Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Luton and Dunstable University Hospital Lewsey Road Luton Bedfordshire LU4 0DZ	As above	Histopathology Non-gynae Cytology Clinical Biochemistry Haematology Blood Transfusion inc management of blood fridge Immunology Management of Point of Care Testing	A
Bedford Hospital Kempston Road Bedford Bedfordshire MK42 9DJ	As Above	Microbiology Histopathology Clinical Biochemistry Haematology Blood Transfusion inc management of blood fridge Immunology Management of Point of Care Testing	В





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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	Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Swabs from eyes, wounds, nose, throat, ears, genital sites, respiratory fluids (sputum, bronchial washings)	General isolation and characterisation of micro- organisms of clinical significance	Manual inoculation of selected culture media using in-house procedures: MMSOP 0024: Investigation of ear swabs and associated specimens MMSOP 0025: Investigation of bacterial eye infections MMSOP 0026: Investigation of sterile fluids MMSOP 0027: Investigation of abscesses, post-operative and deep-seated wounds MMSOP 0029: Investigation of mouth swabs MMSOP 0030: Investigation of throat related specimens MMSOP 0031: Investigation of bone, tissue and biopsy samples MMSOP 0036: Investigation of nasal samples MMSOP 0069: Investigation of skin and wound swabs MMSOP 0110: Investigation of genital samples MMSOP 0123: Culture for N. gonorrhoeae MMSOP 0149: Investigation of orthopaedic implant associated infections MMSOP 0005: MaldiTof (Vitek)	B

DETAIL OF ACCREDITATION



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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Urine	General isolation and characterisation of micro- organisms of clinical significance and antimicrobial susceptibility testing	Investigations of urine MMSOP 0015 in conjunction with manufacturer's instructions using Mast Urisystem MMSOP 014: Urine MC&S, MMSOP 0102: Menarini SediMax Automated Microscopy	В
Fluids from CSF, ascitic and peritoneal fluids	Quantification of white and red blood cells and bacteria	Manual microscopy in conjunction with MMSOP 0064 Investigation of cerebro-spinal fluids, MMSOP 0026 Fluids from sterile sites MSOP 0145: Investigation of ascitic and peritoneal fluid	В
Swabs from nose, perineum and wound sites	Isolation of MRSA	Manual inoculation of chromogenic agar using MMSOP 0105: Investigation of MRSA	В
		Realtime PCR using: MMSOP 0038, Cepheid MRSA NxG assay and Cepheid GeneXpert	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Urine	Detection of: <i>Legionella pneumophilia</i> serotype 1 antigen <i>Streptococcus pneumonia</i> soluble antigen	Membrane immunochromatographic assay using: MMSOP 0103: Antigen testing for Legionella pneumophilia and Streptococcus pneumoniae and Alere Reader	В
Faeces	Detection and isolation of bacterial enteric pathogens: <i>Clostridium difficile, E. coli</i> , Salmonella sp., Shigella spp.	Enteric PCR using the BD MAX followed by manual inoculation of selected culture media using in-house procedure MMSOP 0128	В
Faeces	Detection of <i>Clostridium</i> <i>difficile</i> GDH antigen and toxins A & B	Realtime PCR using: MMSOP 0038, Cepheid Xpert C. difficile assay and: Cepheid GeneXpert	В
		Rapid membrane ELISA using: MMSOP 0012 and TechLab C. DIFF QUIK CHEK COMPLETE	В
Faeces	Detection of <i>Helicobacter pylori</i> antigen	Automated sandwich enzyme immunoassay using in-house procedure: MMSOP 0109In conjunction with manufacturer's instructions using Dynex DS2 and Premier Platinum HpSA Plus	В
Faeces	Detection of Carbapenemase (differentiation of the <i>bla</i> KPC, <i>bla</i> NDM, <i>bla</i> VIM, <i>bla</i> OXA-48, and <i>bla</i> IMP-1 gene sequences)	Realtime PCR using: MMSOP 0085, MMSOP 0038, Cepheid Xpert Carba R assay and: Cepheid GeneXpert	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Blood	Isolation of clinically significant bacteria and fungi	Automated culture using: Biomerieux Virtuo and MMSOP 0065	В
Respiratory samples Early morning urine (EMU Gastric aspirates Fluids Tissues Pus Fine needle aspirates (FNA) Cerebrospinal fluid (CSF) Faeces	Detection of Mycobacterium tuberculosis (DNA Rifampicin- resistance genes)	Manual culture using LJ Media and/or Automated liquid culture using: Biomerieux BacTec MGIT 960 Microbial Detection System and procedures MMSOP 0028 and MMSOP 0111followed by auramine phenol staining and fluorescence microscopy MMSOP 0113 Realtime PCR using: MMSOP 0038, Cepheid Xpert MTB/RIF Assay and: Cepheid GeneXpert	В
Bacterial culture isolates produced by the laboratory	Antimicrobial susceptibility testing	Automated and/or manual methods and EUCAST Guidelines using: photometry using Beckman Coulter Microscan Walkaway Plus using documented in-house procedure MMSOP 0035 Manual disc diffusion using documented in-house procedure MMSOP 0042 Biomerieux Biofire	В
Nose swabs, throat swabs, nose and throat swabs	Detection of respiratory pathogens	BIOFIRE® Respiratory 2.1 (RP2.1) Panel	Б
CSF	Detection of community- acquire meningitis and encephalitis	Meningitis/Encephalitis (ME) Panel	



