


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	North West Anglia NHS Foundation Trust	
	Issue No: 008 Issue date: 25 April 2019	
	Pathology Department Department 413 Peterborough City Hospital Edith Cavell Campus Bretton Gate PE3 9GZ	Contact: Kerry Winham-Whyte Tel: +44 (0)1733678000 E-Mail: Kerry.winham-whyte@nhs.net Website: www.peterboroughandstamford.nhs.uk

Site activities performed away from the location listed above:

Location details	Activity
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
Thorpe Hall Hospice Thorpe Road PE3 6LW	Blood storage only Fridge managed by laboratory

Additional site activity performed away from the laboratory

Location details	Activities
On-site Mortuary and Body Store	Storage of bodies Record keeping (body identification and audit trail)



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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
Serum/heparinised plasma	Albumin Alkaline Phosphatase ALT Amylase Bicarbonate Bilirubin C Reactive Protein Cholesterol Creatine Kinase (CK) Creatinine Creatinine (Enzymatic) Gamma GT Gentamycin HDL Cholesterol Inorganic Phosphate Lithium Magnesium Paracetamol Salicylate T.Cal/Correct Cal Total Protein Triglyceride Urea Uric Acid	Roche Cobas 701 module - multi assay photometry unit BIO-LP-Cobas8000 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-CRTE BIO-LP-GGT BIO-LP-GENT 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
FI-EDTA Plasma	Glucose Lactate Ammonia	BIO-LP-GLU BIO-LP-LACT BIO-LP-NH3
Serum/heparinised plasma	Therapeutic Drugs: Carbamazepine Digoxin Ethanol Phenytoin Phenobarbitone Theophylline Tobramycin Vancomycin	BIO-LP-CMZ BIO-LP-Digoxin BIO-LP-ETOH BIO-LP-PNT BIO-LP-PNO BIO-LP-Theophylline BIO-LP-TOB BIO-LP-VANC



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> <u>Clinical Biochemistry (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant
Urine	Calcium Creatinine Magnesium Microalbumin Phosphate Urea Uric Acid Total protein Urine Protein CSF Protein	Roche Cobas 701 module - multi assay BIO-LP-CAL BIO-LP-CRT BIO-LP-MAG BIO-LP-ALBU BIO-LP-IPH BIO-LP-UREA BIO-LP-UIC BIO-LP-PRTU BIO-LP-TPUC BIO-LP-CSFprot
CSF		Roche Cobas 701 IonSelective Electrode Unit
Serum/heparinised plasma, urine	Electrolytes: Sodium Potassium Chloride	BIO-LP-Cobas8000 BIO-LP-ISE BIO-LP-ISE BIO-LP-ISE
		Roche Cobas 502 module - multi assay photometry unit BIO-LP-Cobas8000
Serum/heparinised plasma	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 Serum Free Light Chains Vancomycin	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 BIO-LP-SFLC BIO-LP-VANC



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CSF Urine	Protein Oxalate	Roche Cobas 502 module - multi assay photometry unit BIO-LP-Cobas8000 BIO-LP-CSFprot BIO-LP-OXALU
Serum/heparinised plasma	A-TPO B12 Folate Ferritin Free T3 Free Thyroxine NT Pro BNP Testosterone Troponin T TSH AFP BHCg CA 125 CEA Cortisol FSH Folate LH Progesterone TPSA CA 19.9 C-Peptide HGH Oestradiol Prolactin Trop T 250H Vitmain D	Roche e602 immunoassay module Electrochemiluminescence for sandwich and competitive immunoassays BIO-LP-TPO BIO-LP-B12 BIO-LP-FOL BIO-LP-FER BIO-LP-FT3 BIO-LP-FT4 BIO-LP-proBNP BIO-LP-TT 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-FOL 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-TROP BIO-LP-VITD
FI-EDTA Plasma	PTH	BIO-LP-PTH
Whole Blood (EDTA)	Immunosuppressant analysis: Tacrolimus Cyclosporin	BIO-LP-TAC BIO-LP-CYC



