


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8212 Accredited to ISO 15189:2012	Bedfordshire Hospitals NHS Foundations Trust Issue No: 005 Issue date: 09 August 2021	
	Bedfordshire Hospitals NHS Foundation Trust Lewsey Road Luton Bedfordshire LU4 0DZ	Contact: Marie Sprakes Tel: +44 (0)1582 718141 E-Mail: Marie.Sprakes@ldh.nhs.uk Website: www.ldh.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Bedfordshire Hospitals NHS Foundation Trust Lewsey Road Luton Bedfordshire LU4 0DZ	Marie Sprakes Tel: +44 (0)1582 718141 E-Mail: Marie.Sprakes@ldh.nhs.uk Microbiology Histopathology Non-gynae Cytology Clinical Biochemistry Haematology Coagulation Blood Transfusion Immunology Management of Point of Care Testing	A



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
Bedfordshire Hospitals NHS Foundation Trust Lewsey Road Luton Bedfordshire LU4 0DZ Marie Sprakes Tel: +44 (0)1582 718141 E-Mail: Marie.Sprakes@ldh.nhs.uk	Mortuary Services (body receipt, storage and release)	A
Hospital Wards, Clinics and Outpatients Luton & Dunstable University Hospital NHS Trust Site - as above Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing – Clinical Chemistry	B
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 – Clinical Chemistry	C
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 – Clinical Chemistry	D
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 – Clinical Chemistry	E
Limb Fitting Travel Lodge Dunstable Rd Luton Bedfordshire Alison McAuliffe Tel: +44 (0)1582 497991 E-Mail: Alison.McAuliffe@ldh.nhs.uk	Point of Care Testing – Clinical Chemistry	F



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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 Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation of selected culture media using in-house procedures: MMSOP 0069 Wound Swab MMSOP 0019 Gynae MMSOP 0036 Nose Swab, MMSOP 0030 Investigation of Throat Related Specimens, MMSOP0025 Eye Swab MMSOP 0026 Fluids from sterile sites MMSOP 0022 Investigation of Bronchoalveolar Lavage, Sputum and Associated Specimens</p>	A
Urine	General isolation and characterisation of micro-organisms of clinical significance and antimicrobial susceptibility testing	MMSOP060 Investigations of urine MMSOP 0015 in conjunction with manufacturer's instructions using Mast Urisystem	
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Inverted microscopy in conjunction with MMSOP 0060 Investigations of urine	
Fluids from CSF, ascetic 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	
Swabs from nose, perineum and wound sites	Isolation of MRSA	<p>Manual inoculation of chromogenic agar using MMSOP0077 Investigation of MRSA</p> <p>Realtime PCR using: MMSOP 0038, Cepheid MRSA NxG assay and Cepheid GeneXpert</p>	



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HUMAN TISSUES AND FLUIDS	<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)	A
Urine	Detection of: <i>Legionella pneumophila</i> serotype 1 antigen <i>Streptococcus pneumonia</i> soluble antigen	Membrane immunochromatographic assay using: MMSOP 0056/0061, Binax NOW Legionella and Pneumococcal urinary antigens kits and: Alere Reader	
Faeces	Isolation of bacterial enteric pathogens: <i>Clostridium difficile</i> , <i>E. coli</i> O157, <i>Salmonella</i> sp., <i>Shigella</i> spp.	Manual inoculation of selected culture media using in-house procedure MMSOP 0063 Faeces and MMSOP 0012 C.difficile	
Faeces	Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B	Realtime PCR using: MMSOP 0038, Cepheid Xpert C. difficile assay and: Cepheid GeneXpert	
Faeces	Detection of Norovirus GI and GII antigens	Rapid membrane ELISA using: MMSOP 0012 and TechLab C. DIFF QUIK CHEK COMPLETE	
Faeces	Detection of <i>Helicobacter pylori</i> antigens	Rapid membrane immunoassay using MMSOP 0010 and ProLab Proflow Norovirus test	
Faeces	Detection of <i>Helicobacter pylori</i> antigens	Realtime PCR using: MMSOP 0038, Cepheid Xpert Norovirus assay and: Cepheid GeneXpert	
Faeces	Detection of <i>Helicobacter pylori</i> antigens	Rapid lateral flow immunoassay using MMSOP 0017 and Meridian Bioscience ImmunoSTAT HpSA	
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	



