


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL <b>8055</b>  Accredited to <b>ISO 15189:2012</b>	<b>North West Anglia NHS Foundation Trust</b>  Issue No: 022 Issue date: 13 November 2023	
	<b>Pathology Department</b> <b>Department 413</b> <b>Peterborough City Hospital</b> <b>Edith Cavell Campus</b> <b>Bretton Gate</b> <b>PE3 9GZ</b>	<b>Contact: Kerry Winham-Whyte</b> <b>Tel: +44 (0)1733678441</b> <b>E-Mail: <a href="mailto:kerry.winham-whyte@nhs.net">kerry.winham-whyte@nhs.net</a></b> <b>Website: <a href="http://www.peterboroughandstamford.nhs.uk">www.peterboroughandstamford.nhs.uk</a></b>

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

Location details	Activity
<b>Peterborough City Hospital</b> Mortuary	<b>Mortuary Services</b> <b>Body store</b>
Stamford and Rutland Hospital Ryhall Road Stamford PE9 1UA	Phlebotomy Blood storage Fridge managed by laboratory
Ramsay Fitzwilliam Hospital Milton Way South Bretton Peterborough Cambridgeshire PE3 9AQ	Blood storage only Fridge managed by laboratory



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Issue No:022 Issue date: 13 November 2023

#### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Examination activities for the purpose of clinical diagnosis</u>  <u>Clinical Biochemistry</u>	In house documented methods incorporating manufacturers' instructions where relevant  Roche Cobas 702 module - multi assay photometry unit BIO-LP-Cobas8000
Serum/heparinised plasma	Albumin Alkaline Phosphatase ALT Amylase Bicarbonate Bilirubin C Reactive Protein Cholesterol Creatine Kinase (CK) Creatinine Gamma GT HDL Cholesterol Inorganic Phosphate Lithium Magnesium Paracetamol Salicylate T.Cal/Correct Cal Total Protein Triglyceride Urea Uric Acid Alpha 1 Antitrypsin ACE AST Bile Acids B2 Microglobulin C3 C4 Caeruloplasmin Direct Bilirubin Iron Immunoglobulins (IgA, IgG, IgM)  Unsaturated Iron Binding Capacity Lactate Dehydrogenase Rheumatoid Factor	BIO-LP-ALB BIO-LP-ALP BIO-LP-ALT BIO-LP-AMY BIO-LP-CO2 BIO-LP-TBIL BIO-LP-CRP BIO-LP-CHOL BIO-LP-CPK BIO-LP-CRT BIO-LP-GGT BIO-LP-HDL BIO-LP-IPH BIO-LP-LIT BIO-LP-MAG BIO-LP-PARA BIO-LP-SAL BIO-LP-CAL BIO-LP-TPR BIO-LP-TG BIO-LP-UREA BIO-LP-UIC BIO-LP-AAT BIO-LP-ACE BIO-LP-AST BIO-LP-BILAC BIO-LP-B2M BIO-LP-C3 BIO-LP-C4 BIO-LP-CAER BIO-LP-DBIL BIO-LP-FE BIO-LP-IGA BIO-LP-IGG BIO-LP-IGM BIO-LP-UIBC  BIO-LP-LDH BIO-LP-RF



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Clinical Biochemistry (cont'd)</u>	Roche Cobas 702 module - multi assay photometry unit BIO-LP-Cobas8000
EDTA Plasma	Glucose Lactate Ammonia	BIO-LP-GLU BIO-LP-LACT BIO-LP-NH3
Serum/heparinised plasma	Therapeutic Drugs: Carbamazepine Digoxin Ethanol Gentamicin Phenytoin Phenobarbitone Theophylline Tobramycin Vancomycin	BIO-LP-CMZ BIO-LP-Digoxin BIO-LP-ETOH BIO-LP-GENT BIO-LP-PNT BIO-LP-PNO BIO-LP-Theophylline BIO-LP-TOB BIO-LP-VANC
		Roche Cobas C702 module - multi assay
Urine	Calcium Amylase Creatinine Magnesium Microalbumin Phosphate Urea Uric Acid Urine Protein	BIO-LP-CAL BIO-LP-AMY BIO-LP-CRT BIO-LP-MAG BIO-LP-MALB BIO-LP-IPH BIO-LP-UREA BIO-LP-UIC BIO-LP-TPUC
CSF CSF CSF	Protein Lactate Glucose	BIO-LP-TPUC BIO-LP-LACT BIO-LP-GLU
		Roche Cobas 8000 Ion Selective Electrode Unit
Serum/heparinised plasma, urine	Electrolytes: Sodium Potassium Chloride	BIO-LP-Cobas8000 BIO-LP-ISE BIO-LP-ISE BIO-LP-ISE