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> <u>Clinical Biochemistry (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant
Urine (acidified with glacial acetic acid)	Metanephrines and normetanephrine	Recipe kit using Waters Alliance HPLC system BIO-LP-Alliance BIO-LP-MET
Urine (acidified with glacial acetic acid)	5-hydroxyindoleacetic acid (5-HIAA)	Chromosystems kit using Waters Alliance HPLC system BIO-LP-HIAA
Whole Blood: EDTA	Haemoglobin A1c	Tosoh G8 HPLC BIO-LP-HbA1c
Serum	Detection and quantification of paraproteins	Capillary Zone Electrophoresis (Sebia Capillarys) Electrophoresis and Immunofixation BIO-LP-SERUMEPS/BIO-LP-SERUMIF
Urine	Detection and quantification of Bence Jones Protein	Sebia Phoresis system Electrophoresis and Immunofixation BIO-LP-UrineEPS/BIO-LP-UrineIF
Serum	Cryoglobulin	BIO-LP-CRYO
Serum and Urine	Osmolality	Vitech Advanced 3320 Osmometer BIO-LP-Osmometer
Faeces	Occult Blood	Beckman Coulter Haemoccult (Colorimetric utilising guaiac) BIO-LP-Faecal occult blood
Urine	Detection of hCG (Pregnancy Test)	Invitech kit (thin-layer chromatography dual antibody immunoassay) BIO-LP-Pregnancy Tests
Arterial whole blood (heparinised)	Blood Gas: pH pCO ₂ pO ₂ Standard Bicarbonate Base Excess Carboxyhaemoglobin Methaemoglobin	Cobas b221 Blood Gas Analyser pH glass electrode Severinghouse type electrode Clark-Electrode Calculated parameter Calculated parameter Spectrophotometry Spectrophotometry BIO-LP-BGA



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CSF	<u>Clinical Biochemistry (cont'd)</u> Haem Pigments	Lambda 35 Spectrophotometer BIO-LP-LAMBDA 35 BIO-LP-CSFHP
Serum	<u>Immunology</u> Specific IgE testing Total IgE testing Mast Cell Tryptase testing Specific IgG testing Anti-Cardiolipin antibodies B2GP1 antibodies CCP antibodies dsDNA antibodies ENA profile antibodies ENA Screen GBM antibodies MPO/PR3 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-DNA IMM-LP-EIA-ENAP IMM-LP-EIA-ENAS IMM-LP-EIA-GBM IMM-LP-EIA-EANCA IMM-LP-EIA-TTG IMM-LP-EIA-TTG IMM-LP-EIA-CALPRO
Serum	ANA Screen GAD Antibodies Intrinsic factor antibodies TSH Receptor antibodies Interferon-gamma released from T cells (Latent TB testing)	Dynex DS2 ELISA Automated Platform using IMM-LP-EIA-DS2 And kits as stated: Werfen Bioflash CIA IMM-LP-CIA-CTD Euroimmun kit - IMM-LP-EIA-GAD Euroimmun kit - IMM-LP-EIA-IFS RSR kit - IMM-LP-TRAB Qiagen QFT kit - IMM-LP-EIA-QTFG



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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>Immunology (cont'd)</u>	
Serum	ANCA Liver autoantibodies Pernicious anaemia antibodies Pancreatic islet cell antibodies Paraneoplastic antibodies Skin antibodies Endomysial antibodies ANA antibodies (HEp-2) dsDNA antibodies (Crithidia)	Indirect Immunofluorescence, Werfen Quantalyser 2 Indirect Immunofluorescence automated platform IMM-LP-IIF-Quantalyser2 IMM-LP-IIF-ANCA IMM-LP-IIF-LAB/PAB IMM-LP-IIF-TissueAAB
Serum	Liver Antibodies	Immunoblot IMM-LP-EIA-Liver Lineblot
Serum	Paraneoplastic antibodies	Immunoblot IMM-LP-EIA-PNP Lineblot
HUMAN BODY FLUIDS AND TISSUES	<u>Haematology</u>	
Whole Blood: EDTA	Full Blood Count	Sysmex XE-5000 by photometry/ fluorescence/impedance HAE-LP HAE 259, HAE-LP HAE 262
Whole Blood: EDTA	ESR	Sysmex Interrliner and Autocompact and Microvette CB200. Westergren method HAE-LP HAE 263, HAE-LP HAE 271
Whole Blood: EDTA	Reticulocytes	Sysmex XE-5000 fluorescence HAE-LP HAE 259
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 500 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>	
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	HAE-LP HAE 024
Plasma: EDTA	Infectious Mononucleosis screen (qualitative) – detection of Epstein-Barr Virus (EBV) antibodies	Horse Cells and Accusay Mono-antibody capture HAE-LP HAE 222, HAE-LP HAE 223
Whole Blood: EDTA	Blood Film	Sysmex SP1000i and Romanowski Staining and microscopy HAE-LP HAE 261, HAE-LP HAE 211, HAE-LP-HAE 237, HAE-LP-HAE 212