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HUMAN TISSUES AND FLUIDS (cont'd)	Parasitological examination activities for the purpose of clinical diagnosis	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Faeces	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance)	Apacor Parasep Faecal Parasite Concentrators and manual microscopy MMSOP 0043 and MMSOP 0113	В
Faeces	Examination for the presence of <i>Cryptosporidium</i> Oocysts	Auramine phenol staining and fluorescence microscopy using MMSOP 0113	В
Clear tape slide Perianal swab	Detection of <i>Enterobius vermicularis</i> larvae and ova	Microscopic examination using in- house procedure: MMSOP 0043	В
Urine	Detection of Schistosoma haematobium ova	Microscopic examination using in- house procedure: MMSOP 0043	В
Bile Duodenal aspirates Jejunal aspirates	Detection of OCP including: Strongyloides stercoralis larvae, Giardia lamblia trophozoites Cryptosporidium oocysts Cyclospora cayetanesis oocysts Cystoisospora belli oocysts	Auramine phenol staining and incident-light fluorescence, Ziehl- Neelsen, iodine staining as appropriate and microscopic examination using in-house procedure: MMSOP 0043	В
Female genital tract swabs	Detection of <i>Trichomonas vaginalis</i> ova	Culture and microscopic examination using in-house procedure: MMSOP 0110: Investigation of genital specimens	В
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopic examination against Hay's criteria using in-house procedure: MMSOP 0110: Investigation of genital specimens	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Serum	Toxoplasma Total Antibody	MMSOP 0074 Serological tests using the Biomerieux Vidas 30(immunoassay)	В
	Measles IgG	MMSOP 0074 Serological tests using the Biomerieux Vidas 30(immunoassay)	В
	Varicella zoster IgG	MMSOP 0074 Serological tests using the Biomerieux Vidas 30(immunoassay)	В
Serum	Hepatitis E IgM and IgG	Fortress Diagnostics ELISA in conjunction with manufacturer's instructions and procedure MMSOP 0058 Hep E IgG & IgM Test	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Serum	Antistreptolysin-O	Latex agglutination using Biokit - Rheumajet ASO kit in conjunction with manufacturer's instructions and procedure MMSOP0053 Rheumajet ASO latex agglutination test	В
	Detection of:	Roche Cobas 8000 e602 Elecsys Sandwich assay	
Serum	HIV antigen	MMSOP 0095	В
Serum	Hepatitis B antibody (immunity)	MMSOP 0873 Hepatitis B serology	В
Serum	Hepatitis B core total antibody (HBcT)	MMSOP 0873 Hepatitis B serology	В
Serum	Hepatitis C /Antibody	MMSOP 0872 Hepatitis C serology	В
		Documented-in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening programme as defined in the laboratory QA evidence requirements (targets marked *)	
Serum	HBsAg* HIV-1&2 Antibody & HIV-1 p24 Antigen* Syphilis IgG/IgM*	Roche Cobas 8000 e602 Elecsys Sandwich assay MMSOP 0873 Hepatitis B serology MMSOP 0846 HIV serology MMSOP 0874 Syphilis serology	В



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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	Haematological examination activities for the purpose of clinical diagnosis	Using manufacturer's instructions and documented in-house procedures	
	Full Blood Count:		A and B
EDTA whole blood	Haemoglobin Red blood cell count MCH MCHC MCV RDW Platelet count White blood cell count Neutrophil count Lymphocyte count Eosinophil count Basophil count Nucleated RBC Automated Reticulocyte Count	Beckman Coulter DxH900 Full Blood Count Analyser using flow cytometry, impedance and spectrophotometry, laser light scatter, calculated Parameters with specific reference to procedure HSOP 0005	
Citrated Plasma	Coagulation Screen: Prothrombin time INR Prothrombin time correction with normal plasma APTT APTT correction with normal Plasma Fibrinogen D Dimer Thrombin time Low molecular weight heparin	Werfen TOP550 and TOP 350 Coagulometric Chromogenic and Immunological: based on procedures: HSOP0104 Routine Coagulation on the ACL TOP 550 and TOP 350 analysers	A and B
EDTA whole blood	Erythrocyte Sedimentation Rate (ESR)	Menarini Vesmatic Cube 30 Red cell sedimentation measurement based on modified Westergren Sedimentation Method: HSOP0300 Operating the Vesmatic Cube 30	A and B



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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)	<u>Haematological examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	Using manufacturer's instructions and documented in-house procedures	
EDTA whole blood	Haemoglobinopathy Screening:	Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme, as defined in laboratory QA evidence requirements	A
	HbA2, HbF, HbA, HbS, HbC, HbD, HbE	HSOP0002 Sebia Capillarys OCTA3 for haemoglobinopathy and thalassaemia screening	
EDTA whole blood	Sickle Cell Test	HSOP 0506 Sickle Cell Solubility Test using STRECK Sickledex Solubility Screen Kit	В
Citrated Plasma	Thrombophilia Screening: Anti-thrombin 3 activity Protein C activity Free Protein S level Lupus Anticoagulant Assay Clotting Factor Assays: Factor II Assay Factor V Assay Factor VII Assay Factor VIII Assay Factor VIII Chromogenic Assay Factor IX Assay Factor IX Assay Factor IX Assay Factor XII Assay Factor XII Assay	Werfen TOP550 Coagulometric Chromogenic and Immunological: based on procedures HSOP0105 Special Coagulation on the ACL TOP550	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	Using manufacturer's instructions and documented in-house procedures	
EDTA whole blood	Glucose 6 Phosphate Dehydrogenase (G6PD) screen	Trinity Biotech G-6-PDH screening test kit using red cell enzyme rate reaction based on procedures:	A
		HSOP0505 G6PD Fluorescent Spot Test	
Serum or EDTA plasma	Infectious Mononucleosis Screen	Lateral flow immunoassay for the detection of IM heterophile antibodies, based on procedures:	В
		HSOP 0511 Clearview IM II kit for infectious mononucleosis (glandular fever) screening	
Bone Marrow aspirate or EDTA whole blood	Film examination and reporting of normal and abnormal morphologies. Manual white cell differential	Manual Romanowsky stain, Automated staining and Microscopy:	A and B
		Aerospray Pro 7152 slide stainer HSOP 0500	А
		Beckman Coulter SMS II Slide maker and stainer using May Grunwald/Giemsa stain HSOP 0006.	A and B
		Preparation and Examination of Blood and Bone Marrow Film HSOP 0500	A and B
		Manual microscopy and reporting of blood films HSOP 0500	A and B



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HUMAN BODY FLUIDS (cont'd)	Haematological examination activities for the purpose of clinical diagnosis (cont'd)	Using manufacturer's instructions and documented in-house procedures	
EDTA whole blood	Screening for the detection of: <i>Plasmodium falciparum</i> and Plasmodium spp. Including: <i>Plasmodium ovale</i> <i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium vivax</i>	CareStart Malaria Antigen Test Rapid diagnostic test HSOP 0502	A and B
	Detection and Identification of: Plasmodium species: Plasmodium falciparum Plasmodium vivax Plasmodium ovale Plasmodium malariae Plasmodium knowlesi	Manual microscopy of thick films stained with Field's stain and thin films stained with Romanowsky stain based on procedures: Malaria Diagnosis HSOP0502,	A and B



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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis	Using manufacturer's instructions and documented in-house procedures	
Whole blood	Foetal Maternal Haemorrhage (semi quantitative)	Manual Kleihauer using Foetal Red Cell Detection Kit (FCD), supplied by Guest Medical	A and B
EDTA whole blood	Blood grouping: ABO and RhD typing by detection & identification of the following antigens: A RhD Positive AB Rh D Positive B RhD Positive O RhD Positive A RhD Negative B RhD Negative B RhD Negative O RhD Negative O RhD Negative	Automated using Grifols Eflexis Analysers and Manual Grifols Technique using Column Agglutination Technology SOP BTSOP 0002	A and B
EDTA plasma	Detection and identification of the following antibodies Rh: C, D, E, c,e Cw Kell: K, k, Kpa Duffy: Fya, Fyb MNSs: M, N, S, s Kidd: Jka, Jkb Lewis: Lea, Leb Lutheran: Lua, Lub P: P1	Automated using Grifols Eflexis Analysers and Manual Grifols Technique using Column Agglutination Technology SOP BTSOP 0002 SOP BTSOP 0015	A and B
EDTA whole blood	Red cell phenotyping: Rh: C, D, E, c,e Kell: K Duffy: Fya, Fyb MNSs: N, S, s Kidd: Jka, Jkb ABO: A1	Automated using Grifols Eflexis Analysers and Manual Grifols Technique using Column Agglutination Technology SOP BTSOP 0016 Manual tube / LISS IAT (Luton only) SOP BTSOP 0016	A and B