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Faeces	<u>Clinical Biochemistry</u> (cont'd)  Faecal Haemoglobin (FIT)	Roche Cobas C702 module - multi assay photometry unit BIO-LP-Cobas8000 BIO-LP-FIT  Roche C801 immunoassay module Electrochemiluminescence for sandwich and competitive immunoassays
Serum/heparinised plasma	A-TPO B12 CA15-3 Folate Ferritin Free T3 Free Thyroxine IGF1 NT Pro BNP Testosterone SHBG Troponin T (HS) TSH AFP BHCG CA 125 CEA Cortisol FSH LH Progesterone TPSA CA 19.9 C-Peptide HGH Oestradiol Prolactin Macroprolactin 25OH Vitamin D	BIO-LP-TPO BIO-LP-B12 BIO-LP-CA153 BIO-LP-FOL BIO-LP-FER BIO-LP-FT3 BIO-LP-FT4 BIO-LP-IGF1 BIO-LP-proBNP BIO-LP-TT BIO-LP-SHBG BIO-LP-TROP BIO-LP-TSH BIO-LP-AFP BIO-LP-hCG BIO-LP-CA125 BIO-LP-CEA BIO-LP-COR BIO-LP-FSH BIO-LP-LH BIO-LP-PROG BIO-LP-tPSA BIO-LP-CA199 BIO-LP-CPEP BIO-LP-GH BIO-LP-E2 BIO-LP-PROL BIO-LP-MPROL BIO-LP-VITD
FI-EDTA Plasma Whole Blood (EDTA)	PTH Immunosuppressant analysis: Tacrolimus Cyclosporin	BIO-LP-PTH  BIO-LP-TAC BIO-LP-CYC
Serum/Heparinised plasma	Anti-SARS-CoV-2 ab	BIO-LP-ACOV



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Clinical Biochemistry (cont'd)</u>	
Urine (acidified with glacial acetic acid)	Metanephrines and normetanephrine	Recipe kit using Waters Alliance/Agilent 1100 HPLC system BIO-LP-Alliance, BIO-LP-Aligent BIO-LP-MET
Urine (acidified with glacial acetic acid)	5-Hydroxyindoleacetic acid (5-HIAA)	Chromosystems kit using Waters Alliance/Agilent 1100 HPLC system BIO-LP-Alliance, BIO-LP-Aligent BIO-LP-HIAA
Serum and Urine	Osmolality	Vitech Osmo1 Osmometer BIO-LP-Osmometer
Urine	Detection of hCG (Pregnancy Test)	Invitech kit (thin-layer chromatography dual antibody immunoassay) BIO-LP-Pregnancy Tests
CSF	Haem Pigments	Lambda 35 Spectrophotometer BIO-LP-CSFHP
Calculated tests	eGFR (Estimated glomerular filtration rate)	
	AKI stage (Acute Kidney Injury)	
	Free Testosterone	
	Adjusted Calcium	
	Non-HDL Cholesterol	
	LDL	
Whole blood	HbA1c	TOSOH G11 using SOP BIO-LP-HbA1c
Urine	Porphobilinogen screen	Manual Hoesch test (DMAB) BIO-LP-PBG



