanin Bleach (HI-SOP-MELANIN)	Y
	Calcium salts	Von Kossa (HI-SOP-VON KOSSA)	Y
	Hepatitis surface antigen, elastic fibres and copper associated protein	Shikata Orcein (HI-SOP-ORCEIN)	Y



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
Formalin fixed paraffin embedded tissue samples (unless stated) (cont'd)	Special staining to identify the following: (cont'd)	Manual staining with reference to documented procedures listed below	
	Bacteria	Gram (HI-SOP-GRAM)	Y
	Acid fast bacilli	Ziehl-Neelsen (HI-SOP-ZN)	Y
	Polysaccharide in walls of fungi and other opportunistic organisms	Tome and Hayashi HI-SOP-GROCOTT)	Y
	Detection of Helicobacter pylori	Giemsa (HI-SOP-GIEMSA)	Y
	Leprosy bacilli	Wade-Fite (HI-SOP-WF)	Y
	Mast cell granules	Toluidine Blue (HI-SOP-TOL BLUE)	Y
HUMAN BODY TISSUE	<u>Molecular Diagnostic examination activities: Examination of tissues to identify or exclude mutations within DNA for the purpose of clinical diagnosis, prognosis and treatment options.</u>	Documented in-house procedures in conjunction with manufacturers instructions for Biocartis Idylla Molecular platform and test cartridges.	Y
	KRAS	HI-SOP-IKRAS	Y
	BRAF (SKIN)	HI-SOP-BRAF SKIN	Y
	NRAS/BRAF	HI-SOP-INRAS-BRAF	Y



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u>	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Identification of liver disease, yolk sac and mixed germ cell tumours	Alpha fetoprotein	Y
	Smooth muscle cells	Alpha smooth muscle actin	Y
	Identification of several malignancies, including B-cell chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphomas (NHL), mainly low-grade and follicular in type	BCL2	Y
	Epithelial cell types	BER	Y
	Malignant ovarian epithelial cells, seminal vesical carcinoma and anaplastic lymphoma	CA125	Y
	Identifies medullary Ca of thyroid	Calcitonin	Y
	Identification of smooth muscle and tumour cells in smooth muscle	Caldesmon	Y
	Mesothelioma from adenocarcinoma	Calretinin	Y
Identification of neoplasms of epithelial origin	CAM 5.2	Y	
Distinguish between adenocarcinomas and mesotheliomas. Identify the origin of certain metastatic carcinomas	Carcinoembryonic antigen (CEA)	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omnis HI-SOP-IMMUNO	
	Pan T-cell marker used for the identification of immature and mature T-cell malignancies	CD3	Y
	Identification of Burkitts lymphoma, follicular germ cell lymphoma and RCC	CD10	Y
	Expressed in Reed-Sternberg cells and is thus a useful marker for identifying Hodgkin's lymphoma.1	CD15	Y
	Directed against any epitope present on human B lymphocytes, plasma cells are negative	CD20	Y
	Identification of classical Hodgkin's lymphoma and anaplastic large cell lymphoma	CD30	Y
	Identify vascular origin of neoplasms	CD31	Y
	Identification of blasts in acute leukaemia and as a marker for endothelial cells in differential diagnosis of poorly differentiated malignant tumours	CD34	Y
Identification of all haematopoietic cells (except erythrocytes)	CD45	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Leucocyte differentiation	CD56	Y
	Identification of macrophages	CD68	Y
	Identification in GIST, some positivity in seminoma, melanoma, some breast ca types and small cell ca	CD117	Y
	Usually present in gastrointestinal epithelium. Useful to determine origin of metastatic carcinomas and carcinoids	CDX2	Y
	Tissue of neuroendocrine origin	Chromogranin A	Y
	Mesothelioma, prostate carcinoma	CK5/6	Y
	Normal and neoplastic epithelia	CK7	Y
	Squamous cell carcinomas, metaplastic carcinomas of the breast	CK14	Y
Marker for papillary thyroid carcinoma	CK19	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Gastric and intestinal epithelium, urothelium and Merkel cells	CK20	Y
	Cytomegalovirus	Cytomegalovirus	Y
	Reacts with tumours of myogenic and striated muscle origin	Desmin	Y
	Diagnosis of GIST	DOG-1	Y
	Normal duct epithelial cells, ductal carcinoma	E-CADHERIN	Y
	Many carcinomas – normal and neoplastic cells from various tissues	Epithelial Membrane Antigen	Y
	Oestrogen receptor antigen	Estrogen Receptor	Y
Benign and neoplastic neoplasms and anaplastic large cell lymphoma	Galectin-3	Y	
Identifies breast carcinomas and urothelial carcinomas	GATA 3	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Differentiate breast carcinoma metastatic to ovary (positive) from primary ovarian carcinoma (negative)	Gross Cystic Disease Fluid Protein (GCDF)	Y
	Identification of mesothelioma and papillary thyroid carcinoma	HBME-1	Y
	Identification of cells and tumours of trophoblastic origin	hCG	Y
	Recognises benign and malignant liver	Hepatocyte	Y
	Assessment of suitability of breast cancer patients in respect of the drug Herceptin	HER2	Y
	Classification of melanomas	HMB45	Y
	Differentiation between adrenal cortical tumours and renal cell carcinomas, also interuterine v ectopic pregnancy	Inhibin	Y
Assess the proliferative activity of normal and neoplastic tissue	Ki-67	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omnis	
		HI-SOP-IMMUNO	
	Primary and metastatic malignant melanoma	MELANA	Y
	Melanocytes	MelanA red chromogen	Y
	DNA mismatch repair protein. Useful marker for the classification of colorectal cancer	MLH1	Y
	Mismatch repair protein MSH2	MSH2	Y
	DNA mismatch repair protein. Useful marker for the classification of colorectal cancer	MSH6	Y
	Useful as a first line marker for epithelial tumours	MNF116	Y
	Alveolar macrophages, pneumocytes, lung adenocarcinoma	Napsin A	Y
Marker for germ cell tumours	OCT3/4	Y	
Classification of premalignant high-grade prostatic intraepithelial neoplasia (HGPIN) and prostate adenocarcinoma.	P504S	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins HI-SOP-IMMUNO	
	Classification of cervical dysplasia and in the differential diagnosis of cervical adenocarcinoma v endometrial adenocarcinoma	P16	Y
	Squamous cell carcinoma	P40	Y
	Tumour expressor gene found in malignancies	P53	Y
	Identification of complete hydatidiform mole	P57	Y
	Benign and malignant prostatic or breast lesions, differentiation of lung squamous cell carcinoma and lung adenocarcinoma	P63	Y
		P63/p504S dual staining	Y
	Tumour types including thyroid, renal cell and ovarian serous carcinomas	PAX8	Y
Germ cell tumours	Placental Alkaline Phosphatase	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	DNA mismatch repair protein. Useful marker for the classification of colorectal cancer	PMS2	Y
	Expressed in lymphatic endothelium as well as lymphangiomas, and Kaposi sarcomas. Podoplanin has also been shown to be expressed in epithelioid mesotheliomas and seminomas	Podoplanin	Y
	Progesterone Receptor antigen	Progesterone Receptor	Y
	Prostate secretory and ductal epithelium	Prostatic Specific Antigen	Y
	Identification of metastatic adenocarcinoma of the prostate	Prostatic Acid Phosphatase	Y
Identifies 90% of primary renal cell carcinomas and 85% of metastatic RCC	Renal Cell Carcinoma	Y	
Used to distinguish between benign sclerosing breast lesions and infiltrating carcinomas	Smooth muscle myosin	Y	