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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis	Using manufacturer's instructions and documented in-house procedures	
EDTA whole blood	Direct Antiglobulin Test (DAT)	Automated using Grifols Eflexis Analysers and Manual Grifols Technique using Column Agglutination Technology SOP BTSOP 0018	A and B
EDTA Plasma	Crossmatch (compatibility testing):		
	Serological IAT Crossmatch	Automated using Grifols Eflexis Analysers and Manual Grifols Technology SOP BTSOP 0001 SOP BTWI 0001A	A and B
	Serological IAT Crossmatch	LISS IAT Tube Technology SOP BTSOP 0001	А
	Electronic Issue	BTSOP 0001	A and B
	Issue of Group specific Red Cells	BTSOP 0001	A



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HUMAN TISSUES AND FLUIDS (cont'd)	Diagnostic cytology examination activities for the purpose of clinical diagnosis	Using manufacturer's instructions and documented in-house procedures	
Body fluids: Serous and general body fluids Urine Bronchial Specimens Sputa Cerebrospinal Fluid (CSF) Brushings Fine Needle Aspirations (FNA) Endo-bronchial ultrasound (EBUS)	Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	Sample preparation using the Thermo Shandon Cytospin 4 CPSOP 0301 CPWI 0301 D-K	A
Cerebrospinal Fluid (CSF)	Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	Sample preparation using the Thermo Shandon Cytospin 4 CPSOP 0301 CPWI 0301 D-K	В
Urine	Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	Sample preparation using the Hologic T2000 processor CPSOP 0310	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Diagnostic cytology examination activities for the purpose of clinical diagnosis	Using manufacturer's instructions and documented in-house procedures	
Slides prepared in-house from sample types listed above		Automated staining using Leica ST5020 Staining Machines & Manual Coverslipper and in-house procedures listed above and: CPWI 0061A, CPWI 005 CPWI0052	
		Haematoxylin & Eosin May Grunwald Giemsa	A A
		Papanicolau Staining	A and B
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: Reporting Results in Cellular Pathology CPSOP 003	A



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues	Preparation and examination to identify or exclude morphological & cytological abnormalities	Macroanalysis and dissection Manual method using: CPWI 0430 CPWI 0402 Protocols for Gastrointestinal Tract CPWI 0403 Protocols and Dataset for Colorectal Cancer CPWI 0407 Surgical Histology Cut- Up - Breast Pathology CPWI 0405 Breast Screening Generated Core Biopsies and Aspiration Cytology Samples CPWI0405Protocols and Dataset for Histological Reporting of Cervical Neoplasia CPWI 0411 Protocol for Endometrial Biopsies and Hysterectomy Specimens including Endometrial Cancer CPWI 0412 Protocols and Dataset for Gastric Carcinoma CPWI 0413 Specimens from Head and Neck Region CPWI 0413 Instruction for examination of liver biopsies CPWI 0414Protocols and Dataset for Oesophageal Carcinoma CPWI 0415 Protocol and Dataset for the Histopathological reporting of Ovarian Tumours, and Fallopian Tube and Primary Peritoneal Carcinomas CPWI 0416 Protocol for POC and Placenta	A and B



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues	Preparation and examination to identify or exclude morphological & cytological abnormalities	Macroanalysis and dissection (cont'd) Manual method using:CPWI 0417 Protocols and Dataset for Prostate Cancer Histopathology Reports CPWI 0418 Protocol for Requesting Oestrogen and Progesterone Hormone Receptors on Invasive Breast Cancer Specimens CPWI 0419 Laryngeal, Bronchial and Other Respiratory Tract Biopsies including Pleura CPWI 0420 Handling Sentinel Lymph Node Biopsies from Patients with Carcinoma of the Breast CPWI 0421Protocol and Dataset for Skin Biopsy Specimens CPWI 0422 Specimen Macroscopy: Appendix CPWI 0425 Protocol for Soft Tissue "Tumours" CPWI 0426 Protocols and Dataset for Histopathology Reports for Testicular Tumours CPWI 0427 Protocol and Dataset for Tumours of the Urinary Collecting System CPWI 0427 Protocol and Dataset for Histological Reporting of Vulval Neoplasms CPWI 0008 Instructions for Handling Muscle Biopsies BED-SOP 361 BED-SOP 347 BED-SOP 626	A and B