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Serum	<u>Immunology</u>  Specific IgE testing Total IgE testing Mast Cell Tryptase testing Specific IgG testing Anti-Cardiolipin antibodies B2GP1 antibodies CCP antibodies CTD assay dsDNA antibodies ENA profile antibodies ENA Screen GBM antibodies MPO/PR3 antibodies Intrinsic factor antibodies TSH receptor antibodies TTG antibodies (IgA) TTG antibodies (IgG) Faecal Calprotectin	ImmunoCAP 250 – ImmunoCAP and ELiA technology (IMM-LP-IC250)  IMM-LP-CAP-ALLERGY IMM-LP-CAP-ALLERGY IMM-LP-CAP-Tryptase IMM-LP-CAP-SIGG IMM-LP-EIA-ACA IMM-LP-EIA-B2G IMM-LP-EIA-CCP IMM-LP-EIA-CTD IMM-LP-EIA-DNA IMM-LP-EIA-ENAP IMM-LP-EIA-ENAS IMM-LP-EIA-GBM IMM-LP-EIA-EANCA IMM-LP-EIA-IFS IMM-LP-EIA-TRAB IMM-LP-EIA-TTG IMM-LP-EIA-TTG IMM-LP-EIA-CALPRO
Serum	GAD Antibodies Interferon-gamma released from T cells (Latent TB testing)	Dynex DS2 ELISA Automated Platform using IMM-LP-EIA-DS2 And kits as stated: Euroimmun kit - IMM-LP-EIA-GAD Qiagen QFT kit - IMM-LP-EIA-QTFG
Serum	Anti-nuclear antibodies (CTD) screen	Werfen Bioflash CIA IMM-LP-CIA-CTD
Serum	ANCA Liver autoantibodies Gastric parietal cell antibodies Pancreatic islet cell antibodies Paraneoplastic antibodies Skin antibodies Endomysial antibodies ANA antibodies (HEp-2) dsDNA antibodies (Crithidia)	Indirect Immunofluorescence, Werfen Quantalyser 3000 Indirect Immunofluorescence automated platform IMM-LP-IIF-QL3000 IMM-LP-IIF-ANCA IMM-LP-IIF-LABPAB IMM-LP-IIF-TissueAAB



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Serum	Liver Antibodies	Immunoblot IMM-LP-EIA-Liver Lineblot
Serum	Paraneoplastic antibodies	Immunoblot IMM-LP-EIA-PNP Lineblot
Serum	Serum Free Light Chains	Binding site Optilite- immunoturbidmetric IMM-LP-Optilite IMM-LP-SFLC
Serum	Detection and quantification of paraproteins	Capillary Zone Electrophoresis using Sebia Capillarys 3 Octa Electrophoresis and Immunofixation IMMUNO-LP-SERUMEPS/IMMUNO-LP- IMMUNOFIX
Urine	Detection and quantification of Bence Jones Protein	Sebia Phoresis system Electrophoresis and Immunofixation IMMUNO-LP-UrineEPS/IMMUNO-LP- IMMUNOFIX
Serum	Cryoglobulin	IMMUNO-LP-CRYO
HUMAN BODY FLUIDS AND TISSUES	<u>Haematology</u>	
Whole Blood: EDTA	Haemoglobinopathy Screen	Biorad Variant 2 - HPLC HAE-LP HAE 351, HAE-LP HAE 355, HAE-LP HAE 357
Whole Blood: EDTA	Haemoglobin Electrophoresis	Sebia hydrasys using Sebia Alkaline and Acid Gel plates HAE-LP HAE 357
Plasma: Citrate	Coagulation Screen: APTT and mixing studies PT QFA Thrombin Thrombin time	Instrumentation Laboratories ACL TOP 550 photometry / turbidity HAE-LP HAE 005, HAE-LP HAE 102 HAE-LP HAE 004, HAE-LP HAE 101 HAE-LP HAE 006, HAE-LP HAE 103 HAE-LP HAE 011



