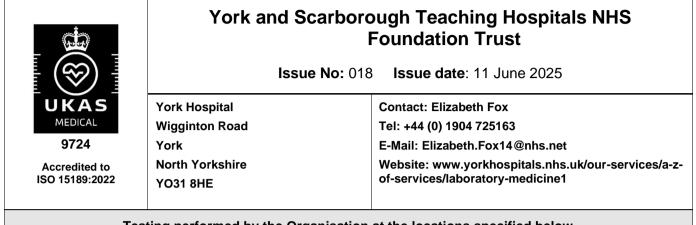
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Testing performed by the Organisation at the locations specified below

#### Locations covered by the organisation and their relevant activities

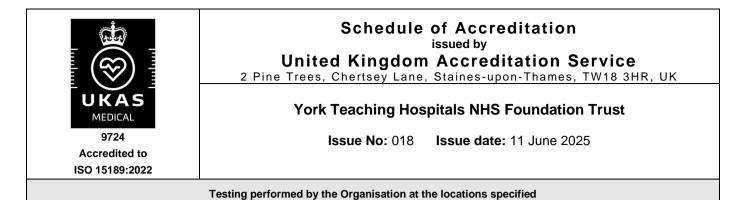
#### Laboratory locations:

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

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UKAS	York Teaching Hospitals NHS Foundation Trust
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	Testing performed by the Organisation at the locations specified

#### 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



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	Microbiological examinations for the purpose of clinical diagnosis	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	Y
		Gram film by light microscopy if positive	
		Manual Subculture using pre- prepared media	
		MB-SOP-BCULT	
Sputum, Pleural fluid, BAL	Isolation of microorganisms of clinical significance	Light Microscopy – Gram film as required	Y
		Manual Culture using pre-prepared media	
		MB-SOP-ROU-SPT	
Vaginal swabs Cervical swabs Urethral swabs	Isolation of microorganisms of clinical significance	Light microscopy - wet film only for T vaginalis	Y
		Gram film for B. vaginalis	
		Manual direct culture	
		MB-SOP-GENITAL	
Urine	Identification of WBC, RBC, Epithelial cells, Bacterial count	Automated urine microscopy using SediMAX con TRUST PRO urine sediment analyser	Y
		MB-SOP-UR-MCS	

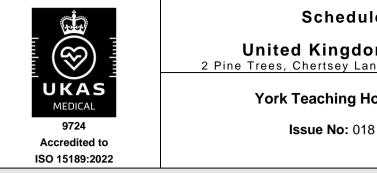


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Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/	Location
	measurement	Equipment/Techniques used	Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations for the purpose of clinical diagnosis (cont'd)	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	Y
		MGIT BD BACTEC™ MGIT™ 960 Mycobacterial continuous Liquid culture monitoring system.	
		Solid culture using non-acidified pyruvate LJ slopes	
		MB-SOP-AFB-CUL	
Swabs Ear, nose, throat, eye	Isolation of microorganisms of clinical significance	Light Microscopy of Gram film	Y
		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	
Swabs from wounds	Isolation of microorganisms of	Microscopy	Y
	clinical significance	Direct manual culture onto solid media and enrichment MB-SOP-AMC-ABS MB-SOP-AMC-ANID MB-SOP-AMC-SK&WS	



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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
CSF Ascetic fluid Bone Joint fluid	Isolation of microorganisms of clinical significance	Microscopy Manual cell count via Fast Read 102 Disposable Counting Chambers.	Y
CAPD fluid		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	
Faeces	Isolation of microorganisms of clinical significance	Manual direct culture and enrichment for enteric pathogens	Y
		MB-SOP-FAE-PAR MB-SOP-FAE-SU	
Faeces	Detection of Rotavirus antigen	Rotavirus antigen detection using Meridian Biosciences ImmunoCARD STAT – immunogold based horizontal lateral flow technology. MB-SOP-FAE-ROT	Y
Bacterial cultures of Enterobacteriaciae	Detection of Carbapenemase producing Enterobacteriaciae	Lateral flow assay using O.K.N.V.I RESIST-5 MB-SOP-TES-CARB	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
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	Y
		ETEST using concentration gradient strips manufactured by BioMerieux to provide measurement of MIC. MB-SOP-TES-ABS	