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Decalcification Manual method using: CPWI 0045 BED-SOP-361	A and B
Formalin fixed tissues		<u>Tissue Processing</u> Automated method using: Leica ASP300s Tissue Processors and SOP Operation of the Leica Tissue Processors (A,B) Sakura VIP 6 (B) BED-SOP-356	A and B
		Embedding Manual method using: Leica HistoCore Arcadia H Embedding Centres/ HistoCore Arcadia C Cold Plate - SOP Embedding Histology Blocks CPWI 0002 Sakura Tissue Tek	А
		BED-SOP-349	В
Formalin fixed paraffin embedded (FFPE) tissue		<u>Microtomy</u> Manual method using: Leica RM 2235 Rotary microtomes - SOP Sectioning Histology Blocks CPWI 0057 BED-SOP—351	A and B
		HistoCore BIOCUT microtome BED-SOP-251	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin & Eosin (H&E) staining and coverslipping, Automated method using:	
		Leica ST5020 Staining Machines CPWI 0061B & CV5030 Coverslipper - SOP Operation of the Staining Machine ST5020 CPWI 0061A, SOP Staining Haematoxylin & Eosin Slides CPWI 0052	A
		Leica XL ST5010 Stainer Leica CV5030 coverslipper BED-SOP-353 and 715	В
		Leica Spectra stainer CPSOP 0004	В
Fresh frozen tissue	Intra-operative diagnosis (Frozen section including rapid manual staining)	Leica CM 1860 cryostat Manual H&E stain CPWI 0003A.5	A
FFPE tissue	Detection of the following:	<u>Special staining</u> Manual methods using: BED-SOP-353 BED-SOP-715	
	Acid mucins (sulphomucins & sialomucins)	SOP Alcian Blue for Acid Mucosubstances CPWI 0002A	В
	Acid mucins (sulphomucins & sialomucins)	SOP Alcian Blue-PAS CPWI 0002B	В
	Acid mucins (sulphomucins & sialomucins) Neutral mucins Mixed mucins	SOP Alcian Blue-PAS with Diastase Digestion CPWI 0002C	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
		Manual special stains (cont'd)	
	Amyloid	SOP Congo Red Stain for Amyloid CPWI 0002D	В
	Collagen and muscle	SOP Miller's Elastic Van Gieson CPWI 0002F	В
	Helicobacter Pylori	SOP Giemsa (For Helicobacter Pylori) CPWI0002H	В
	Gram positive and gram- negative organisms	SOP Gram Stain CPWI 0002I	В
	Fungi	SOP Grocott Hexamine Silver Stain for Fungi CPWI 0002J	В
	Collagen and fibrosis	SOP Haematoxylin Van Gieson CPWI 0002L	В
	<i>Helicobacter pylori</i> & <i>Helicobacter</i> -like organisms	SOP Modified Giemsa for Helicobacter Pylori CPWI 0002N	В
	Hepatitis B antigen, elastic fibres and copper associated protein	SOP Orcein CPWI 0002O	В
	Glycogen and other tissues containing aldehydes	SOP Periodic Acid-Schiff (PAS) Stain CPWI 0002P	В
	Diastase Digestion PAS	SOP Diastase Digestion-PAS CPWI 0002E	В
	Haemosiderin & ferric salts	SOP Perl's Prussian Blue CPWI 0002 R	В
	Type IV collagen fibres (Reticulin)	SOP Gordon & Sweet Reticulin Stain CPWI0002Q	В
	Mycobacterium tuberculosis	SOP Ziehl Neelsen Stain CPWI 0002U	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following:	Immunohistochemistry Automated methods using Roche Ventana Benchmark and the following antibodies:	
		CPSOP0101 BED-SOP-624 BED-SOP-715	
	Hepatocellular carcinomas, yolk sac tumours	Alpha Fetoprotein (AFP)	В
	Muscle	Actin	В
	Epithelial marker	Alpha-Methylacyl-CoA-Racemase (AMACR)	В
	Detection of Cell adhesion marker	Beta Catenin	В
	T-cell lymphocytes	Bcl-2	В
	Broad reactivity with epithelial cells. Mesothelial negative	Epithelial Antigen (Ber-EP4)	В
	Expressed in normal endometrial glands, ovary and cervix. Expressed in ovarian carcinoma	CA125	В
	Medullary thyroid tumour marker	Calcitonin	В
	Labels tumours of smooth muscle, and myofibroblastic and myoepithelial differentiation	Caldesmon	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Useful in differentiating malignant mesothelioma from adenocarcinomas (in particular of the lung). Also used to differentiate adrenal cortical neoplasms from pheochromacytomas	Calretinin	В
	Liver: Malignant vs Benign, Pleura: Adenocarcinoma vs Mesothelioma, Carcinomas, HCC	Carcinoembryonic Antigen (CEA)	В
	Preferred marker for T-cells. A polyclonal pan T antibody, but occasional T-cell neoplasms	CD3	В
	Mantle cell lymphomas	CD5	В
	Expressed on cells of lymphoblastic, Burkitt's & Follicle centre cell lymphomas and on cells of patients with chronic myelocytic leukaemia (CML). But can also be expressed on normal cells, i.e. early lymphoid progenitor cells, immature B cells within adult BM & germinal centre B cells within lymphoid tissue. Also expressed in myoepithelial cells (breast), bile canaliculi, fibroblasts & brush border of kidney & gut epithelial cells	CD10	В



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HUMAN TISSUES AND FLUIDS (conťď)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>I</u> mmunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Neutrophils, dendritic reticulum cells and most glandular epithelium. Cells of the monocyte/macrophage lineage are negative, so too are non-Hodgkins lymphomas. Hodgkins and RS cells are strongly positive, but the lymphocyte predominant type occasionally negative	CD15	В
	Pan B-cell marker, also some Reed-Sternberg (RS) cells. Preferred marker for B-cells	CD20	В
	Anaplastic large cell lymphomas, mononuclear HD & RS cells. Will also demonstrate plasma cells. (Outside lymphoid tissue, Ber H2 labels pancreatic acinar cells and occasionally carcinomas derived from these cells)	CD30	В
	Endothelial Cells, Activated B and T Lymphocytes	CD 31	В
	Endothelial cells but also expressed on human lymphoid and myelopoetic progenitor cells. Useful to identify vascular tumours and characterise leukaemias	CD34	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	All lymphoid cells, variable reaction with macrophages, histiocytes, monocytes. Myeloid cells are unreactive	CD45 (Leucocyte Common Antigen)	В
	A cell adhesion molecule expressed by most neuroectodermal-derived tissues and their tumours. Also labels NK cells	CD56 (N-CAM)	В
	Macrophages, myeloid cells and histiocytes and their derived neoplasms	CD68	В
	B cell antigen receptor, found in the majority of acute leukaemias of precursor B cell type, in B cell lines, B cell lymphomas and in some myelomas. Is NOT present in myeloid or T cell lines	CD79alpha	В
	Expressed at late stages of B cell differentiation; by normal and malignant plasma cells and lymphoplasmocytoid cells. Also expressed by normal epithelial cells in some tissues	CD138	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Transcription factor expressed in nuclei of intestinal epithelial cells from duodenum to rectum. Useful marker for identifying primary and metastatic tumours of the GI tract	CDX2	В
	Endocrine cells, neuroendocrine cells and their derived tumours	Chromogranin A	В
	High molecular weight Cytokeratins 5 and 6. Expressed in epithelial cells: stratified, transitional, complex, mesothelial, and proliferating squamous epithelium. Useful for distinguishing between: SCC and adenocarcinoma, epithelioid mesothelioma and lung carcinoma when used together with a panel of antibodies	Cytokeratin 5/6 (CK5)	В
	Intermediate filament protein expressed in simple, complex, transitional, ductal and glandular epithelium. Useful in distinguishing metastatic breast and colonic adenocarcinomas	Cytokeratin 7 (CK7)	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Basal and myoepithelial cells of human complex epithelia	Cytokeratin 17 (CK17)	В
	G I tract epithelium	Cytokeratin 19 (CK19)	В
	Reacts with gastric and intestinal epithelium, urothelium and Merkel cells. Useful in distinguishing between GI tract and breast adenocarcinomas	Cytokeratin 20 (CK20)	В
	Epithelial differentiation, Small round blue cell tumours, Specific soft tissue tumour	Cytokeratin (AE1/AE3)	В
	Differential diagnosis: Carcinoma vs non- epithelial tumour	Cytokeratin (CAM5.2)	В
	Cytokeratins 1,5,10, and 14	Cytokeratin High MWt (34betaE12)	В
	Epithelial cells	Cytokeratin MNF 116	В
	Reacts with 53kD intermediate filament protein in muscle cells. Skeletal, cardiac (Z bands) and smooth muscle cells react as well as tumours of myogenic origin i.e. leiomyo & rhabdomyosarcomas	Desmin	В
	GIST, interstitial cells	DOG-1	В