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Haematology (cont'd)</u>	Instrumentation Laboratories ACL TOP 550 photometry / turbidity
Plasma: Citrate	D-Dimer INR Factor Assays: Intrinsic VIII, IX, XI and XII Extrinsic II, V, VII, X Factor XIII	HAE-LP HAE 007 HAE-LP HAE 004, HAE-LP HAE 101  HAE-LP HAE 010 HAE-LP HAE 019 HAE-LP HAE 025
Plasma: Citrate	Von Willebrand screens; Von Willebrand factor antigen quantitation and ristocetin cofactor activity (RiCof) levels as %	HAE-LP HAE 017
Plasma: Citrate	Thrombotic Screens (Antithrombin, Protein C, Protein S and Activated protein C Resistance)	HAE-LP HAE 015,
Plasma: Citrate	Lupus Screens; Investigation of antiphospholipid syndromes by quantitation of antiphospholipid inhibition antibody (Weak Moderate or Strong)	HAE-LP HAE 009
Plasma: Citrate	Low Molecular Weight Heparin Screens	HAE-LP HAE 021
Plasma: Citrate	Direct Xa Inhibitors: Rivaroxaban Apixaban Endoxaban	HAE-LP HAE 024 HAE-LP-HAE-026 HAE-LP-HAE-027
Plasma: EDTA	Infectious Mononucleosis screen (qualitative) – detection of Epstein-Barr Virus (EBV) antibodies	Accusay Mono-antibody capture HAE-LP HAE 222, HAE-LP HAE 223





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Blood	Morphological appearance	Sysmex SP50 automated staining HAE-LP-HAE 261/237/212
Bone Marrow	Morphological appearance	Sysmex SP50 automated staining HAE-LP-HAE 238/261
Whole Blood: EDTA Thick and thin films	Detection of Malarial parasites, % parasitaemia	Romanowski staining and microscopy HAE-LP HAE 217, HAE-LP HAE 219
	Malarial confirmation and species identification: Falciparum, P.Vivax, P.Ovale or P.Malariae.	CareStart antibody capture HAE-LP HAE 218
Whole Blood: EDTA	G6PD screen	Biotech fluorescence HAE-LP HAE 224
Whole blood: EDTA	Detection of HbS (Sickle Solubility Screen)	Microgen Bioproducts S-Test Kit HAE-LP HAE 355 to also include Documented in-house methods to meet the requirements of the NHS Sickle Cell and Thalassaemia screening programme in pregnancy as defined in July 2018 NHS Sickle Cell and Thalassaemia screening programme in pregnancy laboratory quality assurance evidence requirements.
	<u>Haematology Molecular Markers</u>	
Whole blood: EDTA	V Leiden/Prothrombin	Dx System – Gene Xpert – PCR HAE-LP HAE 517



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Whole blood: EDTA	<u>Haematology Leucocyte Subtyping</u>	
Whole blood: EDTA	Leukaemia immunophenotyping - % positivity of gated cells of interest	Beckman Coulter Aquios CL Flow cytometer system with Aquios System software and the Aquios Tetra Combo Test Immunophenotyping – fluorescence detection HAE-LP HAE 308 (Acute Leukaemia Panel) HAE-LP HAE 309 (Chronic Leukaemia Panel)
Whole blood: EDTA	CD3,4 &8 counts	HAE-LP HAE 305, HAE-LP HAE 311
	T and B cell and NK subsets	HAE-LP HAE 305, HAE-LP HAE 311
	Immune deficiency incorporating CD3,4,8 analysis (HIV monitoring- CD3,4 &8 counts)	SOP-HAE-LP-HAE-366
	<u>Haematology Cont'd</u>	
Whole Blood EDTA	FBC Reticulocytes	Using the Sysmex XN 10, Sysmex XN 20 using Photometry, Fluorescence and Impedance HAE-LP-HAE 259/290/262 HAE-LP-HAE 259/290
Whole Blood EDTA	ESR	Systemx interliner and autocompact. HAE-LP-HAE 263



