


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8212</p> <p>Accredited to ISO 15189:2022</p>	<p>Bedfordshire Hospitals NHS Foundation Trust</p> <p>Issue No: 022 Issue date: 18 February 2026</p>	
	<p>Bedfordshire Hospitals NHS Foundation Trust</p> <p>Lewsey Road</p> <p>Luton</p> <p>Bedfordshire</p> <p>LU4 0DZ</p>	<p>Contact: Halima Ayub</p> <p>Tel: +44 (0)1582 718308</p> <p>E-Mail: Pathologyqualityteam@ldh.nhs.uk</p> <p>Website: www.bedfordshirehospitals.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Luton and Dunstable University Hospital Lewsey Road Luton Bedfordshire LU4 0DZ</p> <p style="text-align: right;">As above</p>	<p>Histopathology Clinical Biochemistry Haematology Blood Transfusion inc management of blood fridge Immunology Management of Point of Care Testing</p>	A
<p>Bedford Hospital Kempston Road Bedford Bedfordshire MK42 9DJ</p> <p style="text-align: right;">As Above</p>	<p>Microbiology Histopathology Diagnostic Cytology Clinical Biochemistry Haematology Blood Transfusion inc management of blood fridge Immunology Management of Point of Care Testing</p>	B



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Site activities performed away from the locations listed above: Location details	Activity	Location code
Hospital Wards, Clinics and Outpatients Luton and Dunstable University Hospital Site Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing	C1
Hospital Wards, Clinics and Outpatients Bedford Hospital Site Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing	C2
Dermatology Clinic 1st Floor Arndale House The Mall Luton LU1 2LJ Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing	D
Luton Sexual Health 1st Floor Arndale House The Mall Luton LU1 2LJ Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing	E
Orthopaedic Clinic Travel Lodge Dunstable Rd Luton Bedfordshire Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing	F
Limb Fitting Lewsey Road Luton Bedfordshire Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing	G
Theatres Bedford Hospital Khuram Shahzad Tel: +44 (0)1582 498832	Management of Blood Fridge	
Delivery Suite Bedford Hospital Khuram Shahzad Tel: +44 (0)1582 498832	Management of Blood Fridge	
Delivery Suite Luton and Dunstable University Hospital Khuram Shahzad Tel: +44 (0)1582 498832	Management of Blood Fridge	
Emergency Department Luton and Dunstable University Hospital Khuram Shahzad Tel: +44 (0)1582 498832	Management of Blood Fridge	



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN TISSUES AND FLUIDS</p> <p>Swabs from eyes, wounds, nose, throat, ears, genital sites, respiratory fluids (sputum, bronchial washings)</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance</p>	<p>In-house documented procedures following current United Kingdom Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation of selected culture media using in-house procedures:</p> <p>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</p>	<p>B</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Urine</p> <p>Fluids from CSF, ascitic and peritoneal fluids</p> <p>Swabs from nose, perineum and wound sites</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance and antimicrobial susceptibility testing</p> <p>Quantification of white and red blood cells and bacteria</p> <p>Isolation of MRSA</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Investigations of urine MMSOP 0015 in conjunction with manufacturer's instructions using Mast Urisystem MMSOP 0104: Urine MC&S, MMSOP 0102: Menarini SediMax Automated Microscopy</p> <p>Manual microscopy in conjunction with MMSOP 0064 Investigation of cerebro-spinal fluids, MMSOP 0026 Fluids from sterile sites MMSOP 0145: Investigation of ascitic and peritoneal fluid</p> <p>Manual inoculation of chromogenic agar using MMSOP 0105: Investigation of MRSA</p> <p>Realtime PCR using: MMSOP 0038: Cepheid MRSA NxG assay and Cepheid GeneXpert MMSOP 0038A: Use of the Cepheid GeneXpert Analyser Xpert MRSA NxG Assay</p>	<p>B</p> <p>B</p> <p>B</p> <p>B</p>