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	<u>Haematology (cont'd)</u>	
Bone marrow: EDTA	Bone Marrow film; Quantification and morphology of Marrow cells	Sysmex SP1000i and Romanowsky Staining and microscopy HAE-LP HAE 238
Whole Blood: EDTA	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
Serum	Haptoglobin	Siemens NOR-Haptoglobin Plates - Radial Immuno Diffusion (RID) technique HAE-LP HAE 273
Whole blood: EDTA	Detection of HbS (Sickle Solubility Screen)	Microgen Bioproducts S-Test Kit HAE-LP HAE 355
	<u>Haematology Molecular Markers</u>	
Whole blood: EDTA	V Leiden/Prothrombin	Dx System – Gene Xpert - DNA extraction, PCR HAE-LP HAE 510, HAE-LP HAE 517
Whole blood: EDTA	<u>Haematology Leucocyte Subtyping</u>	
Whole blood: EDTA	Leukaemia immunophenotyping - % positivity of gated cells of interest	Beckman Coulter Navios Flow cytometer Immunophenotyping – fluorescence detection HAE-LP HAE 308 (Acute Leukaemia Panel) HAE-LP HAE 309 (Chronic Leukaemia Panel)
Whole blood: EDTA	T and B cell subsets for HIV monitoring	HAE-LP HAE 305, HAE-LP HAE 311
Whole blood: EDTA	HLA-B27	Beckman Coulter Navios Flow cytometer DuraClone B27 HAE-LP-HAE 364



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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"> • 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-Jka anti-Jkb • Duffy blood group antibodies:anti-Fya anti-Fyb • Lutheran blood group antibodies: anti-Lua • MNS blood group antibodies:anti-M, anti-N, anti-S, anti-s, • Lewis blood group antibodies:anti-Lea anti-Leb • P blood group antibodies: anti-P1 	Ortho Innova 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 017 Manual Acid elution TRA-LP 017
		Manual Column Agglutination in Bio-Vue cards TRA-LP 052, TRA-LP080



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	<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 Innova and manual column agglutination TRA-LP 050, TRA-LP052
	<u>Serology/Virology</u>	
Serum	Rubella IgG Hepatitis BsAg HIV Ag-Ab Testing Syphilis testing Hepatitis C Ab Epstein-Barr Virus (IgM, IgG, EBNA) Hepatitis BcAg Anti-HBc Hepatitis Be Ag Anti-HBe CMV IgM Hepatitis A IgM	Abbott Architect analyser Measurement principle CMIA V051
Serum	Rubella IgG, IgM Varicella zoster IgG Hepatitis BsAg Anti- HBs Hepatitis C Ab Toxoplasma IgG	Biomerieux VIDAS Measurement principle CMIA V045
Serum	Syphilis RPR	RPR charcoal agglutination V034
Serum	Syphilis TPPA	TPPA – haemagglutination in microtitre plate V034
Serum	Rheumatoid factor	RF latex agglutination V045
Serum	Anti-streptolysin-OASD	ASO Biomerieux ASD kit (based on antibody inhibition of streptodornase B on DNA substrate. Detected by colour change) V019