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Whole blood: EDTA	<u>Blood Transfusion</u>  Group and Antibody Screening <ul style="list-style-type: none"> <li>• ABO groups and RhD typing</li> <li>• Rhesus blood group antibodies: anti-Cw anti-C, anti-c, anti-D, anti-E, anti-e</li> <li>• Kell system blood group antibodies: antiK, anti-k, anti Kpa</li> <li>• Kidd blood group antibodies:anti-Jka anti-Jkb</li> <li>• Duffy blood group antibodies:anti-Fya anti-Fyb</li> <li>• Lutheran blood group antibodies: anti-Lua</li> <li>• MNS blood group antibodies:anti-M, anti-N, anti-S, anti-s,</li> <li>• Lewis blood group antibodies:anti-Lea anti-Leb</li> <li>• P blood group antibodies: anti-P1</li> </ul>	Ortho Vision column agglutination TRA-LP 016, TRA-LP 050, TRA-LP 100, TRA-LP-049
Whole blood: EDTA	Rh & Kell phenotyping	Manual Column Agglutination in Bio-Vue cards TRA-LP 0052
Whole blood: EDTA	Foetal Maternal Haemorrhage Estimation – quantitation of foetal bleed in maternal circulation	Beckman Coulter Navios Flow cytometer – fluorescence detection HAE-LP HAE 328
Plasma: EDTA	Cross Matching	Manual Acid elution (Kleihauers) TRA-LP 017Manual Acid elution TRA-LP 017  Manual Column Agglutination in Bio-Vue cards TRA-LP 052, TRA-LP080



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Blood Transfusion (cont'd)</u>	
Plasma: EDTA	NHSBT Antibody Panels Panel 1 ICT + ENZ Panel 2 ICT	Manual Column Agglutination in Bio-Vue cards TRA-LP 052
Whole blood: EDTA	Direct Coombs Test	Ortho Vision and manual column agglutination TRA-LP 050, TRA-LP052
	<u>Serology/Virology</u>	
Serum	Hepatitis BsAg HIV Ag-Ab Testing Syphilis testing Hepatitis C Ab Epstein-Barr Virus (IgM, IgG, EBNA) Hepatitis Bc IgM Anti-HBc Hepatitis Be Ag Anti-HBe CMV IgM Hepatitis A IgM Rubella IgG	Abbott Architect analyser Measurement principle CMIA V051 and to include Documented in-house methods to meet the requirements of the NHS Infectious diseases in pregnancy screening programme as defined in July 2018 NHS Infectious diseases in pregnancy screening programme:laboratory quality assurance evidence requirements.
Serum	Hepatitis BsAg Anti- HBs Hepatitis C Ab Toxoplasma IgG Rubella IgG/M Varicella Zoster IgG	Biomerieux VIDAS Measurement principle ELFA V045
Serum	HIV I/II confirmation	BioRad Geenius HIV I/II immunochromatographic assay and Geenius Reader SOP V035
Serum	Syphilis RPR	RPR charcoal agglutination V034
Serum	Syphilis TPPA	TPPA – haemagglutination in microtitre plate V034
Serum	Rheumatoid factor	RF latex agglutination V045



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Serum	<u>Serology/Virology (cont'd)</u> Anti-streptolysin-OASD	ASO Biomerieux ASD kit (based on antibody inhibition of streptodornase B on DNA substrate. Detected by colour change) V019
Swabs (Cervical/urethral/rectal/urine)	<u>Molecular microbiology/virology</u> Chlamydia trachomatis plasmid DNA/Neisseria gonorrhoeae genomic DNA	Abbott m2000 system - PCR M002
Plasma: EDTA	Hepatitis C viral load testing	Abbott m2000 system – PCR M002, M011
Nasopharyngeal and combined Nose/throat swabs in viral transport media (VTM)	Detection of SARS-CoV-2 RNA (COVID-19) specific gene sequences, N gene and RdRp RNA	Real time PCR using Abbott m2000 system-using the m2000 amplification kit. MIC-LP-M018
Faeces	Clostridium difficile toxin genes	Cepheid GeneXpert PCR V050
Sputum, bronchial aspirates/lavages.	Mycobacterium tuberculosis complex plus rifampicin resistance specific genes	Cepheid GeneXpert PCR M001, M009
Virology respiratory (nose or throat) swabs	Influenza A/B/Swine influenza RNA	ABI Prism - and GeneXpert PCR M001, M005, M007
Virology Respiratory (nose swabs, throat swabs, sputum,PNS, Bronchial aspirate, Broncho-alveolar lavage)	Influenza A,B,H1N1, Coronaviruses (NL63,229E,0C43,HKU1),Para influenza 1-4, Human metapneumovirus A&B, Rhinovirus, RSV A&B, Adenovirus, Enterovirus, Parechovirus, Bocavirus, Mycoplasma pneumoniae	Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism 7500 using PCR amplification and dye detection. SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M015 – Respiratory Multiplex PCR