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



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Blood and sterile fluids	Isolation of clinically significant bacteria and fungi	Automated culture using: Biomerieux Virtuo and MMSOP 0065	A and B
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 0111 followed by auramine phenol staining and fluorescence microscopy MMSOP 0113 Realtime PCR using: MMSOP 0038, Cepheid Xpert MTB/RIF Assay and: Cepheid GeneXpert and MMSOP 0038A: Use of the Cepheid GeneXpert Analyser, Xpert Carba-R assay.	B
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	B
Nose swabs, throat swabs, nose and throat swabs	Detection of respiratory pathogens	Biomerieux Biofire BIOFIRE® Respiratory 2.1 (RP2.1) Panel MMSOP 0086A	B
CSF	Detection of community-acquire meningitis and encephalitis	Meningitis/Encephalitis (ME) Panel MMSOP 0078A	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Parasitological examination activities for the purpose of clinical diagnosis</u>	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	B
Faeces	Examination for the presence of <i>Cryptosporidium</i> Oocysts	Auramine phenol staining and fluorescence microscopy using MMSOP 0113	B
Clear tape slide Perianal swab	Detection of <i>Enterobius vermicularis</i> larvae and ova	Microscopic examination using in-house procedure: MMSOP 0043	B
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination using in-house procedure: MMSOP 0043	B
Bile Duodenal aspirates Jejunal aspirates	Detection of OCP including: <i>Strongyloides stercoralis</i> larvae, <i>Giardia lamblia</i> trophozoites <i>Cryptosporidium</i> oocysts <i>Cyclospora cayetanesis</i> oocysts <i>Cystoisospora belli</i> oocysts	Auramine phenol staining and incident-light fluorescence, Ziehl-Neelsen, iodine staining as appropriate and microscopic examination using in-house procedure: MMSOP 0043	B
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	B
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	B



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	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)	B
	Measles IgG	MMSOP 0074 Serological tests using the Biomerieux Vidas 30(immunoassay)	B
	<i>Varicella zoster</i> IgG	MMSOP 0074 Serological tests using the Biomerieux Vidas 30(immunoassay)	B
	HIV antigen/antibody	MMSOP 0074 Serological tests using the Biomerieux Vidas 30 (immunoassay)	B
	Mumps IgG	MMSOP 0074 Serological tests using the Biomerieux Vidas 30 (immunoassay)	
Serum	Hepatitis E IgM and IgG	Fortress Diagnostics ELISA in conjunction with manufacturer's instructions and procedure MMSOP 0058 Hep E IgG & IgM Test	B



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	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	B
Serum	Detection of:	Roche Cobas 8000 e602 Elecsys Sandwich assay e801 MMSOP 0095: Use of Cobas 8000)	
Serum	CMV IgG and IgM antibody	MMSOP 0886	B
Serum	HIV antigen/antibody	MMSOP 0095, MMSOP 0846	B
Serum	Hepatitis A IgG and IgM antibody	MMSOP 0886, MMSOP 0876	B
Serum	Hepatitis B antibody (immunity)	MMSOP 0873 Hepatitis B serology	B
Serum	Hepatitis B core total antibody (HBcT)	MMSOP 0873 Hepatitis B serology	B
Serum	Hepatitis C Antibody	MMSOP 0872 Hepatitis C serology	B
Serum	HBsAg* HIV-1&2 Antibody & HIV-1 p24 Antibody + Antigen* Syphilis IgG/IgM*	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 *) Roche Cobas 8000 e602 e801 Elecsys Sandwich assay MMSOP 0873 Hepatitis B serology MMSOP 0846 HIV serology MMSOP 0874 Syphilis serology	B