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HUMAN BODY TISSUE (cont'd)	<u>Immunocytochemistry for the identification of cells/diseases below:-</u> (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Sensitive marker of melanoma for conventional, and desmoplastic subtypes	SOX-10	Y
	Melanomas, neural cells	S-100	Y
	Classification of neural type neoplasms and neuroendocrine neoplasms of epithelial type	Synaptophysin	Y
	Diagnosis of mesothelioma	Thyroglobulin	Y
	Neoplasms of lung and thyroid, mesothelioma	TTF-1	Y
	Identification of urothelial carcinomas and as a tool to pinpoint metastases of unknown primary	Uroplakin	Y
Endothelial cells, fibroblasts, smooth muscle	Vimentin	Y	
Identification of mesoderm-derived tumours including epithelioid mesothelioma and ovarian serous carcinoma	WT-1	Y	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Fresh Tissue	Identification of basophilic and eosinophilic structures	Routine Staining of Frozen Sections using fluorescent labelled antibodies Leica CM1860UV Cryostat HI-SOP-FROZENS	Y
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis <u>Diagnostic Non-Gynaecological Cytopathology</u>	Light microscopy with reference to HI-SOP-MICROSCOP	
Body fluids / Fine needle aspirations, bronchial samples, CSF's, urines, and serous effusions	Detection of abnormal cells	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: CY-SOP-NG PREP manual methods using documented procedures CY-SOP-MYREVA Automated Papanicolaou staining using the Myreva SS30 Slide Stainer CY-SOP-P-MGGHAND Hand staining of air dried cytology slide preparations	Y
Synovial fluid specimens	Diagnostic assessment for the presence of crystals	CY-SOP-SYF Polarised Light Microscopy	Y