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HUMAN TISSUES AND FLUIDS	<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)	A
Blood	Isolation of clinically significant bacteria and fungi	Automated culture using: Biomerieux BACT/ALERT VIRTUO Microbial Detection System and procedures MMSOP 0001	
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)	Automated culture using: Biomerieux BACT/ALERT 3D Microbial Detection System, MMSOP 0028 and Realtime PCR using: MMSOP 0038, Cepheid Xpert MTB/RIF Assay and: Cepheid GeneXpert	
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	
Nasopharyngeal aspirates	Detection of RSV fusion protein antigen	Automated multiplex real-time RT-PCR using the Cobas Liat System in conjunction with manufacturer's instructions and procedure MMSOP 0018	



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HUMAN TISSUES AND FLUIDS	<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)	A
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	
Hair, skin scrapings and nail clippings	<u>Mycological examination activities for the purpose of clinical diagnosis</u> General isolation and characterisation of fungi of clinical significance	MMSOP 0041 Manual method using direct microscopy of KOH digested samples and culture on slopes	
Serum	<u>Serological examination activities for the purpose of clinical diagnosis</u> Detection of: Hepatitis A IgM, total HAV Rubella IgM and IgG CMV IgG and IgM Toxoplasma Total Antibody Mumps IgG Measles IgG <i>Varicella zoster</i> IgG	Use of the Biomerieux Vidas 30(immunoassay) in conjunction with manufacturer's instructions and procedures: MMSOP 0074 Serological tests	
Serum	HIV antigen	MMSOP 0095 Blood Bourne viruses' investigation	



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HUMAN TISSUES AND FLUIDS	<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)	A
Serum	Detection of: Hepatitis E IgM and IgG	Fortress Diagnostics ELISA in conjunction with manufacturer's instructions and procedure MMSOP 0058 Hep E IgG & IgM Test	
Serum	Antistreptolysin-O	Latex agglutination using Biokit - Rheumajet ASO kit in conjunction with manufacturer's instructions and procedure MMSOP0053 Serological tests	
Cervix/Urethral/Vaginal swabs and urine	<u>Molecular examination activities for the purpose of clinical diagnosis</u> Detection of <i>Chlamydia trachomatis</i> and Neisseria gonorrhoea DNA, HSV 1 & 2 Trichomonas vaginalis NAAT testing	Strand Displacement Amplification (SDA) using the Becton Dickinson VIPER XTR in conjunction with manufacturer's instructions and procedure MMSOP 0006	
Plasma	HIV-1 Viral Load Hepatitis B Viral Load Hepatitis C Viral Load	In vitro nucleic acid amplification using Roche Cobas Ampliprep and TaqMan in conjunction with manufacturer's instructions and procedure MMSOP 0007	



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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	A
Whole Blood	FBC / Retic & NRBC count: Haemoglobin White Blood Count Platelet Count Red Blood Count Haematocrit MCV MCH MCHC RDW Hypochromic RBC % Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Large unstained cells Reticulocytes	Beckmann Coulter DxH900 analyser using flow cytometry, impedance and spectrophotometry, laser light scatter, calculated parameters with specific reference to procedures: HSOP0005	
Plasma	Coagulation Screen: Prothrombin time Prothrombin time correction with normal plasma APTT APTT correction with normal Plasma Clauss fibrinogen D Dimer Low molecular weight heparin	Werfen TOP500 Coagulometric Chromogenic and Immunological: based on procedures: HSOP0100, HWI0100A, HWI0100B, HWI0100C, HWI0100D, HWI0100E, HWI0101A, HWI0101B, HWI0101C, HWI0101D, HWI0101E	
Whole blood: citrated	Erythrocyte Sedimentation Rate (ESR)	Menarini Vesmatic Red cell sedimentation measurement based on procedures: HSOP0300, HWI0300A, HWI0300B	