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Virological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Nose and throat swabs, nasopharyngeal aspirates	SARS-CoV-2, Flu A, Flu B, RSV Multiplex	Realtime PCR using Cepheid GeneXpert and Xpert express CoV-2/Flu/RSV Plus Realtime PCR assay MMSOP 0038A Roche Cobas 6800 Realtime PCR	B
Nose and throat Swabs	Detection of SARS-CoV-2 RNA	MMSOP 0099A	B
Plasma	Quantitative detection of HIV-1 RNA	MMSOP 0099A	B
Plasma and serum	Quantitative detection of Hepatitis B DNA	MMSOP 0099A	B
Plasma and serum	Quantitative detection of Hepatitis C RNA	MMSOP 0099A	B
Genital swabs	Detection of Herpes Simplex Virus type I and II DNA	MMSOP 0099A	B
Genital swabs and Urine	Detection of Chlamydia trachomatis and Neisseria gonorrhoea	MMSOP 0099A	B
Genital swabs and Urine	Detection of Trichomonas vaginalis and Mycoplasma genitalium	MMSOP 0099A	B
Roche PCR medium for genital swabs and urine	Detection of Mycoplasma genitalium macrolide resistance markers	Realtime PCR using Cepheid GeneXpert MMSOP 0038A	B
Roche PCR medium for genital swabs and urine	Confirmation of Neisseria gonorrhoea DNA detection	Realtime PCR using Cepheid GeneXpert MMSOP 0038A	B



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HUMAN BODY FLUIDS	<u>Haematological examination activities for the purpose of clinical diagnosis</u>	Using manufacturer's instructions and documented in-house procedures	
EDTA whole blood	Full Blood Count: 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	A and B
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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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	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	A and B
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 X Assay Factor IX 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 activities for the purpose of clinical diagnosis (cont'd)</u>	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: HSOP0505 G6PD Fluorescent Spot Test	A and B
Serum or EDTA plasma	Infectious Mononucleosis Screen	Lateral flow immunoassay for the detection of IM heterophile antibodies, based on procedures: HSOP 0511 Clearview IM II kit for infectious mononucleosis (glandular fever) screening	A and B
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	A
		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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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>EDTA whole blood</p>	<p><u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Screening for the detection of: <i>Plasmodium falciparum</i> and <i>Plasmodium</i> spp. Including: <i>Plasmodium ovale</i></p> <p><i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium vivax</i></p> <p>Detection and Identification of: <i>Plasmodium</i> species: <i>Plasmodium falciparum</i> <i>Plasmodium vivax</i> <i>Plasmodium ovale</i> <i>Plasmodium malariae</i> <i>Plasmodium knowlesi</i></p>	<p>Using manufacturer's instructions and documented in-house procedures</p> <p>CareStart Malaria Antigen Test Rapid diagnostic test HSOP 0502</p> <p>Manual microscopy of thick films stained with Field's stain and thin films stained with Romanowsky stain based on procedures:</p> <p>Malaria Diagnosis HSOP0502,</p>	<p>A and B</p> <p>A and B</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	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	A and B
EDTA Plasma	Crossmatch (compatibility testing):	using Column Agglutination Technology SOP BTSOP 0018	
	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	A
	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)	<u>Diagnostic cytology examination activities for the purpose of clinical diagnosis</u>	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, CPSOP 0302 and 306	B
Slides prepared in-house from sample types listed above		Automated staining using Leica ST5020 Staining Machines & Manual Coverslipper and in-house procedures: Routine Staining in Cytology CPSOP 0304	
		Haematoxylin & Eosin May Grunwald Giemsa	B B
		Papanicolau Staining	B
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: Diagnostic Cytology Reporting CPWI 0316	A and B



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed tissues</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis</u></p> <p>Preparation and examination to identify or exclude morphological & cytological abnormalities</p>	<p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p><u>Macroanalysis and dissection</u> Manual method using:</p> <p>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</p>	<p>A and B</p>



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Formalin fixed tissues	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	<u>Decalcification</u> Manual method using: CPWI 0045	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)	B
Formalin fixed paraffin embedded (FFPE) tissue		<u>Embedding</u> Manual method using: Leica HistoCore Arcadia H Embedding Centres/ HistoCore Arcadia C Cold Plate - SOP Embedding Histology Blocks CPWI 0002 Sakura Tissue Tek CPSOP0006	B
		<u>Microtomy</u> Manual method using: Leica RM 2235 Rotary microtomes - SOP Sectioning Histology Blocks CPWI 0057	B