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Nasopharyngeal and combined Nose/throat swabs in viral transport media (VTM)	<u>Molecular microbiology/virology (cont'd)</u>  Detection of SARS-CoV-2 RNA (COVID-19) specific gene sequences, orf1ab and E gene RNA	RNA Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism 7500 using PCR amplification and dye detection, using Launch Biosphere PCR assay. MIC- LP-M018
CSF Samples	Molecular testing of clinical samples for Herpes simplex 1&2, Varicella zoster virus, Mumps virus, Enterovirus, Human Parechovirus	Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism using PCR amplification and dye detection SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M013 – CSF Virology
Vesicle swabs in virus transport medium, Vesicle fluid	Molecular testing of clinical samples for Herpes simplex 1&2, Varicella zoster virus	Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism using PCR amplification and dye detection SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M014 – HSV & VZV PCR
Swabs or urine in Abbott Multicollect kits	Confirmation of positive Neisseria gonorrhoeae screening results in clinical samples	Extraction via Euroclone Duplica-Prep using magnetic bead extraction. Target amplification and detection by ABI Prism using PCR amplification and dye detection SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M004 – Chlamydia and Neisseria gonorrhoea



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swabs Sterile Fluids Drains Tissue Faeces Line/catheter tips Spinal fluid Sputum/respiratory</p> <p>Bacterial Cultures</p> <p>Bacterial Cultures</p> <p>Bacterial Cultures</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Bacteriology</u></p> <p>Isolation and Identification of pathogens</p> <p>Antibiotic sensitivity testing</p> <p>Identification of microorganisms</p> <p>Identification of microorganisms</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Microscopy &amp; culture B015 (Routine), B012 (Faeces), B014 (Respiratory)</p> <p>Sensitivity by disc diffusion (EUCAST standards) B015 B028</p> <p>Sensitivity by break point strips (E-Tests, MICE) B011 (Blood cultures)</p> <p>Bruker MALDI-ToF using Mass Spectrometry ionisation</p> <p>Confirmation tests: catalase, Staph latex agglutination, tube coagulase, strep grouping, agglutinating sera, API tests, Rapid ANA, Auxocolour (based on biochemical tests and sugar utilisation tests) B019</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Bacteriology</u>	
Whole Blood in blood culture bottles	Detection of micro organisms of pathogenic significance	Biomerieux BacT/ALERT Virtuo: Detection of pH changes due to CO <sub>2</sub> B011 (followed by manual culture, sensitivity and identification as above )
Urine	Urine Microscopy and Culture	Menarini Sedimax for microscopy Mast Uriplus microtitre plate culture B017
Sputum Bronchial washings/aspirate Tissue Urines	Detection of Mycobacterium spp.	BD Diagnostic Systems MGIT. Detects growth by fluorescent detection of oxygen B016, B026 Manual methods: slope cultures, microscopy B016
Faeces	Helicobacter Antigen tests GDH	Launch Diagnostics DS2; EIA V048, V039
Swabs Urine	Isolation of Methicillin Resistant <i>Staph aureus</i> (MRSA)	Culture using Chromogenic media B015
Faeces	Presence of ova, cysts and parasites	Direct microscopy and microscopy following faecal concentration method