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Whole blood	Haemoglobinopathy Screening: HbA2, HbF, HbA, HbS, HbC, HbD, HbE	BioRad Variant II by HPLC based on procedures: Documented in-house methods to meet the requirements of the Sick cell and Thalassaemia screening programme, as defined in the as defined in the July 2018 Sick cell and Thalassaemia screening programme: laboratory QA evidence requirements HSOP0600, HWI0600A, HWI0600B, HWI0600C, HWI0600D, HWI0600E, HWI0600F, HWI0600G	
HUMAN BODY FLUIDS Plasma	<u>Haematological examination activities for the purpose of clinical diagnosis</u> Thrombophilia Screening: Anti-thrombin 3 activity Protein C activity Free Protein S level Thrombin time Reptilase time Thrombophilia screening: Anti-thrombin 3 activity Protein C activity Clotting Factor Assays: Factor II Assay (FAC2) Factor V Assay (FAC5) Factor VII Assay (FAC7) Factor VIII Assay (FAC8) Factor VIII B-Domain Depleted Assay (FAC8BDD) Factor VIII Chromogenic Assay (FAC8CHR) Factor IX Assay (FAC9) Factor X Assay (FAC10) Factor IX Assay (FAC11) Factor XII Assay (FAC12)	Using manufacturer's instructions and documented in-house procedures Werfen TOP500 Coagulometric Chromogenic and Immunological: based on procedures HSOP0100, HWI0100A, HWI0100B, HWI0100C, HWI0100D, HWI0100E, HSOP0101, HWI0101A, HWI0101B, HWI0101C, HWI0101D, HWI0101E	A



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Whole Blood	G6PD screen	Trinity Biotech G-6-PDH screening test kit using red cell enzyme rate reaction based on procedures: HSOP0505, HWI0505	
HUMAN BODY FLUIDS	<p><u>Haematological examination activities for the purpose of clinical diagnosis</u></p> <p>Film examination and reporting of normal and abnormal morphologies manual white cell differential</p> <p>Screening for the detection of <i>Plasmodium falciparum</i> and <i>Plasmodium</i> spp. Including: <i>Plasmodium ovale</i> <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>Manual Romanowsky stain and Microscopy based on procedures: HWI0500A, HWI0500B, HWI0500C, HWI0500D, HWI0500E, HWI0500F, HWI0500G</p> <p>CareStart RapydTest Malaria antigen kit</p> <p>HSOP0502 HWI0502B</p> <p>Manual microscopy of thick films stained with Field's stain and thin films stained with Romanowsky stain based on procedures:</p> <p>HSOP0502, HWI0502A, HWI0502B, HWI0502C</p>	A



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HUMAN BODY FLUIDS	<p><u>Haematological examination activities for the purpose of clinical diagnosis</u></p> <p>Foetal Maternal Haemorrhage (semi quantitative)</p>	<p>Using manufacturer's instructions and documented in-house procedures</p> <p>Manual Kleihauer based on BCSH semi quantitative method using: Source Bioscience kit based on procedures: BTSOP0025</p>	A
<p>HUMAN TISSUES AND FLUIDS</p> <p>Body fluids: Serous and general body fluids Urine Bronchial Specimens Sputa Cerebrospinal Fluid (CSF) Brushings Fine Needle Aspirations (FNA) Endo-bronchial ultrasound (EBUS)</p> <p>Slides prepared in-house from sample types listed above</p>	<p><u>Diagnostic cytology</u></p> <p>Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p><u>Preparation/centrifugation</u></p> <p>Sample preparation using the Thermo Shandon Cytospin 4 in conjunction with manufacturer's instructions and in-house procedures: CPSOP 0301 CPWI 0301 D-K</p> <p><u>Haematoxylin & Eosin, May Grunwald Giemsa and Papanicolau Staining</u></p> <p>Automated staining the Leica ST5020 Staining Machines & Manual Coverslipper and in-house procedures listed above and: CPWI 0061A, CPWI 005 CPWI0052</p> <p><u>Microscopy (qualitative analysis)</u> In-house procedures: Reporting Results in Cellular Pathology CPSOP 003</p>	A