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of 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)	
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin & Eosin (H&E) staining and coverslipping, Automated method using: Leica XL ST5010 Stainer Leica CV5030 coverslipper	B
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: CPSOP0021 SPECIAL STAINS	
	Acid mucins (sulphomucins & sialomucins)	SOP Alcian Blue for Acid Mucosubstances	B
	Acid mucins (sulphomucins & sialomucins)	SOP Alcian Blue-PAS	B
	Acid mucins (sulphomucins & sialomucins) Neutral mucins Mixed mucins	SOP Alcian Blue-PAS with Diastase Digestion	B



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of 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)	
		Manual special stains (cont'd)	
	Amyloid	SOP Congo Red Stain for Amyloid	B
	Collagen and muscle	SOP Miller's Elastic Van Gieson	B
	Helicobacter Pylori	SOP Giemsa (For Helicobacter Pylori)	B
	Gram positive and gram-negative organisms	SOP Gram Stain	B
	Fungi	SOP Grocott Hexamine Silver Stain for Fungi	B
	Collagen and fibrosis	SOP Haematoxylin Van Gieson	B
	<i>Helicobacter pylori</i> & <i>Helicobacter</i> -like organisms	SOP Modified Giemsa for Helicobacter Pylori	B
	Hepatitis B antigen, elastic fibres and copper associated protein	SOP Orcein	B
	Glycogen and other tissues containing aldehydes	SOP Periodic Acid-Schiff (PAS) Stain	B
	Diastase Digestion PAS	SOP Diastase Digestion-PAS	B
	Haemosiderin & ferric salts	SOP Perl's Prussian Blue	B
Type IV collagen fibres (Reticulin)	SOP Gordon & Sweet Reticulin Stain	B	
<i>Mycobacterium tuberculosis</i>	SOP Ziehl Neelsen Stain	B	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of 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:	<u>Immunohistochemistry</u> Automated methods using Roche Ventana Benchmark and the following antibodies: CPSOP 020 GENERAL IMMUNOHISTOCHEMISTRY	B
	Hepatocellular carcinomas, yolk sac tumours	Alpha Fetoprotein (AFP)	B
	Muscle	Actin	B
	Epithelial marker	Alpha-Methylacyl-CoA-Racemase (AMACR)	B
	Detection of Cell adhesion marker	Beta Catenin	B
	T-cell lymphocytes	Bcl-2	B
	Broad reactivity with epithelial cells. Mesothelial cells are negative	Epithelial Antigen (Ber-EP4)	B
	Expressed in normal endometrial glands, ovary and cervix. Expressed in ovarian carcinoma	CA125	B
	Medullary thyroid tumour marker	Calcitonin	B
	Labels tumours of smooth muscle, and myofibroblastic and myoepithelial differentiation	Caldesmon	B



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of 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)	
	Useful in differentiating malignant mesothelioma from adenocarcinomas (in particular of the lung). Also used to differentiate adrenal cortical neoplasms from pheochromocytomas	Calretinin	B
	Liver: Malignant vs Benign, Pleura: Adenocarcinoma vs Mesothelioma, Carcinomas, HCC	Carcinoembryonic Antigen (CEA)	B
	Preferred marker for T-cells. A polyclonal pan T antibody, but occasional T-cell neoplasms	CD3	B
	Mantle cell lymphomas	CD5	B
	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	B



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FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry 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	B
	Pan B-cell marker, also some Reed-Sternberg (RS) cells. Preferred marker for B-cells	CD20	B
	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	B
	Endothelial Cells, Activated B and T Lymphocytes	CD 31	B
	Endothelial cells but also expressed on human lymphoid and myelopoetic progenitor cells. Useful to identify vascular tumours and characterise leukaemias	CD34	B