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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Urine</p> <p>Nail Hair Skin</p> <p>Body fluids / Fine needle aspirations</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Bacteriology (cont'd)</u></p> <p>Detection of Schistosoma haematobium ova</p> <p><u>Mycology</u></p> <p>Isolation and identification of pathogenic fungi</p> <p><u>Cytopathology</u></p> <p>Diagnostic Cytology examination for cell morphology changes/abnormalities and diagnosis for the purposes of disease identification</p> <p>Reading and interpretation of slides from processed fluids</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Microscopy following urine concentration method B012 – Faeces bench</p> <p>Fluorescent microscopy, wet-film microscopy, plate culture SOP: B013</p> <p>Centrifugation, staining and microscopy Hereas centrifuge CP-N-014 Thermo cytospin CP-N-016 Routine Papanicolaou stain CP-H-314 Diff-Quick staining CP-N-009 MGG staining CP-H-400</p> <p>Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-C-002 Non-gynae reporting CP-CLIN-N001</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human tissue samples/ organs, cell blocks formalin fixed</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u> <u>Histopathology</u></p> <p>Examination to identify cell morphology changes/abnormalities, and diagnosis for the purposes of disease identification</p> <p>Routine staining for identification of basophilic and eosinophilic structures</p> <p><b>Special staining for identification of:</b> Acid mucins</p> <p>Glycogen, Neutral and Acid Mucins</p> <p>Neutral and Acid Mucins</p> <p>Amyloid</p> <p>Elastic Fibres</p> <p>Helicobacter pylori</p> <p>Gram +ve&amp;-ve bacteria</p> <p>Melanin and argentaffin granules</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Specimen dissection: SOP Dissection Protocols CP-H-036</p> <p>Decalcification CP-H-011</p> <p>Tissue processing: Thermo Excelsior tissue processor CP-MAN-013 Fixation and Processing Tissue Protocols CP-H-009 Leica Peloris tissue processor CP-MAN-001</p> <p>Microtomy: Leica / Thermo microtomes CP-H-280</p> <p>Routine H&amp;E staining: Sakura Prisma staining machine and film coverslipper CP-H-314</p> <p><b>Manual staining</b></p> <p>Alcian Blue CP-H-400</p> <p>Alcian Blue/ Periodic Acid Schiffs CP-H-400</p> <p>Alcian Blue/ Periodic Acid Schiffs with Diastase CP-H-400</p> <p>Stoke's Congo Red CP-H-400</p> <p>Elastic Van Gieson CP-H-400</p> <p>Modified Giemsa for H. pylori CP-H-400</p> <p>Gram CP-H-400</p> <p>Masson Hamperl CP-H-400</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Histopathology (cont'd)</u>	
	<b>Special staining for identification of (cont'd):</b>	<b>Manual staining (cont'd)</b>
Human tissue samples/ organs, cell blocks (cont'd)	Glycogen, Fungi and Neutral Mucins	Periodic Acid Schiff CP-H-400
	Fungi and Neutral Mucins	Periodic Acid Schiff with Diastase CP-H-400
	Ferric Iron	Perl's Prussian Blue CP-H-400
	Insoluble Calcium Salts	Von Kossa CP-H-400
	Mycobacterium tuberculosis	Ziehl Neelsen CP-H-400
Human tissue samples/ organs, cell blocks (cont'd)	<b>Immunohistochemistry for identification of:</b>	<b>Immunohistochemistry:</b> Roche Benchmark Ultra platform SOPs CP-H-700, CP-H-701, CP-H-701a, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:
	Normal/neoplastic tissue epithelial in origin	AE1/3
	Companion test for lung carcinoma	ALK
	Follicular lymphomas and various diffuse lymphoproliferative diseases	Bcl-2
	Adenocarcinoma vs malignant mesothelioma	BerEP4



