Schedule of Accreditation

United Kingdom Accreditation Service

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



8055

Accredited to ISO 15189:2012

North West Anglia NHS Foundation Trust

Issue No: 024 Issue date: 25 January 2024

Pathology Department

Department 413

Peterborough City Hospital

Edith Cavell Campus

Bretton Gate PE3 9GZ

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Website: www.peterboroughandstamford.nhs.uk

Site activities performed away from the location listed above:

Location details	Activity
Peterborough City Hospital Mortuary	Mortuary Services Body store
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

Assessment Manager: MG Page 1 of 24



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DETAIL OF ACCREDITATION

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Clinical Biochemistry	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-CRP BIO-LP-CPK BIO-LP-CPK BIO-LP-GGT BIO-LP-HDL BIO-LP-HDL BIO-LP-HDL BIO-LP-HDR BIO-LP-HRAG BIO-LP-CAL BIO-LP-CAL BIO-LP-TR BIO-LP-TR BIO-LP-TR BIO-LP-TR BIO-LP-TR BIO-LP-UREA BIO-LP-UREA BIO-LP-AAT BIO-LP-ACE BIO-LP-BZM BIO-LP-BZM BIO-LP-C3 BIO-LP-BZM BIO-LP-C4 BIO-LP-C4 BIO-LP-CBIL BIO-LP-CBIL BIO-LP-CBIL BIO-LP-CBIL BIO-LP-CBIL BIO-LP-LDI BIO-LP-IGG BIO-LP-IGG BIO-LP-IGM BIO-LP-UIBC BIO-LP-LDH BIO-LP-RF



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Clinical Biochemistry (cont'd)	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)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Faeces	Clinical Biochemistry (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-AFP BIO-LP-CA125 BIO-LP-CA125 BIO-LP-COR BIO-LP-COR BIO-LP-FSH BIO-LP-FSH BIO-LP-FSH BIO-LP-PROG BIO-LP-CA199 BIO-LP-CPEP BIO-LP-CPEP BIO-LP-GH BIO-LP-BOL BIO-LP-PROL BIO-LP-PROL BIO-LP-NITD
FI-EDTA Plasma Whole Blood (EDTA)	PTH Immunosuppressant analysis:	BIO-LP-PTH
Serum/Heparinised plasma	Tacrolimus Cyclosporin Anti-SARS-CoV-2 ab	BIO-LP-TAC BIO-LP-CYC BIO-LP-ACOV



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HUMAN BODY FLUIDS (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Clinical Biochemistry (cont'd)	
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 SpectrophotometerBIO-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)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Serum	<u>Immunology</u>	ImmunoCAP 250 – ImmunoCAP and ELiA technology (IMM-LP-IC250)
	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	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-ENAS IMM-LP-EIA-EANCA IMM-LP-EIA-IFS IMM-LP-EIA-TTG IMM-LP-EIA-TTG IMM-LP-EIA-CALPRO Dynex DS2 ELISA Automated Platform using
		IMM-LP-EIA-DS2 And kits as stated:
Serum	GAD Antibodies Interferon-gamma released from T cells (Latent TB testing)	Euroimmun kit - IMM-LP-EIA-GAD Qiagen QFT kit - IMM-LP-EIA-QTFG
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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HUMAN BODY FLUIDS (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
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)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Haematology (cont'd)	Instrumentation Laboratories ACL TOP 550 photometry / turbidity
Plasma: Citrate	D-Dimer INR Factor Assays:	HAE-LP HAE 007 HAE-LP HAE 004, HAE-LP HAE 101
	Intrinsic VIII, IX, XI and XII Extrinsic II, V, VII, X Factor XIII	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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
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)	Sickledex Kit HAE-LP HAE 369 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.
	Haematology Molecular Markers	
Whole blood: EDTA	V Leiden/Prothrombin	Dx System – Gene Xpert – PCR HAE-LP HAE 517



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Whole blood: EDTA	Haematology Leucocyte Subtyping	
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
Whole Blood EDTA	Haematology Cont'd 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 Sysmex interliner and autocompact.
Whole Blood EDTA	ESR	HAE-LP-HAE 263