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue (cont'd)</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of the following: (cont'd)</p> <p>All lymphoid cells, variable reaction with macrophages, histiocytes, monocytes. Myeloid cells are unreactive</p> <p>A cell adhesion molecule expressed by most neuroectodermal-derived tissues and their tumours. Also labels NK cells</p> <p>Macrophages, myeloid cells and histiocytes and their derived neoplasms</p> <p>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</p> <p>Expressed at late stages of B cell differentiation; by normal and malignant plasma cells and lymphoplasmacytoid cells. Also expressed by normal epithelial cells in some tissues</p>	<p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Immunohistochemistry using Roche Ventana Benchmark (cont'd)</p> <p>CD45 (Leucocyte Common Antigen)</p> <p>CD56 (N-CAM)</p> <p>CD68</p> <p>CD79alpha</p> <p>CD138</p>	<p></p> <p>B</p> <p>B</p> <p>B</p> <p>B</p> <p>B</p>



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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	B
	Endocrine cells, neuroendocrine cells and their derived tumours	Chromogranin A	B
	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)	B
	Intermediate filament protein expressed in simple, complex, transitional, ductal and glandular epithelium. Useful in distinguishing metastatic breast and colonic adenocarcinomas	Cytokeratin 7 (CK7)	B



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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)	B
	G I tract epithelium	Cytokeratin 19 (CK19)	B
	Reacts with gastric and intestinal epithelium, urothelium and Merkel cells. Useful in distinguishing between GI tract and breast adenocarcinomas	Cytokeratin 20 (CK20)	B
	Epithelial differentiation, Small round blue cell tumours, Specific soft tissue tumour	Cytokeratin (AE1/AE3)	B
	Differential diagnosis: Carcinoma vs non- epithelial tumour	Cytokeratin (CAM5.2)	B
	Cytokeratins 1,5,10, and 14	Cytokeratin High MWt (34betaE12)	B
	Epithelial cells	Cytokeratin MNF 116	B
	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	B
	GIST, interstitial cells	DOG-1	B



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FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Lymphatic endothelium, lymphangiomas, Kaposi sarcoma. Useful for identifying lymphatic metastases	D240	B
	Transmembrane cell adhesion molecule in epithelial cells. Useful in identifying lobular 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	Epithelial Membrane Antigen (EMA)	B
	Aids in identification of prostate adenocarcinomas.	ERG	B
	Wildtype ERG and truncated ERG resulting from ERF gene rearrangement.		
	Positive in dermatofibroma, haemangioblastoma, hepatocellular carcinoma	Factor 13A	B
	Identification of breast carcinomas and urothelial carcinomas	GATA-3	B
	Apocrine epithelia i.e., glands. Specific marker for breast carcinoma	GCDFP-15	B



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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)	B
	Melanocytic Lesions, PEComa, Adrenal tumours	HMB-45 (melanosome)	B
	Germ cell tumour marker	Human Chorionic Gonadotrophin (hCG)	B
	Polyclonal light chains of kappa type	Kappa	B
	Ki-67 Protein	Ki-67 Antigen	B
	Polyclonal light chains of lambda type	Lambda	B
	Melanoma marker	Melan A	B
	Smooth muscle	Myosin Heavy Chain Smooth Muscle (MHC-SM)	B
	Oestrogen Receptor	ER	B
	Nuclei of embryonic stem cells and germ cells. Useful marker for germ cell tumours	OCT 3/4	B
	Nuclei and/or cytoplasm of carcinoma cells. Mutated in many tumours. Indicated in HPV infected cells	P16	B



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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	B
	Nuclei of tumour cells. A tumour suppressor gene. Overexpressed in many tumours	p53	B
	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	B
	Confirming Uro-genital, Gynae tumours. Thyroid	PAX8	B
	Germ cell tumour marker	PLAP	B
	Breast tumour marker	Progesterone Receptor (PR)	B
	Reacts with secretory and ductal epithelium in normal & neoplastic tissue	Prostatic Specific Antigen (PSA)	B
	Prostate glandular epithelium, prostatic carcinoma	PSAP	B