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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) Histopathological examination activities for the purpose of clinical diagnosis (cont'd) Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant) Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant) B FFPE tissue (cont'd) Detection of the following: (cont'd) Immunohistochemistry using Roche Ventana Benchmark (cont'd) B Uymphatic endothelium, lymphatic metastases D240 B Transmembrane cell adhesion molecule in epithelial colls. Useful in identifying Iboliar breast carcinomas E-cadherin B Useful in classifying tumours of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell lymphomas and plasma cells ERG B Alids in identification of prostate adenocarcinomas. Factor 13A B Vilidype ERG and truncated ERG resulting from ERF gene rearrangement. Factor 13A B Apocrine epithelial i.e., glands. Specific marker for breast carcinomas GCDFP-15 B				
FLUIDS (cont'd) activities for the purpose of clinical diagnosis (cont'd) examination using in-house procedures (listed) in-doubles for the following methods (where relevant) FFPE tissue (cont'd) Detection of the following: (cont'd) Immunohistochemistry using Roche Ventana Benchmark (cont'd) B Lymphatic endothelium, lymphatic metastases D240 B Transmembrane cell adhesion molecule in epithelial cells. Useful in classifying tumours of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell lymphomas and plasma cells Epithelial Membrane Antigen (EMA) B Aids in identification of prostate adenocarcinomas. Heapatocellular carcinoma and urothelial carcinomas ERG B Identification of breast carcinomas and urothelial carcinomas and urothelial carcinomas GATA-3 B	Materials/Products tested	measured/Range of		
(cont'd)Roche Ventana Benchmark (cont'd)Lymphatic endothelium, lymphangiomas, Kaposi sarcoma. Useful for identifying lymphatic metastasesD240BTransmembrane cell adhesion molecule in epithelial cells. Useful in identifying lobular breast carcinomasE-cadherinBUseful in classifying tumours of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell lymphomes and plasma cellsEpithelial Membrane Antigen (EMA)BAids in identification of prostate adenocarcinomas.ERGBWildtype ERG and truncated ERG resulting from ERF gene rearrangement.Factor 13ABIdentification of breast carcinomas and urothelial carcinomas and urothelial carcinomas and urothelial carcinomasGCDFP-15B		activities for the purpose of clinical diagnosis	examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where	
lymphangiomas, Kaposi sarcoma. Useful for identifying lymphatic metastasesE-cadherinBTransmembrane cell adhesion molecule in epithelial cells. Useful in identifying lobular breast carcinomasE-cadherinBUseful in identifying lobular breast carcinomasE-itelial Membrane Antigen (EMA)BUseful in classifying tumours of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell lymphomas and plasma cellsEpithelial Membrane Antigen (EMA)BAids in identification of prostate adenocarcinomas.ERGBWildtype ERG and truncated ERG resulting from ERF gene rearrangement.Factor 13ABPositive in dermatofibroma, haemagioblastoma, hepatocellular carcinomasFactor 13ABIdentification of breast carcinomas and urothelial carcinomasGATA-3BApocrine epithelia i.e., glands. Specific marker for breastGCDFP-15B	FFPE tissue (cont'd)		Roche Ventana Benchmark	
molecule in epithelial cells. Useful in identifying lobular breast carcinomasEpithelial Membrane Antigen (EMA)BUseful in classifying tumours of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell lymphomas and plasma cellsEpithelial Membrane Antigen (EMA)BAids in identification of prostate adenocarcinomas.ERGBWildtype ERG and truncated ERG resulting from ERF gene rearrangement.Factor 13ABPositive in dermatofibroma, haemagioblastoma, hepatocellular carcinomasFactor 13ABIdentification of breast carcinomas and urothelial carcinomasGATA-3BApocrine epithelia i.e., glands. Specific marker for breast carcinomasGCDFP-15B		lymphangiomas, Kaposi sarcoma. Useful for identifying	D240	В
of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell 		molecule in epithelial cells. Useful in identifying lobular	E-cadherin	В
prostate adenocarcinomas.Wildtype ERG and truncated ERG resulting from ERF gene rearrangement.Positive in dermatofibroma, haemagioblastoma, 		of epithelial origin but should be used in conjunction with LCA & cytokeratins. May be positive in large cell		В
ERG resulting from ERF gene rearrangement.Factor 13ABPositive in dermatofibroma, haemagioblastoma, hepatocellular carcinomaFactor 13ABIdentification of breast carcinomas and urothelial carcinomasGATA-3BApocrine epithelia i.e., glands. Specific marker for breastGCDFP-15B			ERG	В
haemagioblastoma, hepatocellular carcinomaGATA-3BIdentification of breast carcinomas and urothelial carcinomasGATA-3BApocrine epithelia i.e., glands. Specific marker for breastGCDFP-15B		ERG resulting from ERF gene		
carcinomas and urothelial carcinomas and urothelial carcinomas b Apocrine epithelia i.e., glands. Specific marker for breast GCDFP-15 B		haemagioblastoma,	Factor 13A	В
Specific marker for breast		carcinomas and urothelial	GATA-3	В
		Specific marker for breast	GCDFP-15	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of <u>clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Positive on membrane of mesothelial cells. Some adenocarcinomas are positive but show cytoplasmic staining	HBME-1 (Mesothelial Cell)	В
	Melanocytic Lesions, PEComa, Adrenal tumours	HMB-45 (melanosome)	В
	Germ cell tumour marker	Human Chorionic Gonadotrophin (hCG)	В
	Polyclonal light chains of kappa type	Карра	В
	Ki-67 Protein	Ki-67 Antigen	В
	Polyclonal light chains of lambda type	Lambda	В
	Melanoma marker	Melan A	В
	Smooth muscle	Myosin Heavy Chain Smooth Muscle (MHC-SM)	В
	Oestrogen Receptor	ER	В
	Nuclei of embryonic stem cells and germ cells. Useful marker for germ cell tumours	OCT 3/4	В
	Nuclei and/or cytoplasm of carcinoma cells. Mutated in many tumours. Indicated in HPV infected cells	P16	В



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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)	Histopathological examination activities for the purpose of <u>clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	P40 in breast myoepithelial cells to aid in differentiating between benign and malignant breast lesions	P40	В
	Nuclei of tumour cells. A tumour suppressor gene. Overexpressed in many tumours	p53	В
	Nuclei of a variety of tissues: basal cells of normal epithelium in ectocervix, urothelium, oesophagus, and skin. Also, basal cells of glands in breast, bronchi and prostate. Myoepithelial cells express this as well	p63	В
	Confirming Uro-genital, Gynae tumours. Thyroid	PAX8	В
	Germ cell tumour marker	Placental Alkaline Phosphatase (PLAP)	В
	Breast tumour marker	Progesterone Receptor (PR)	В
	Reacts with secretory and ductal epithelium in normal & neoplastic tissue	Prostatic Specific Antigen (PSA)	В
	Prostate glandular epithelium, prostatic carcinoma	PSAP	В