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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>Molecular microbiology/virology</u>	
Swabs (Cervical/urethral/rectal/urine)	Chlamydia trachomatis plasmid DNA/Neisseria gonorrhoeae genomic DNA	Abbott m2000 system - PCR M002
Swabs/urine	Neisseria gonorrhoeae DNA(confirmation)	Instrumentation lab Cepheid SmartCycler - PCR M005
Virology swabs (any anatomical site, in viral transport media) CSF	Herpes simplex 1 and 2 (HSV) DNA; Varicella Zoster DNA (VZV); Enterovirus RNA	Instrumentation lab Cepheid SmartCycler - PCR M005
Nose swabs	MRSA DNA screening	Cepheid GeneXpert PCR M001, M002
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	Cepheid SmartCycler and GeneXpert PCR M001, M005, M007
Plasma: EDTA	Hepatitis C viral load testing	Abbott m2000 system – PCR M002, M011



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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
Swabs Sterile Fluids Drains Tissue Faeces Line/catheter tips Spinal fluid Sputum/respiratory	<u>Bacteriology</u> Isolation and Identification of pathogens and antibiotic sensitivity testing	Microscopy & culture B015 (Routine), B012 (Faeces), B014 (Respiratory) Sensitivity by disc diffusion (EUCAST standards) B015 B028 Sensitivity by break point strips (E-Tests, MICE) B011 (Blood cultures) 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
Whole Blood in blood culture bottles	Detection of micro organisms of pathogenic significance	Biomerieux BacT/ALERT 3d Signature: 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 <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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Urine	<u>Bacteriology (cont'd)</u> Detection of Schistosoma haematobium ova	Microscopy following urine concentration method B012 – Faeces bench
Nail Hair Skin	<u>Mycology</u> Isolation and identification of pathogenic fungi	Fluorescent microscopy, wet-film microscopy, plate culture SOP: B013
Cervical cells (LBC sample)	<u>Cytopathology</u> Cervical cytology examination to identify pre-cancerous and cancerous cell morphology changes/abnormalities and infection HPV testing – detection of 14 subtypes (HPV 16, 18 and 12 grouped subtypes)	Slide preparation and staining with Hologic – autoloader T5000. CP-C-029 Microscopy CP-C-002, CP-C-007, CP-MPC-006 Abbott – real time HPV PCR instrument CP-C-032
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-016 Thermo cytospin CP-N-014 Thermo staining machine – Papanicolau stain only CP-C-012 Diff-Quick staining CP-N-009 MGG staining CP-N-018 Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-C-002



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human tissue samples/ organs, cell blocks</p>	<p><u>Examination activities for the purpose of clinical diagnosis</u></p> <p><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>Special staining for identification of:</p> <p>Acid mucins</p> <p>Glycogen, Neutral and Acid Mucins</p> <p>Neutral and Acid Mucins</p> <p>Amyloid</p> <p>Helicobacter pylori</p> <p>Gram +ve&-ve bacteria</p> <p>Fungi</p> <p>Fungi</p> <p>Nuclei</p> <p>Collagen</p> <p>Melanin and argentaffin granules</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</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&E staining: Sakura Prisma staining machine and film coverslipper CP-H-314</p> <p>Manual staining</p> <p>Alcian Blue CP-H-500</p> <p>Alcian Blue/ Periodic Acid Schiffs CP-H-502</p> <p>Alcian Blue/ Periodic Acid Schiffs with Diastase CP-H-502</p> <p>Stoke's Congo Red CP-H-506</p> <p>Modified Giemsa for H. pylori CP-H-515</p> <p>Gram CP-H-516</p> <p>Grocott CP-H-519</p> <p>Rapid Grocott CP-H-320</p> <p>Haematoxylin counterstain CP-H-525</p> <p>Haematoxylin picro-ponceau (Curtis) CP-H-526</p> <p>Masson Hamperl CP-H-530</p>