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FFPE tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry using Roche Ventana Benchmark (cont'd)	
	Melanocytes, Langerhans 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 tumours	S100	B
	Smooth muscle cells	Smooth Muscle Actin	B
	Melanoma cells and peripheral nerve sheath tumour cells	SOX10	B
	Endocrine cells, neuroendocrine cells and their derived tumours	Synaptophysin	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
	Vimentin intermediate filament	Vimentin	B
	Wilm's and mesothelioma tumour marker	WT1	B



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue</p> <p>Slides prepared in-house from sample types listed above</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Various - mast cells, stem cells, Cajal cells, melanocytes, basal cells (skin) and mammary duct epithelium</p> <p>GIST, interstitial cells</p> <p>Identification of breast carcinomas and urothelial carcinomas</p> <p>Identification of normal and neoplastic hepatocytes.</p> <p>Used in differentiating primary lung adenocarcinoma</p> <p>Identification of primary renal cell carcinomas and metastatic renal cell carcinomas</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>CD117</p> <p>DOG-1</p> <p>GATA3</p> <p>Hepatocyte specific antigen (HSA)</p> <p>Napsin A</p> <p>RCC</p>	<p>A and B</p>



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	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
and Urine, CSF Plasma	ACE Albumin Alcohol ALP ALT Amikacin Ammonia AST	CBSOP 0201.3	
Plasma			
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 Carbamazepine Chloride Cholesterol Conjugated Bilirubin Creatine Kinase Creatinine (enzymatic) Creatinine (jaffe) CRP		
and Urine	Digoxin Ethanol Gamma-glutamyl-transferase Gentamycin		
Serum/plasma	Glucose HDL Cholesterol Immunoglobulin A Immunoglobulin G Immunoglobulin M		
and Urine, CSF, Plasma	Iron Lactate Lactate Dehydrogenase Lipase Lithium		



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



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Plasma Plasma Plasma Plasma</p> <p>Plasma Plasma</p> <p>Serum (unless stated otherwise)</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>FSH FT3 FT4 HCG</p> <p>IGE LH</p> <p>Oestradiol</p> <p>Progesterone Prolactin PSA PTH Folate SHBG Testosterone Troponin T TSH Vitamin B12 Vitamin D</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Automated using the Roche Cobas e602 and e801 module using electrochemiluminescence CBSOP 0201.3</p>	<p>B only</p> <p>B only</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood	pH pCO ₂ K ⁺ Na ⁺ Cl ⁻ cLac pO ₂ ctHb sO ₂ FO ₂ Hb FCOHb FHHb FMetHb FHbf	ABL 90 Flex Blood Gas analyser using LI-BIO-ABL90lab, PTSOP 0004 and measurement principle stated: Potentiometry Amperometry Optical Density Spectrophotometry	A and B
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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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	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	B
	Actual bicarbonate Standard bicarbonate CO ₂ Content Base Excess Oxygen Saturation	Calculated from the above	
Sweat	Chloride Conductivity	Wescor Chlorocheck Model 3400 using LI-BIO-SwtWcrSOP and measurement principle stated: Coulometric Conductivity	A
Faeces	Total Porphyrin Coproporphyrin I Coproporphyrin III % Coproporphyrin III Dicarboxylate Porphyrin	Agilent HPLC system HPLC fractionation CBSOP 0232G	B
Urine	Uroporphyrin I Uroporphyrin III Total Uroporphyrin (I+III) Heptacarboxylate Porphyrin Coproporphyrin I Coproporphyrin III	Agilent HPLC system HPLC fractionation CBSOP 0232G	B
Urine	5-Aminolaevulinic acid (ALA) Porphobilinogen (PBG)	Recipe chemicals urine ALA and PBG (Ion exchange Chromatography) kit CBSOP 0232C	B