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FLUIDS (cont'd) activities for the purpose of clinical diagnosis (cont'd) examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant) FFPE tissue (cont'd) Detection of the following: (cont'd) Immunohistochemistry using Roche Ventana Benchmark (cont'd) FFPE tissue (cont'd) Detection of the following: (cont'd) Immunohistochemistry using Roche Ventana Benchmark (cont'd) Melanocytes, Langerhans cells, histicozytes, skeletal and cardiac muscle, Schwann ocells, epithelial and mycepithelial cells of the breast, salivary and sweat glands, gilat cells. Useful in identifying melanomas and other tumours Smooth Muscle Actin B Melanoma cells and peripheral nerve sheath tumour cells Sox10 B Positive in thyroid epithelium, thyroid tumours & follicular adenoma Thyroglobulin B Thyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumours Thyroid Transcription Factor (TTF-1) B Wilm's and mesothelioma WT1 B B	Materials/Products tested	measured/Range of		
(cont'd)Roche Ventana Benchmark (cont'd)Melanocytes, Langerhans cells, histicytes, ichondrocytes, lipocytes, skeletal and cardiac muscle, Schwann cells, epithelial and myoepithelial cells of the breast, salivary and sweat glands, glial cells. Useful in identifying melanomas and other tumoursS100BSmooth muscle cellsSmooth Muscle ActinBMelanoma cells, and peripheral nerve sheath tumour cellsSOX10BEndocrine cells, neuroendocrine cells and their derived tumoursSynaptophysinBPositive in thyroid epithelium, thyroid Transcription Factor (TTF- 1)Thyroid Transcription Factor (TTF- 1)BVimentin intermediate filament Wilm's and mesotheliomaVimentinBWilm's and mesotheliomaWT1B		activities for the purpose of clinical diagnosis	examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where	
cells, histiocytes, chondrocytes, lipocytes, skeletal and cardiac muscle, Schwann cells, epithelial and myoepithelial cells of the breast, salivary and sweat glands, glial cells. Useful in identifying melanomas and other tumoursSmooth Muscle ActinBSmooth muscle cellsSmooth Muscle ActinBMelanoma cells and peripheral nerve sheath tumour cellsSOX10BEndocrine cells, neuroendocrine cells and their derived tumoursSynaptophysinBPositive in thyroid epithelium, thyroid tumours & follicular 	FFPE tissue (cont'd)		Roche Ventana Benchmark	
Melanoma cells and peripheral nerve sheath tumour cellsSOX10BEndocrine cells, neuroendocrine cells and their derived tumoursSynaptophysinBPositive in thyroid epithelium, thyroid tumours & follicular adenomaThyroglobulinBThyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumoursThyroid Transcription Factor (TTF- 1)BVimentin intermediate filamentVimentinBWilm's and mesotheliomaWT1B		cells, histiocytes, chondrocytes, lipocytes, skeletal and cardiac muscle, Schwann cells, epithelial and myoepithelial cells of the breast, salivary and sweat glands, glial cells. Useful in identifying melanomas and	S100	В
nerve sheath tumour cellsSynaptophysinBEndocrine cells, neuroendocrine cells and their derived tumoursSynaptophysinBPositive in thyroid epithelium, thyroid tumours & follicular adenomaThyroglobulinBThyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumoursThyroid Transcription Factor (TTF- 1)BVimentin intermediate filamentVimentinBWilm's and mesotheliomaWT1B		Smooth muscle cells	Smooth Muscle Actin	В
neuroendocrine cells and their derived tumoursThyroid ranscriptionBPositive in thyroid epithelium, thyroid tumours & follicular adenomaThyroglobulinBThyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumoursThyroid Transcription Factor (TTF- 1)BVimentin intermediate filamentVimentinBWilm's and mesotheliomaWT1B			SOX10	В
thyroid tumours & follicular adenomaThyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumoursThyroid Transcription Factor (TTF- 1)BVimentin intermediate filamentVimentinBWilm's and mesotheliomaWT1B		neuroendocrine cells and their	Synaptophysin	В
nuclear: positive in lung adenocarcinomas, thyroid tumours1)Vimentin intermediate filamentVimentinWilm's and mesotheliomaWT1B		thyroid tumours & follicular	Thyroglobulin	В
Wilm's and mesothelioma WT1 B		nuclear: positive in lung adenocarcinomas, thyroid		В
		Vimentin intermediate filament	Vimentin	В
			WT1	В



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue		Immunohistochemistry using the Leica Bond III and Bond Refine detection kit CPSOP 0101 CPWI 0101B CPWI 0101C	A
	Various - mast cells, stem cells, Cajal cells, melanocytes, basal cells (skin) and mammary duct epithelium	CD117	
	GIST, interstitial cells	DOG-1	
	Identification of breast carcinomas and urothelial carcinomas	GATA3	
	Identification of normal and neoplastic hepatocytes.	Hepatocyte specific antigen (HSA)	
	Used in differentiating primary lung adenocarcinoma	Napsin A	
	Identification of primary renal cell carcinomas and metastatic renal cell carcinomas	RCC	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: Reporting Results in Cellular Pathology CPSOP 0003 BED-SOP-698	A and B



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Testing performed by the Organisation at the locations specified				
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code	
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant		
Serum (unless stated otherwise)		Automated using the Roche Cobas c702 module photometric assay	A and B	
		CBSOP 0201.3		
and Urine, CSF Plasma	Albumin Alcohol ALP ALT Amikacin			
Plasma	Ammonia AST			
Serum/plasma	Beta 2 Microglobulin Beta-hydroxybutyrate		B only	
and Urine	Bicarbonate Bile Acids Bilirubin (total) C3 Complement C4 Complement	BED-SOP-857		
and Urine	Calcium			
and Urine	Carbamazapine Chloride Cholesterol Conjugated Bilirubin Creatine Kinase Creatinine (enzymatic)			
and Urine	Creatinine (jaffe) CRP			
Serum/plasma	Digoxin Ethanol Gamma-glutamyl-transferase			
and Urine, CSF, Plasma	Gentamycin Glucose HDL Cholesterol Immunoglobulin A Immunoglobulin G Immunoglobulin M Iron			
and CSF	Lactate Dehydrogenase Lipase Lithium			



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Piechomiatry examination	In house decumented methods