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	Documented procedure & manufacturer's instructions	
Semen	<u>Post vasectomy:</u> Detection of sperm	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 CY-SOP-PVAS	Y
Semen	<u>Fertility testing:</u> Volume pH Sperm morphology including TZI scoring Sperm concentration Sperm motility	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure SOP CY-SOP-INF Volume/weight Colorimetric strips Stained slides (Papanicolau) microscopy (Bright field) Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast)	Y



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Whole Blood EDTA	Full Blood Count WBC RBC ESR HGB HCT MCH MCHC PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count	Sysmex XN3100(S) Sysmex XN9100 Analyser (Y) Hb measurement by laurel sulphate conversion and colorimetry HA-SOP-FBC	S, Y
		Sysmex XN550 Analyser (haematology clinic) HA-SOP-XN-550 Hb measurement by laurel sulphate conversion and colorimetry (not used for NRBC or Reticulocyte counts)	Y
Whole Blood	Blood Film Morphology	Staining and light microscopy of blood and bone marrow smears using May Grunwald & Giemsa Automated using Sysmex SP50 HA-SOP-SP50 And manual with reference to HA-SOP-FILMREP	Y S
Stained Blood Films	Blood Film Morphology	Digital imaging using DI 60 Analyser HA-SOP-DI	Y



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
Bone Marrow	Detection of abnormal cells in bone marrow	Manual staining of bone marrow smears using May Grunwald & Giemsa Light Microscopy HA-SOP-BMLAB	S, Y
Bone Marrow	Evaluation of body iron stores by examination of bone marrow smears	Manual Perl's Reaction staining (HA-SOP-PERLS)	Y
Whole Blood	Detection & speciation of malaria parasites: All plasmodium species known to cause human disease	Manual Staining of thick and thin films- Giemsa and Fields stain HA-SOP-MALARIA	S, Y
EDTA Whole Blood	Malaria Parasite Screen: P. falciparum (HRP2) and P. falciparum, P. vivax, P. malariae and P.ovale (pLDH)	CareUS – Rapydtest using combined HRP23/PLDH Technology HA-SOP-MALARIA	S, Y
Whole blood	Blood cell sedimentation measurement - ESR	Sysmex InteRRliner ESR FRL Analyser HA-SOP-AUTOESR	Y
EDTA Whole Blood	Haemoglobinopathy screening: Structural variants Thalassaemias Failure to switch from foetal to adult Hb	HPLC using TOSOH G11 HA-SOP-HGP	Y
EDTA Whole Blood / Plasma or Serum	Detection of Infectious Mononucleosis: IgM heterophile antibodies	DIALAB – DIAQUICK Mononucleosis Cassette using Immunochromatographic lateral flow HA-SOP-IMSCREEN	S, Y



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
		Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia screening programme as defined in the 2018 "Sickle Cell and Thalassaemia screening laboratory QA evidence requirements"	Y
EDTA Whole Blood	Sickle Screening	Microgen S-Test (sodium dithionate) HA-SOP-HBSDETECT	Y
EDTA Whole Blood	Detection of Sickle Haemoglobin (HbS)	Streck – SICKLEDEX qualitative solubility test kit HA-SOP-HBSDETECT	Y
EDTA Whole Blood	G6PD Screening	Trinity Biotech G-6-PDH Kit (Part No. 203-A) – HA-SOP-G6PD	Y
EDTA Whole Blood	Hb electrophoresis (Alkaline pH 8.4-8.6)	Sebia Hydragel Kit; Sebia Hydrasys 2 analyser HA-SOP-HEP	Y
EDTA Whole Blood	Hb electrophoresis (Acid pH 6.0)	HA-SOP-CAGHEP	Y



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
Citrated plasma	Coagulation examinations to assist in clinical investigations	ACLTOP 500 (Y&S) ACLTOP 300 (S) Turbidimetric method Clot detection by optical rate of change of absorbance end point, chromogenic assay, one stage assay	
Citrated plasma	Prothrombin Time (PT) and International Normalised Ratio (INR)	CO-SOP-COAGSCREEN	S, Y
Citrated plasma	Activated Partial Thromboplastin (APTT) and APTT ratio		
Citrated plasma	Clauss Fibrinogen (CFib) D-dimer Thrombin Time Mixing Studies	CO-SOP-D-DIMER CO-SOP-TT CO-SOP-MIX	S, Y
Citrated plasma	Anti-Xa (for LMWH, Danaparoid and DOAC) Factor Assays (II, V, VII, VIII, IX, X, XI, XII)	CO-SOP-Anti-Xa CO-SOP-FACTORS CO-SOP-REFACTO	Y
Citrated plasma	Antithrombin Protein C Protein S	Chromogenic assays Latex Immunoassay CO-SOP-TBP	Y
Citrated plasma	Lupus Inhibitor Screen	CO-SOP-LUPUS	Y
Citrated plasma	Factor VIII Inhibitor (Nijmegen Modification Assay)	CO-SOP-F8INH	Y
Citrated plasma	Von Willebrand Factor Antigen (vWF:Ag)	Immunoturbidometric assay CO-SOP-vWD_Screen	Y
Citrated plasma	Von Willebrand Factor Activity (vWF:RCo)	Immunoturbidometric assay CO-SOP-vWD_Screen	Y