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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)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
	<u>Histopathology (cont'd)</u>	
	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-537
	Fungi and Neutral Mucins	Periodic Acid Schiff with Diastase CP-H-538
	Ferric Iron	Perl's Prussian Blue CP-H-539
	Reticulin Fibres	Reticulin CP-H-542
	Insoluble Calcium Salts	Von Kossa CP-H-544
	Mycobacterium leprae	Wade Fite CP-H-545
	Mycobacterium tuberculosis	Ziehl Neelsen CP-H-547
Human tissue samples/ organs, cell blocks (cont'd)	Immunohistochemistry for identification of:	Immunohistochemistry:
	Normal/neoplastic tissue epithelial in origin	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:
	Non-neoplastic, neoplastic liver disease, yolk sac and mixed germ tumours	AE1/3
	Prostate adenocarcinoma	AFP
	Follicular lymphomas and various diffuse lymphoproliferative diseases	AMACR
	Adenocarcinoma vs malignant mesothelioma	Bcl-2
	Differential diagnosis of fibromatosis lesions and spindle cell lesions of breast	BerEP4
		Beta-Catenin



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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
Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology (cont'd)</u> Immunohistochemistry for identification of:	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:
	Differential diagnosis of adenocarcinomas	Ca125
	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
	B-cells, some T-cells	CD23
	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)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology (cont'd)</u> Immunohistochemistry for identification of:	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:
	Plasma cells, Multiple myeloma	CD138
	GI origin of metastatic adenocarcinomas	CDX2
	Surface of GI cells, colon carcinomas	CEA (mono) CEA (poly)
	Secretory granules of endocrine cells	CHROMOGRANIN
	Squamous epithelium and Neoplasms of type	CK5/6
	Glandular and transitional epithelia and neoplasia of type	CK7
	Differentiating squamous cell carcinomas versus other epithelial tumours	CK14
	Normal GI epithelia and urothelium and neoplasia of type	CK20
	Mantle cell lymphomas	Cyclin D1
	Rhabdomyosarcomas, Leiomyomas, Mesotheliomas	Desmin
	Ductal breast carcinomas	E-cadherin
	Normal and neoplastic neoplasia	EMA
	Breast and Urothelial carcinomas	GATA3



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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>Breast carcinoma and metastatic tumours</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>Primary lung adenocarcinomas</p> <p>Prostate carcinomas versus Urothelial carcinomas</p> <p>Normal and neoplastic cells of neuronal and neuro-endocrine origin</p> <p>OCHIE5 (HepPar1)</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>GCDFP-15</p> <p>HCG</p> <p>HEME-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> <p>Napsin A</p> <p>NKX3.1</p> <p>NSE</p> <p>Mitochondrial antigen of hepatocytes</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
Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology (cont'd)</u> Immunohistochemistry for identification of:	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:
	Basal epithelial cells	p63
	Renal cell carcinoma marker	PN15 (RCC)
	Differential diagnosis in lung and neck tumours	PAX8
	Neuroendocrine tumours	PGP
	Seminomas, germ cell tumours	PLAP
	MMR proteins in HNPCC	PMS2
	Normal and neoplastic prostate epithelia	PSA
	Malignant melanoma, chondroblastoma, Schwannoma	S100
	Smooth muscle cells, myoepithelial cells, Leiomyosarcomas	SMA
	Smooth muscle cells, myoepithelial cells	SMMS
	Neuroendocrine cells and neoplasms	Synaptophysin
	Pre-cursor B- and T-cell ALL and thymomas	TdT
	Thyroid carcinomas	Thyroglobulin



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> <u>Histopathology (cont'd)</u> Immunohistochemistry for identification of: Normal and neoplastic lung and thyroid cells Primary cells of mesenchymal origin in normal and neoplastic cells Wilms tumour, Malignant mesotheliomas	In house documented methods incorporating manufacturers' instructions where relevant Immunohistochemistry: Roche Ventana Benchmark CP-H-700, CP-H-701, CP-H-707, CTM6 CP-C-036 TTF-1 Vimentin WT-1
Human tissue samples/ organs, cell blocks (cont'd)	Expression of ER containing cells, eg. Normal and neoplastic breast cells Expression of progesterone cells in breast tissue Detection of Her-2 antigen Determination of Her2 gene status Reading and interpretation of slides from processed tissue and fluids	ER PR Her2 DDISH Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001
END		