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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations for the purpose of clinical diagnosis (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	1, 2, 3: Pre poured screening agar for CPE, ESBL, VRE testing	Y
	2.Detection of bacteria with ESBL	MASTDISCS ID AmpC and ESBL detection discs.	
	3.Vancomycin Resistant Enterococci	MB-SOP-TES-CARB MB-SOP-TES-ESBL MB-SOP-TES-VRE	
Skin Hair Nails	Isolation and presumptive identification of fungi of clinical significance	Microscopy following treatment with Potassium hydroxide.	Y
INdits	significance	Fluorescent microscopy using Fluorescent Brightener	
		Light microscopy of fungal cultures using Lactophenol Blue	
		Manual inoculation and culture using solid agar MB-SOP-MYCOL	
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	Y
		MB-SOP-TRURSV	
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</u> for the purpose of clinical diagnosis (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	Y
		MB-SOP-MALDI	
Nasopharyngeal aspiration and swabs	Detection of Respiratory Syncytial Virus	Meridian Bioscience Inc. TRU RSV-Rapid qualitative lateral flow for detection of RSV antigen	Y
		MB-SOP-TRURSV	
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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Urine	Detection of Legionella pneumophilia 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Serological examinations for investigation for immunity and markers of infectious disease	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-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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Serological examinations for investigation for immunity and markers of infectious disease (cont'd)	In-house documented methods following manufacturers' instructions (cont'd)	
		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'.	Y
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 VCAG EBV VCAM CMVIgG CMVIgM Syphilis TP Quantitative detection of: AHBs Vancomycin Gentomycin Rubella IgG	Architect i2000SR fully automated immunoassay system utilising Chemiluminescent microparticle immunoassay (CMIA) SE-SOP-HAVM SE-SOP-CMV SE-SOP-GENT SE-SOP-HEAG SE-SOP-HEPB SE-SOP-HEPC SE-SOP-HEPC SE-SOP-MEASLES SE-SOP-RUB SE-SOP-STS SE-SOP-EBV	Y



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Serological examinations for investigation for immunity and markers of infectious disease (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 $\beta$ -betacoronavirus ( $\beta$ - $\beta$ 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 $\beta$ -betacoronavirus ( $\beta$ - $\beta$ 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	Υ



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purpose of clinical diagnosis	Documented in-house procedures with manufacturer's instructions	
Serum/Heparinised plasma (unless stated)	Routine Biochemistry:	Roche Cobas 8000 c702 Module: Photometry	
	ACE Albumin Alanine Aminotransferase Alkaline Phosphatase Alpha-1-Antitrypsin Amylase Aspartate Amino Transferase Beta-2-Microglobulin Bicarbonate Bile Acids Bilirubin (Total) Bilirubin (Direct/Indirect) C3 Complement C4 Complement Caeruloplasmin Cholesterol (Total) Creatine Kinase CRP Creatinine Calcium Gamma GT Haptoglobin HDL Immunoglobulins (IGG,IGA,IGM) Iron Lactate Dehydrogenase Magnesium Phosphate Protein (Total) Transferrin Triglyceride Urate Urea	CB-SOP-ACE CB-SOP-ALB CB-SOP-ALT CB-SOP-ALP CB-SOP-AAT CB-SOP-AAT CB-SOP-AST CB-SOP-BIL CB-SOP-BIL CB-SOP-BIL CB-SOP-BIL CB-SOP-CB CB-SOP-CA CB-SOP-CAE CB-SOP-CAE CB-SOP-CAE CB-SOP-CRP CB-SOP-CRP CB-SOP-CRP CB-SOP-CALCIUM CB-SOP-GGT CB-SOP-HAP CB-SOP-IGG, -IGA, -IGM CB-SOP-IGG, -IGA, -IGM CB-SOP-IDH CB-SOP-DHAP CB-SOP-DHAP CB-SOP-PHOSPHATE CB-SOP-TOTALPROT CB-SOP-TRF CB-SOP-TRF CB-SOP-URA CB-SOP-URA	S Y, Y, Y S S S S S S S S S S S S S S S



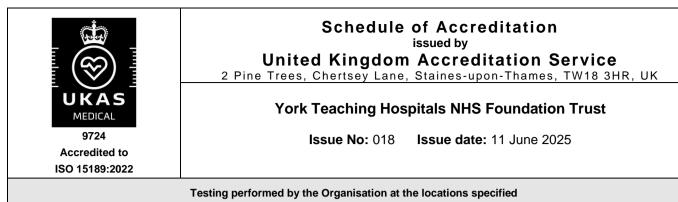
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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purpose of clinical diagnosis (cont'd)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



Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purpose of clinical diagnosis (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
		Roche Cobas 8000 c702 Module: Photometry	
Serum/Heparinised Plasma	Paracetamol Salicylate	CB-SOP-PAR CB-SOP-SAL	Y, S Y, S
Serum only	Lithium	CB-SOP-LITHIUM Roche Cobas 8000 e801 Module: Using Electrochemiluminescence immunoassay analyser (ECLIA):	Y, S
Serum/Heparinised Plasma EDTA: Whole Blood	Digoxin Tacrolimus	CB-SOP-DIG CB-SOP-TAC	Y, S Y

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
	Endocrine Biochemistry:	Roche Cobas 8000 e801 Module: Using Electrochemiluminescence immunoassay analyser (ECLIA):	
Serum	AFP Anti-TSH CA125 CA15-3 CA19-9 CEA Cortisol Ferritin FSH Folate FT3 FT4 Growth Hormone HCG Insulin Like Growth Factor 1 (IGF-1) LH Oestradiol Progesterone Prolactin Prostate Specific Antigen (PSA) SHBG Testosterone Thyroid Antibodies (TPO) Troponin T TSH Vitamin B12 Vitamin D SFLT-1/PIGF NT-ProBNP	CB-SOP-AFP CB-SOP-TRAB CB-SOP-CA125 CB-SOP-CA19-9 CB-SOP-CEA CB-SOP-CEA CB-SOP-FERRITIN CB-SOP-FSH CB-SOP-FOL CB-SOP-FOL CB-SOP-FT4 CB-SOP-GH CB-SOP-IGF1 CB-SOP-IGF1 CB-SOP-IGF1 CB-SOP-PRG CB-SOP-PRG CB-SOP-PRA CB-SOP-PSA CB-SOP-SHBG CB-SOP-TES CB-SOP-TPT CB-SOP-TPT CB-SOP-TSH CB-SOP-TSH CB-SOP-SFLT-1PLGF CB-SOP-BNP	Y Y, Y Y,
EDTA: Heparinised Plasma	РТН	CB-SOP-PTH	Y, S
EDTA: whole blood	Cyclosporin	CB-SOP-CYC	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	
Faeces	Faecal Haemaglobin	Faecal Immunological Test (FIT) - HM-JACKarc (Alpha Laboratories) using latex trubidometry	
		CB-SOP-FIT	Y
	Allergy Testing:	Thermo Fisher Scientific Phadia 250 Immunoassay analyser: Fluorescence enzyme immunoassay (FEIA):	
Serum	IgE (Total) Spe (Almond) Spe (Asp. Fumig.) Spe (Asp. Niger) Spe (Brazil Nut) Spe (Cashew Nut) Spe (Cat) Spe (Coconut) Spe (Coconut) Spe (Cheese) Spe (Cheese) Spe (Cheese) Spe (Cow's Milk) Spe (Cod) Spe (Cod) Spe (Cod) Spe (Cod) Spe (Cod) Spe (Cod) Spe (Feathers Panel) Spe (Feathers Panel) Spe (Fish Panel) Spe (Food Mix) Spe (Grass) Spe (Hazelnut) Spe (Horse) Spe (Inhalent Panel) Spe (Latex) Spe (Mould Panel) Spe (Nut Panel) Spe (Rodent Panel) Spe (Rodent Panel) Spe (Soya) Spe (Tree) Spe (Walnut) Spe (Weed Mix)	CB-SOP-TIGE & SIGE CB-SOP-TIGE & SIGE	$\gamma \gamma $



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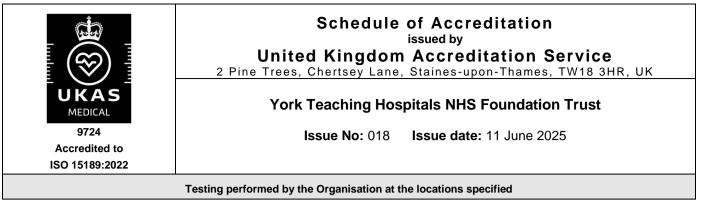
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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
	Special Biochemistry:		
Whole Blood: EDTA	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
	lgG4 subclasses	CB-SOP-GSUBG4	Y

	Schedule of Accreditation issued by United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, York Teaching Hospitals NHS Foundation Trust	
9724 Accredited to ISO 15189:2022	Issue No: 018 Issue date: 11 June 2025	