Testing performed by the Organisation at the locations specified

HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (unless stated otherwise) (cont'd)		Automated using the Roche Cobas c702 module photometric assay	A and B
and Urine Urine, CSF Urine, CSF	Magnesium Micro total Protein Microalbumin Paracetamol Phenytoin	CBSOP 0201.3	
Serum/plasma and Urine and Urine	Phenobarbitone Phosphate Protein Rheumatoid Factor Salicylate Theophylline Tobramycin		В
and Urine and Urine	Transferrin Triglyceride Urate Urea Vancomycin Valproate Sodium		В
and Urine and Urine and Urine	Chloride Potassium Sodium	Automated using the Roche Cobas ISE module using ion selective electrodes CBSOP 0201.3 BED-SOP-857	A and B
Serum (unless stated	Alpha-feto protein	Automated using the Roche Cobas e602 and e801 module using electrochemiluminescence CBSOP 0201.3	A and B
otherwise)	Anti-TPO BNP		
Plasma Plasma Serum/Plasma Plasma Plasma	CA125 CA19-9 CA 15-3 CEA Cortisol		B only
Plasma	Ferritin		

Location

Code



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
		Automated using the Roche Cobas e602 and e801 module using electrochemiluminescence CBSOP 0201.3	
Plasma Plasma Plasma Plasma	FSH FT3 FT4 HCG		
Plasma Plasma	IGE LH		B only
Serum (unless stated otherwise)	Oestradiol Progesterone Prolactin PSA PTH Folate SHBG Testosterone Troponin T TSH Vitamin B12 Vitamin D		B only


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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Blood	pH pCO2 K+ Na+ Cl-	ABL 90 Flex Blood Gas analyser using LI-BIO-ABL90lab, PTSOP 0004 and measurement principle stated: Potentiometry	A and B
	cLac pO2 ctHb sO2 FO2Hb FCOHb FHHb FMetHb FHbf	Amperometry Optical Density Spectrophotometry	
Whole Blood	Glucose	Electrical detection of enzyme reaction on test strip using Roche Accu-Chek Inform II and procedure PTSOP 0007	A
Serum /Urine	Osmolality	Osmo 1 Osmometer Freezing point depression Osmometry: CBSOP 0214.9	A
EDTA blood	HbA1c	Menarini HB 9210 Boron Affinity CBSOP 0219.1	A and B



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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Blood	pH pCO ₂ Sodium pO ₂ Carboxyhaemoglobin Methaemoglobin	Radiometer ABL90 FLEX blood gas analyser BED-SOP-1062 Potentiometry Potentiometry Potentiometry Optical phosphorescence Co-oximetry	В
	Actual bicarbonate Standard bicarbonate CO ₂ Content Base Excess Oxygen Saturation	Calculated from the above	
		Wescor Chlorochek Model 3400 using LI-BIO-SwtWcrSOP and measurement principle stated:	A
Sweat	Chloride Conductivity	Coulometric Conductivity	
Faeces	Total Porphyrin Coproporphyrin I Coproporphyrin III % Coproporphyrin III Dicarboxylate Porphyrin	Varian HPLC system HPLC fractionation BED-SOP-529	В
Urine	Uroporphyrin I Uroporphyrin III Total Uroporphyrin (I+III) Heptacarboxylate Porphyrin Coproporphyrin I Coproporphyrin III	Varian HPLC system HPLC fractionation BED-SOP-529	В
Urine	5-Aminolaevulinic acid (ALA) Porphobilinogen (PBG)	Recipe chemicals urine ALA and PBG (Ion exchange Chromatography) kit CBSOP 0232C	В



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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Blood		Luminescence Spectrophotometer scan	В
	Red Cell Free Protoporphyrin Red Cell Zinc Protoporphyrin	CBSOP 0232E	
	Red Cell HMBS	CBSOP 0232F	
Plasma	Plasma porphyrin fluorescence emission spectroscopy	CBSOP 0232D	В
Urine	Benzodiazipine screen Amphetamine screen Cannabinoids screen Opiates screen Cocaine screen	Chirus XPress reader Chromatographic Membrane immunoassay BED-SOP-465	В



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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)	Immunological examinations for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
Serum/Li-Hep plasma	Total IgE	Thermo Fisher (Phadia) ImmunoCAP 250 (Enzyme-linked fluorescence) - ISOP 0015, ISOP 0015Af, ISOP0015A	A
			_

	diagnosis	Instructions where relevant	
Serum/Li-Hep plasma	Total IgE	Thermo Fisher (Phadia) ImmunoCAP 250 (Enzyme-linked fluorescence) - ISOP 0015, ISOP 0015Af, ISOP0015A	A
Serum/Li-Hep Plasma	Specific IgE: House Dust Mite (d1) Cat Dander (e1) Dog Dander (e5) Egg White (f1) Milk (f2) Fish - Cod (f3) Wheat (f4) Sesame seed (f10) Peanut (f13) Shrimp (f24) Salmon (f41) Strawberry (f44) Alternaria alternata (m6) Mould mix (mx1) Soybean (f14) Hazel Nut (f17) Brazil Nut (f18) Almond (f20) Cashew Nut (f202) Pistachio (f203) Walnut (f256) Mixed Nuts (fx1) Mixed Foods (fx5) Mixed Grass Pollen (gx1) Aspergillus Fumigatus (m3) Mixed Tree Pollen (tx8) Mixed Weed Pollen (wx1)	Thermo Fisher (Phadia) ImmunoCAP 250 (Enzyme-linked fluorescence) - ISOP 0015, ISOP 0015Af, ISOP0015A	A



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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)	Immunological examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
		Thermo Fisher (Phadia) ImmunoCAP 250 (Enzyme-linked fluorescence) - ISOP 0015, ISOP 0015Af, ISOP0015A	A
Serum	IgA Tissue Transglutaminase Antibodies		
Serum	Cyclic Citrulinate Peptide (CCP) Antibodies		
Serum	IgG and IgM Cardiolipin Antibodies		
Serum	CTD (ANA) Screen		
Serum	dsDNA Antibodies		
Serum	ANCA Myeloperoxidase(MPO) Antibodies		
Serum	ANCA Serine Proteinase 3 (PR3) Antibodies		