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



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



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u>	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, Scl-70, Jo-1, CENP B, PCNA, Nucleosomes, Histones, Ribosomal P-protein)	EuroImmuno ANA Profile-3 kit on the EuroBlotOne (Immunoblot assay) - ISOP0006	A
Serum	Myositis Antibodies Panel: Mi-2 β , Ku, PM-Scl-100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52	EuroImmuno Myositis Antigens Profile 3 Kit on the EuroBlotOne (Immunoblot assay) - ISOP0006	A
Serum	Autoimmune Liver Disease Antibodies Panel: AMA-M2, M2-3E (PBO), Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, Ro-52	EuroImmuno Autoimmune Liver Disease Antibodies Kit on the EuroBlotOne (Immunoblot assay) - ISOP0006	A
Serum	Anti Nuclear Antibodies (HEp-2)	Inova Diagnostics (Werfen) Quantalizer 2 (Immunofluorescence) - ISOP 0004	A
Serum	LKS (immunofluorescence) for gastric parietal antibodies, mitochondrial antibodies, smooth muscle antibodies and LKM antibodies.	ISOP 0004 and ISOP 0003A	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	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>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u>	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
	<u>Provision of Point of Care testing related to the following:</u>		
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+ Cl- cLac pO2 ctHb sO2 FO2Hb 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 (Same Day Emergency Care - SDEC)	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 (Eye Day Assessment)	x	
Imaging	x	
Medical Outpatients	x	
Medical OPD Neurophysiology	x	
Oral Surgery	x	
Paediatric Outpatients	x	
Pre-Op Assessment Unit	x	
Respiratory Nurses	x	
St Mary Day Care Unit	x	
Surgical Outpatients	x	
Surgical Short Stay Unit	x	
Surgical Short Stay Unit Recovery 3	x	
Theatres - Gynaecology	x	
Theatres 1 to 6	x	
A&E 3	x	x
Theatres A to D	x	
Ward 1 (AU)	x	
Ward 2 (ESU)	x	
Ward 3	x	
Ward 5	x	x
Ward 10 (Respiratory)	x	x
Ward 11	x	
Ward 12	x	



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Hospital Wards, Clinics and Outpatients Luton & Dunstable University Hospital (cont'd)		C1
	Roche AccuChek Inform II	ABL90 Flex Plus
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 20 (Surgical)	x	x
Ward 21 (SAU)	x	
Ward 22	x	
Ward 23	x	
Ward 23E (Sunflower Discharge Lounge)	x	
Ward 24	x	
Ward 25	x	x
Ward 26	x	x
Ward 26A	x	
Ward 34	x	
Luton & Dunstable University Hospital Hospital Wards, Clinics and Outpatients		
	Roche Cobas Liat PCR	
	POCT Flu A, Flu B and RSV testing on nasal swabs	
Accident and Emergency Department – Paediatric Wards	x	
Respiratory Wards (Luton site)	x	



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Bedford Hospital Hospital Wards, Clinics and Outpatients		C2
	Roche AccuChek Inform II	ABL90 Flex Plus
Accident & Emergency	x	x
Acute Assessment Unit	x	x
Child Assessment Unit (Riverbank ward)	x	x
Critical Care Complex	x	x
Delivery Suite	x	x
Neonatal Intensive Care (Meadowbank)		x
Theatres	x	x
Ambulatory Emergency Care	x	
Arnold Whitchurch Ward	x	
Cardiac Catheter Suite	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	x	
Oral MaxFax Department	x	
Orchard Ward	x	
Pilgrim Ward (Respiratory)	x	X
Primrose Suite (Oncology)	x	
Reginal Hart Ward	x	
Richard Wells	x	
Russell Ward	x	
Shand Ward	x	
Shuttleworth Ward	x	
Tavistock Ward	x	



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Bedford Hospital Hospital Wards, Clinics and Outpatients (cont'd)		C2
	Roche AccuChek Inform II	ABL90 Flex Plus
Urgent Treatment Centre	x	
Urology Department	x	
Surgical Assessment Unit	x	X
Whitbread Ward	x	
Bedford Hospital Hospital Wards, Clinics and Outpatients		C2
	Roche Cobas Liat PCR	
	POCT Flu A, Flu B and RSV testing on nasal swabs	
Accident and Emergency Department	x	
Riverbank Ward	x	

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