Materials/Products tested   Type of test/Properties measurement   Standard specifications/ Equipment/Techniques used   Location Code     HUMAN BODY FLUIDS (contd)   Biochemical examination activities for the purpose of clinical diagnosis (contd)   Documented in-house procedures with manufacturer's instructions   Location     Urine   ACR Acjusted Calcium Anion Gap Serum   ACR Adjusted Calcium Anion Gap AKI (ACB Algoritm)   Calculations referenced in accordance with published papers and methods according to Teitz   Y. S Calculators referenced in accordance with published papers and methods according to Teitz     Serum   AKI (ACB Algoritm) Cholesterol: HDL ratio Creatinne Clearance eGFR   CB-INF-CALC   Y. S CB-INF-CALC   Y.	Testing performed by the Organisation at the locations specified			
Materials/Products testedmeasured/Range of measurementDistribution of SpecificationsCodeHUMAN BODY FLUIDS (cont'd)Biochemical examination activities for the purpose of clinical diagnosis (cont'd)Documented in-house procedures with manufacturer's instructionsUrine SerumACR Adjusted CalciumCalculations referenced in accordance with published papers and methods according to TeitzY, SUrine SerumACR Adjusted Calcium Anion GapCB-INF-CALC CB-INF-CALCY, SSerum SerumAki (ACB Algorithm) Creatinine Clearance eGFRCB-INF-CALC CB-INF-CALCY, SSerum SerumCreatinine Clearance eGFRCB-INF-CALC CB-INF-CALCY, SSerum SerumFree Androgen Index elobutin (total protein – albumin)CB-INF-CALC CB-INF-CALCY, SSerum SerumIndirect Bilirubin equation)CB-INF-CALC CB-INF-CALCY, SSerum SerumIndirect Bilirubin (total protein – albumin)CB-INF-CALC CB-INF-CALCY, SSerum SerumIndirect Bilirubin (kappa and lambda) (kappa and lambda)CB-INF-CALC CB-INF-CALCY, SSerum Monomeric Prolactin (kappa and lambda)CB-INF-CALC CB-INF-CALCY, SSerum Winonemeric Prolactin (kappa and lambda)CB-INF-CALC CB-INF-CALCY, SSerum Wonomeric Prolactin (kappa and lambda)CB-INF-CALC CB-INF-CALCY, SSerum Wonomeric Prolactin (kappa and lambda)CB-INF-CALC CB-INF-CALCY, SSerum Wonomeric Prolactin <b< td=""><td></td><td>Type of test/Properties</td><td></td><td></td></b<>		Type of test/Properties		
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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   Urine Serum Calculated Tests Calculations referenced in accordance with published papers and methods according to Teitz   Urine Serum ACR Adjusted Calcium CB-INF-CALC Y, S   Serum Adivested Calcium CB-INF-CALC Y, S   Serum Aki (ACB Algorithm) CB-INF-CALC Y, S   Serum Cholesterol: HDL ratio CB-INF-CALC Y, S   Serum Cholesterol: HDL ratio CB-INF-CALC Y, S   Serum Cholesterol: HDL ratio CB-INF-CALC Y, S   Serum Free Androgen Index CB-INF-CALC Y, S   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 </td <td>Materials/Froducts tested</td> <td>-</td> <td>Equipment/Techniques used</td> <td>Code</td>	Materials/Froducts tested	-	Equipment/Techniques used	Code
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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES	Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	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	Y
		HI-SOP-TESTES	
		Decalcification using HI-SOP- DECAL	Y
		Tissue processing: Leica Peloris III processor	Y
		HI-SOP-PROCESSOR	
		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



ISO 15189:2022

# Schedule of Accreditation

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

#### York Teaching Hospitals NHS Foundation Trust

Issue No: 018 Issue date: 11 June 2025

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (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	Molecular Diagnostic examination activities: Examination of tissues to identify or exclude mutations within DNA for the purpose of clinical diagnosis, prognosis and treatment options.	Documented in-house procedures in conjunction with manufaturers 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	Immunocytochemistry for the identification of cells/diseases below:-	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	Carcinoembyonic antigen (CEA)	Y



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HUMAN BODY TISSUE (cont'd)	Immunocytochemistry for the identification of cells/diseases below:- (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Pan T-cell marker used for the identification of immature and mature T-cell malignancies	CD3	Y
	Identification of Burkitts Iymphoma, follicular germ cell Iymphoma 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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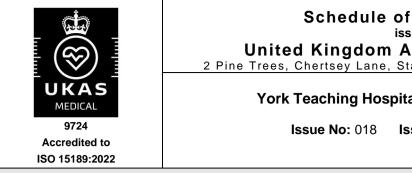
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HUMAN BODY TISSUE (cont'd)	Immunocytochemistry for the identification of cells/diseases below:- (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Leucocyte differentiation	CD56	Y
	Identification 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	СК14	Y
	Marker for papillary thyroid carcinoma	СК19	Y