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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)	Immunological examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum	IgG antibodies against nuclear antigens (nRNP, Sm, SS-A (SS-A Native and Ro-52), SS- B, ScI-70, Jo-1, CENP B, PCNA, Nucleosomes, Histones, Ribosomal P- protein)	EuroImmun ANA Profile-3 kit on the EuroBlotMaster (Immunoblot assay) - ISOP0016, ISOP0016A	A
Serum	Myositis Antibodies Panel: Mi-2β, Ku, PM-Scl-100, PM- Scl75, Jo-1, SRP, PL-7, PL- 12, EJ, OJ, Ro-52	Eurolmmun Myositis Antigens Profile 3 Kit on the EuroBlotMaster (Immunoblot assay) - ISOP0016, ISOP016A	A
Serum	Autoimmune Liver Disease Antibodies Panel: AMA-M2, M2-3E (PBO), Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, Ro-52	Eurolmmun Autoimmune Liver Disease Antibodies Kit on the EuroBlotMaster (Immunoblot assay) - ISOP0016, ISOP016A	A
Serum	Anti Nuclear Antibodies (HEp- 2)	Inova Diagnostics (Werfen) Quantalizer 2 (Immunofluorescence) - ISOP 0004	A
Serum	Vitamin D	IDS iSYS assay (Chemiluminescence) – ISOP 0027, ISOP 0027A	A
Faeces	Faecal Calprotectin	Buhlmann Calprotectin ELISA assay on the Dynex DS2 – ISOP 025, ISOP 0025A	A
Serum	Serum Protein Electrophoresis and Immunotyping	Sebia CapillaryS 3 (Capillary Electrophoresis) - ISOP 0020, ISOP 0020A, ISOP 0020C	A and B
	Free Light Chain FLC	BED-SOP-1125	В



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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)	Immunological examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Urine (Random and 24hr)	Urine Protein Electrophoresis (Bence Jone's Protein - BJP) and Immunotyping	Sebia CapillaryS 3 (Capillary Electrophoresis) - ISOP 0020, IAOP 0020A, ISOP 0020B, ISOP 0020C	A
Serum, Plasma	Detection of Cryoglobulins	Manual screening for Cryoglobulinaemia – ISOP 0023	A
Faecal Extract	Faecal Haemoglobin (FIT)	OC Sensor iO (Latex Agglutination) - ISOP 0034	A
CSF	CSF Xanthochromia	Thermo Evolution 201 (Spectrophotometry) - ISOP0035	A
	Provision of Point of Care testing in accordance with ISO 22870: 2016 related to the following:		
Whole Blood	Glucose	Electrical detection of enzyme reaction on test strip using Roche Accu-Chek Inform II and procedure PTSOP 0007	C1, C2 D, E, F, G
Whole Blood	pH pCO2 K+ Na+ CI- cLac pO2 ctHb sO2 FO2Hb FCOHb FCOHb FHHb FMetHb FHbf Total Bilirubin Ionised Calcium Glucose	ABL 90 Flex Blood Gas analyser using LI-BIO-ABL90lab, PTSOP 0004 and measurement principle stated: Potentiometry Amperometry Optical Density Spectrophotometry	C1, C2



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Hospital Wards, Clinics and Outpatients Luton & Dunstable University Hospital		C1	
	Roche AccuChek Inform II	ABL90 Flex Plus	
A&E	x	x	
Ambulatory Care	x		
Ante-Natal Clinic	x		
Cardiac Cath Lab	x		
Cardiac Rehab	x		
Cardiology	x	x	
Chemotherapy	x		
Cobham Clinic	x		
Delivery Suite	x	x	
Diabetes Centre	x		
Endoscopy Unit	x		
Eye Clinic	x		
Eye Day Surgery (Pre-op Eyes)	x		
HDU SC Babies (NICU 2)	x	x	
HDU SC Nursery (NICU 3)	x		
Imaging	x		
ITU	x	x	
Medical Outpatients	x		
Medical Outpatients Zone A Ground Floor	x		
Medical OPD Neurophysiology	x		
Obesity Research	x		
Oral Surgery	x		
Paediatric Outpatients	x		
Phlebotomy	x		
Pre-Op Asessment Unit	x		
Respiratory Nurses	x		
SCBU ITU (NICU 1)	x	x	
St Marys Care Unit	x		
Surgical Arrivals (Ward 21)	x		
Surgical Outpatients	x		
Surgical Short Stay Unit	x		
Surgical Short Stay Unit Recovery 3	x		
Theatres - Gynaecology	x		
Theatres 1 to 6	x		



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Hospital Wards, Clinics and Outpatier	nts Luton & Dunstable University Hospital (cont'd)	C1
	nts Luton & Dunstable University Hospital (cont'd) Roche AccuChek Inform II	ABL90 Flex Plus
A&E 3		х
Ward 20 (Surgical)		х
Ward 25 (Paeds 2)		x
		-



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Hospital Wards, Clinics and Outpatients Bedford Hospital		C2	
	Roche AccuChek Inform II	ABL90 Flex Plus	
Theatres A to D	X	x	
Ward 1 (EAU)	x		
Ward 10 (Respiratory)	x	x	
Ward 11	x		
Ward 12	x		
Ward 14	x		
Ward 15	x		
Ward 16	x		
Ward 17	x		
Ward 18	x		
Ward 19A	x		
Ward 19A Haematology/Oncology Unit	x		
Ward 19B	x		
Ward 2 (HDU)	x	x	
Ward 20	x		
Ward 21 (SAU)	x		
Ward 22	x		
Ward 23	x	x	
Ward 23E (Surgical Departure Lounge)	x		
Ward 24	x		
Ward 25	x		
Ward 26	x	x	
Ward 26A (Paediatric Assessment Unit)	x		
Ward 3	x		
Ward 31	x		
Ward 32	x		
Ward 32A (Maternity Day Assessment Unit)	x		
Ward 33	x		
Ward 34	x		
Ward 4	x	x	
Ward 6	x		



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Hospital Wards, Clinics and Outpatients Bec	Iford Hospital (cont'd)	C2
nospital Wards, onnos and outpatients bee	Roche AccuChek Inform II	ABL90 Flex Plus
Accident & Emergency	x	X
Acute Assessment Unit	x	x
Child Assessment Unit		x
Critical Care Complex	x	x
Delivery Suite	x	x
Neonatal Intensive Care		x
Respiratory Ward		x
Same Day Emergency Care Unit		X
Theatres	x	x
Ambulatory Emergency Care	x	
Arnold Whitchurch Ward	x	
Cardiac Catheter Suite	x	
Chest Clinic	x	
Coronary Care Unit	x	
Childrens Outpatient Department	x	
Diabetes Centre	x	
Elizabeth Ward	x	
Endoscopy	x	
ENT Clinic	x	
Moorefields Eye Centre	x	
Outpatients Department	x	
Godber Ward	x	
Howard Ward	х	
Oral MaxFax Department	x	
Orchard Ward	x	
Pilgrim Ward	x	
Primrose Suite (Oncology)	x	
Reginal Hart Ward	x	
Richard Wells	x	
Riverbank Ward	x	
Russell Ward	x	
Shand Ward	x	
Shuttleworth Ward	x	
Tavistock Ward	x	



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Hospital Wards, Clinics and Outpatients	Bedford Hospital (cont'd)	C2
· · ·	Roche AccuChek Inform II	ABL90 Flex Plus
Urgent Treatment Centre	X	
Urology Department	X	
Victoria Ward	x	
Whitbread Ward	x	

Off-site POCT as listed		
Site	Roche AccuChek Inform II	
D	X	
E	X	
F	X	
G	X	
	END	