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Blood Transfusion	
Whole blood: EDTA	 ABO groups and RhD typing Rhesus blood group antibodies: anti-Cw anti-C, anti-c, anti-D, anti-E, anti-e Kell system blood group antibodies: antiK, anti-k, anti Kpa Kidd blood group antibodies: anti-Jkb Duffy blood group antibodies:anti-Fya anti-Fyb Lutheran blood group antibodies: anti-Lua MNS blood group antibodies: anti-Lua MNS blood group antibodies:anti-H, anti-N, anti-S, anti-s, Lewis blood group antibodies:anti-Lea anti-Leb P blood group antibodies: anti-P1 	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 Manual Acid elution (Kleihauers) TRA-LP 017Manual Acid elution
Plasma: EDTA	Cross Matching	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)	Examination activities for the purpose of clinical diagnosis Blood Transfusion (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
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
	Serology/Virology	
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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Serology/Virology (cont'd)	
Serum	Anti-streptolysin-OASD	ASO Biomerieux ASD kit (based on antibody inhibition of streptodornase B on DNA substrate. Detected by colour change) V019
	Molecular microbiology/virology	
Swabs (Cervical/urethral/rectal/ urine)	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 systemusing 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Molecular microbiology/virology (cont'd)	
Nasopharyngeal and combined Nose/throat swabs in viral transport media (VTM)	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 Biosphore 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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Bacteriology</u>	
Swabs Sterile Fluids Drains Tissue Faeces Line/catheter tips Spinal fluid	Isolation and Identification of pathogens	Microscopy & culture B015 (Routine), B012 (Faeces), B014 (Respiratory)
Sputum/respiratory Bacterial Cultures	Antibiotic sensitivity testing	Sensitivity by disc diffusion (EUCAST standards) B015 B028
		Sensitivity by break point strips (E-Tests, MICE) B011 (Blood cultures)
Bacterial Cultures	Identification of microorganisms	Bruker MALDI-ToF using Mass Spectrometry ionisation
Bacterial Cultures	Identification of micro organisms	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



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	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 ₂ 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 Staph aureus (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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Bacteriology (cont'd)	
Urine	Detection of Schistosoma haematobium ova	Microscopy following urine concentration method B012 – Faeces bench
	Mycology	
Nail Hair Skin	Isolation and identification of pathogenic fungi	Fluorescent microscopy, wet-film microscopy, plate culture SOP: B013
	Cytopathology	
Body fluids / Fine needle aspirations	Diagnostic Cytology examination for cell morphology changes/abnormalities and diagnosis for the purposes of disease identification Reading and interpretation of slides from processed fluids	Centrifugation, staining and microscopy Hereas centrifuge CP-N-014 Thermo cytospin CP-N-016 Routine Papanicolau stain CP-H-314 Diff-Quick staining CP-N-009 MGG staining CP-H-400 Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-C-002 Non-gynae reporting CP-CLIN-N001



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



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Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/ Equipment/Techniques
	measurement	used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Histopathology (cont'd)	
	Special staining for identification of (cont'd):	Manual staining (cont'd)
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)	Immunohistochemistry for identification of:	Immunohistochemistry: 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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Histopathology (cont'd)	
Human tissue samples/ organs, cell blocks (cont'd)	Immunohistochemistry for identification of:	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:
	Medullary thyroid carcinoma	Calcitonin
	Malignant mesothelioma	Calretinin
	T-cells and T-cell Lymphomas	CD3
	Mature T-cells and T-cell lymphomas	CD5
	Mature B-cells, Burkitt's lymphoma, Follicular lymphoma, Clear cell renal cell carcinoma	CD10
	B-cells and B-cell Lymphomas	CD20
	ALCL, Reed Sternberg cells, Hodgkin's disease	CD30
	Identify vascular origin of neoplasms	CD31
	Vascular and lymphatic tumours	CD34
	Neuroendocrine cells, NK cells	CD56
	T-cells, NK cells, Thymocytes	CD68
	Stem cells. Melanocytes, Mast cells, germ cells, Skin basal cells	CD117



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



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Histopathology (cont'd)	
Human tissue samples/ organs, cell blocks (cont'd)	Immunohistochemistry for identification of:	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:
	hCG containing cells and cells with trophoblastic elements	HCG
	Mesothelial cells	HBME-1
	Melanocytes, Melanomas	HMB45
	Proliferative cells	Ki67
	Leucocytes	LCA
	Melanocytes, Melanomas	Melan A
	MMR proteins in HNPCC	MLH-1
	Normal/neoplastic tissue epithelial in origin	MNF116
	MMR proteins in HNPCC	MSH2
	MMR proteins in HNPCC	MSH6



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Histopathology (cont'd)	
Human tissue samples/ organs, cell blocks (cont'd)	Immunohistochemistry for identification of:	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:
	Basal epithelial cells	p63
	Companion test for NSCLC	PD-L1
	Neuroendocrine tumours	PGP
	MMR proteins in HNPCC	PMS2
	Normal and neoplastic prostate epithelia	PSA
	Malignant melanoma, chondroblastoma, Schwannoma	S100
	Smooth muscle cells, myoepithelial cells, Leiomyosarcomas	SMA
	Neuroendocrine cells and neoplasms	Synaptophysin
	Thyroid carcinomas	Thyroglobulin



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Histopathology (cont'd)	
	Immunohistochemistry for identification of:	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:
	Normal and neoplastic lung and thyroid cells	TTF-1
	Wilms tumour, Malignant mesotheliomas	WT-1
Human tissue samples/ organs, cell blocks (cont'd)	Expression of ER containing cells, e.g. Normal and neoplastic breast cells	ER
	Expression of progesterone cells in breast tissue	PR
	Detection of Her-2 antigen	Her2
	Determination of Her2 gene status	DDISH
	Reading and interpretation of slides from processed tissue and fluids	Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001
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		