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HUMAN BODY TISSUE (cont'd)	Immunocytochemistry for the identification of cells/diseases below:- (cont'd)	In house documented procedures & manufacturer's instructions using Agilent Omins	
		HI-SOP-IMMUNO	
	Gastric and intestinal epithelium, urothelium and Merkel cells	СК20	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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Assessment of suitability of

Classification of melanomas

adrenal cortical tumours and renal cell carcinomas, also interuterine v ectopic

Assess the proliferative activity

of normal and neoplastic

Differentiation between

pregnancy

tissue

breast cancer patients in respect of the drug Herceptin

Υ

Y

Y

Υ

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#### Testing performed by the Organisation at the locations specified Type of test/Properties Location Standard specifications/ measured/Range of Materials/Products tested Equipment/Techniques used Code measurement HUMAN BODY TISSUE In house documented procedures Immunocytochemistry for the identification of cells/diseases & manufacturer's instructions using (cont'd) below:- (cont'd) **Agilent Omins HI-SOP-IMMUNO** Primary and metastatic MELANA Y malignant melanoma Y Melanocytes MelanA red chromogen Y DNA mismatch repair protein. MLH1 Useful marker for the classification of colorectal cancer Mismatch repair protein MSH2 MSH2 Y DNA mismatch repair protein. MSH6 Y Useful marker for the classification of colorectal cancer Useful as a first line marker for **MNF116** Υ epithelial tumours Alveolar macrophages, Napsin A Y pneumocytes, lung adenocarcinoma Marker for germ cell tumours OCT3/4 Υ Classification of premalignant P504S Y high-grade prostatic intraepithelial neoplasia (HGPIN) and prostate adenocarcinoma.

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



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	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 Diagnostic Non-	Light microscopy with reference to HI-SOP-MICROSCOP	
	<u>Gynaecological Cytopathology</u>		
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:	Y
		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	
Synovial fluid specimens	Diagnostic assessment for the presence of crystals	CY-SOP-SYF Polarised Light Microscopy	Y



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HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis	Documented procedure & manufacturer's instructions	
Semen	Post vasectomy: 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	Fertility testing:	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	Y
	Volume	Volume/weight	
	рН	Colorimetric strips	
	Sperm morphology including TZI scoring	Stained slides (Papanicolau) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	



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HUMAN BODY FLUIDS (cont'd)	Haematological examination activities for the purpose of clinical diagnosis	Documented in-house procedures with manufacturer's instructions	
Whole Blood EDTA	Full Blood Count WBC RBC ESR HGB HCT MCH	Sysmex XN3100(S) Sysmex XN9100 Analyser (Y) Hb measurement by laurel sulphate conversion and colorimetry HA-SOP-FBC Sysmex XN550 Analyser	S, Y
	MCHC PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count	(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)	Haematological examination activities for the purpose of clinical diagnosis (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 Blodd	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)	Haematological examination activities for the purpose of clinical diagnosis (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)	Haematological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
	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
	Activated Partial Thromboplastin (APTT) and APTT ratio		
	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
	Antithrombin Protein C Protein S	Chromogenic assays Latex Immunoassay CO-SOP-TBP	Y
	Lupus Inhibitor Screen	CO-SOP-LUPUS	Y
	Factor VIII Inhibitor (Nijmegen Modification Assay)	CO-SOP-F8INH	Y
	Von Willebrand Factor Antigen (vWF:Ag)	Immunoturbidometric assay CO-SOP-vWD_Screen	Y
	Von Willebrand Factor Activity (vWF:RCo)	Immunoturbidometric assay CO-SOP-vWD_Screen	Y

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HUMAN BODY FLUIDS (cont'd)	Haematological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
	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	Von Willebrand Factor Collagen Binging 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
	Molecular		
Whole Blood Citrated & EDTA	Detection of genetic mutation Factor V Leiden & prothrombin mutation	Factor V Leiden/Prothrombin Gene Mutation on Cepheid Gene Xpert CO-SOP-FVL_PGM	Y
	Blood Transfusion examination activities for the purpose of clinical diagnosis	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 positive	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



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination</u> activities for the purpose of clinical diagnosis (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 positive	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)	Haematological examination activities for the purpose of clinical diagnosis (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				