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human tissue samples/ organs, cell blocks (cont'd)</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Immunohistochemistry for identification of:</p> <p>Medullary thyroid carcinoma</p> <p>Malignant mesothelioma</p> <p>T-cells and T-cell Lymphomas</p> <p>Mature T-cells and T-cell lymphomas</p> <p>Mature B-cells, Burkitt's lymphoma, Follicular lymphoma, Clear cell renal cell carcinoma</p> <p>B-cells and B-cell Lymphomas</p> <p>ALCL, Reed Sternberg cells, Hodgkin's disease</p> <p>Identify vascular origin of neoplasms</p> <p>Vascular and lymphatic tumours</p> <p>Neuroendocrine cells, NK cells</p> <p>T-cells, NK cells, Thymocytes</p> <p>Stem cells. Melanocytes, Mast cells, germ cells, Skin basal cells</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:</p> <p>Calcitonin</p> <p>Calretinin</p> <p>CD3</p> <p>CD5</p> <p>CD10</p> <p>CD20</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD56</p> <p>CD68</p> <p>CD117</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human tissue samples/ organs, cell blocks (cont'd)</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Immunohistochemistry for identification of:</p> <p>GI origin of metastatic adenocarcinomas</p> <p>Surface of GI cells, colon carcinomas</p> <p>Secretory granules of endocrine cells</p> <p>Squamous epithelium and Neoplasms of type</p> <p>Glandular and transitional epithelia and neoplasia of type</p> <p>Normal GI epithelia and urothelium and neoplasia of type</p> <p>Rhabdomyosarcomas, Leiomyomas, Mesotheliomas</p> <p>Ductal breast carcinomas</p> <p>Normal and neoplastic neoplasia</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Immunohistochemistry: Roche Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-H-702, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:</p> <p>CDX2</p> <p>CEA (mono)</p> <p>CHROMOGRANIN</p> <p>CK5/6</p> <p>CK7</p> <p>CK20</p> <p>Desmin</p> <p>E-cadherin</p> <p>EMA</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human tissue samples/ organs, cell blocks (cont'd)</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Immunohistochemistry for identification of:</p> <p>hCG containing cells and cells with trophoblastic elements</p> <p>Mesothelial cells</p> <p>Melanocytes, Melanomas</p> <p>Proliferative cells</p> <p>Leucocytes</p> <p>Melanocytes, Melanomas</p> <p>MMR proteins in HNPCC</p> <p>Normal/neoplastic tissue epithelial in origin</p> <p>MMR proteins in HNPCC</p> <p>MMR proteins in HNPCC</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:</p> <p>HCG</p> <p>HBME-1</p> <p>HMB45</p> <p>Ki67</p> <p>LCA</p> <p>Melan A</p> <p>MLH-1</p> <p>MNF116</p> <p>MSH2</p> <p>MSH6</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human tissue samples/ organs, cell blocks (cont'd)</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Immunohistochemistry for identification of:</p> <p>Basal epithelial cells</p> <p>Companion test for NSCLC</p> <p>Neuroendocrine tumours</p> <p>MMR proteins in HNPCC</p> <p>Normal and neoplastic prostate epithelia</p> <p>Malignant melanoma, chondroblastoma, Schwannoma</p> <p>Smooth muscle cells, myoepithelial cells, Leiomyosarcomas</p> <p>Neuroendocrine cells and neoplasms</p> <p>Thyroid carcinomas</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:</p> <p>p63</p> <p>PD-L1</p> <p>PGP</p> <p>PMS2</p> <p>PSA</p> <p>S100</p> <p>SMA</p> <p>Synaptophysin</p> <p>Thyroglobulin</p>



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Human tissue samples/ organs, cell blocks (cont'd)	<p>Expression of ER containing cells, e.g. Normal and neoplastic breast cells</p> <p>Expression of progesterone cells in breast tissue</p> <p>Detection of Her-2 antigen</p> <p>Determination of Her2 gene status</p> <p>Reading and interpretation of slides from processed tissue and fluids</p>	<p>ER</p> <p>PR</p> <p>Her2</p> <p>DDISH</p> <p>Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001</p>
Prepared slides from FFPE tissues	Morphological assessment and interpretation/diagnosis	Diagnostic digital pathology using Philips UFS scanners and Glissando scanner linked to Philips image management software (IMS3.3).
END		