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HUMAN BODY FLUIDS (cont'd)	<p><u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Coagulation examinations to assist in clinical investigations</p>	<p>Documented in-house procedures with manufacturer's instructions</p> <p>ACLTOP 500 (Y&S) ACLTOP 300 (S) Turbidimetric method Clot detection by optical rate of change of absorbance end point, chromogenic assay, one stage assay</p>	
Citrated plasma	Von Willebrand Factor Collagen Binding Assay (vWF:CBA)	Bioflash Analyser – using chemiluminescence CO-SOP-vWF_CBA IM-SOP-Bioflash (Maintenance)	Y
Citrated plasma	Heparin Induced Thrombocytopenia (HIT) Screen	Bioflash Analyser – using chemiluminescence CO-SOP-HIT IM-SOP-Bioflash (Maintenance)	Y
Whole Blood Citrated & EDTA	<p>Molecular</p> <p>Detection of genetic mutation Factor V Leiden & prothrombin mutation</p>	Factor V Leiden/Prothrombin Gene Mutation on Cepheid Gene Xpert CO-SOP-FVL_PGM	Y
EDTA packed red cells	<p>Blood Transfusion examination activities for the purpose of clinical diagnosis</p> <p>Blood Group by detection and identification of antigens:</p> <p>A RhD Positive AB RhD Positive B RhD Positive RhD Positive A RhD Negative AB RhD Negative B RhD Negative RhD Negative O RhD positive O RhD negative</p>	<p>Documented in-house procedures with manufacturer's instructions</p> <p>Grifols Erytra fully automated card IAT and enzyme techniques technology analyser and manual card system BT-SOP-BLD-GRP BT-SOP- ERYTRAOP BT-SOP-DGGEL</p>	Y



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
EDTA packed red cells	Blood Group by detection and identification of antigens: A RhD Positive AB RhD Positive B RhD Positive RhD Positive A RhD Negative AB RhD Negative B RhD Negative RhD Negative O RhD positive O RhD negative	Grifols Eflexis fully automated card IAT and enzyme techniques technology analyser and manual card system BT-SOP-BLD-GRP BT-SOP- EFLEXIS BT-SOP-DGGEL	S
EDTA Whole Blood	Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, c, e, f, Cw K, k, Kpa , Kpb , Fya , Fya , Jka, Jkb Lea, Leb S, s, M, N P1 Lua, Lub	Grifols Erytra fully automated card IAT and enzyme techniques technology, analyser and manual card system BT-SOP-BLD-GRP BT-SOP- ERYTRAOP BT-SOP-DGGEL	Y
EDTA Whole Blood	Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, c, e, f, Cw K, k, Kpa , Kpb , Fya , Fya , Jka, Jkb Lea, Leb S, s, M, N P1 Lua, Lub	Grifols Eflexis fully automated card IAT and enzyme techniques technology, analyser and manual card system BT-SOP-BLD-GRP BT-SOP- EFLEXIS BT-SOP-DGGEL	S



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
EDTA plasma	Crossmatching – compatibility testing of patients' plasma with donor cells	Grifols Erytra fully automated card IAT and enzyme techniques technology, analyser and manual card system BT-SOP-COMP	Y
EDTA plasma	Crossmatching – compatibility testing of patients' plasma with donor cells	Grifols Eflexis fully automated card IAT and enzyme techniques technology, analyser and manual card system BT-SOP-COMP	S
Serum	Kleihauer test and anti-D	Acid-elution (Guest Medical) BT-SOP-KLEIHAUER	S, Y
EDTA Whole Blood	Antibody detection (4 cell screen) 10 cell panel, 11 cell panel, 6 cell Rh(D) panel for prophylactic anti-D	Grifols Erytra fully automated card IAT and enzyme techniques technology, analyser and manual card system BT-SOP-IDENT INVEST BT-SOP-ANTPRO BT-SOP-DGGEL BT-SOP-ERYTRAOP	Y
EDTA Whole Blood	Direct Antiglobulin TEST (DAT)	Grifols Erytra fully automated card and IAT and enzyme techniques technology and manual card systems. BT-SOP-DAT YBT-SOP-ERYTRA BT-SOP-DGGEL	Y
EDTA Whole Blood	Direct Antiglobulin TEST (DAT)	Grifols Eflexis fully automated card and IAT and enzyme techniques technology and manual card systems. BT-SOP-DAT SBT-SOP-EFLEXIS BT-SOP-DGGEL	S
END			