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed tissues</p>	<p><u>Histopathology</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: 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 CPWI0405 Protocols 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 0414 Protocols 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</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed tissues</p>	<p><u>Histopathology (cont'd)</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 (cont'd)</u></p> <p>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 0421 Protocol and Dataset for Skin Biopsy Specimens CPWI 0422 Specimen Macroscopy: Appendix CPWI 0423 Specimen Macroscopy: Gall Bladder CPWI 0424 Protocol for Soft Tissue "Tumours" CPWI 0425 Protocol and Dataset for Histopathology Reports for Testicular Tumours CPWI 0426 Protocols 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</p>	<p>A</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed tissues</p> <p>Formalin fixed tissues</p> <p>Formalin fixed paraffin embedded (FFPE) tissue</p>	<p><u>Histopathology</u> (cont'd)</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>Decalcification</u> Manual method using: CPWI 0045</p> <p><u>Tissue Processing</u> Automated method using: Leica ASP300s Tissue Processors and SOP Operation of the Leica Tissue Processors</p> <p><u>Embedding</u> Manual method using: Leica EG1140C & EG1150C cold plates - SOP Embedding Histology Blocks CPWI 0002 Leica HistoCore Arcadia H Embedding Centres/ HistoCore Arcadia C Cold Plate - SOP Embedding Histology Blocks CPWI 0002</p> <p><u>Microtomy</u> Manual method using: Leica RM 2235 Rotary microtomes - SOP Sectioning Histology Blocks CPWI 0057</p>	<p>A</p>



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Formalin fixed, paraffin embedded (FFPE) tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities		
FFPE tissue	Basophilic and eosinophilic tissue structures	<u>Routine Haematoxylin & Eosin (H&E) staining and coverslipping</u> 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	
	Detection of the following:	<u>Special staining</u> Manual methods using:	
	Acid mucins (sulphomucins & sialomucins)	SOP Alcian Blue for Acid Mucosubstances CPWI 0002A	
	Acid mucins (sulphomucins & sialomucins)	SOP Alcian Blue-PAS CPWI 0002B	
	Acid mucins (sulphomucins & sialomucins) Neutral mucins Mixed mucins	SOP Alcian Blue-PAS with Diastase Digestion CPWI 0002C	
	Amyloid	SOP Congo Red Stain for Amyloid CPWI 0002D	
	Collagen and muscle	SOP Miller's Elastic Van Gieson CPWI 0002F	
	Helicobacter Pylori	SOP Giemsa (For Helicobacter Pylori) CPWI0002H	
	Gram positive and gram-negative organisms	SOP Gram Stain CPWI 0002I	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>Special staining</u> (manual, cont'd)	
	Fungi	SOP Grocott Hexamine Silver Stain for Fungi CPWI 0002J	
	Haematoxylin Van Gieson	SOP Haematoxylin Van Gieson CPWI 0002L	
	Muscle & fibrin	SOP Masson Trichrome CPWI 0002M	
	<i>Helicobacter pylori</i> & <i>Helicobacter</i> -like organisms	SOP Modified Giemsa for Helicobacter Pylori CPWI 0002N	
	Hepatitis B antigen, elastic fibres and copper associated protein	SOP Orcein CPWI 0002O	
	Glycogen and other tissues containing aldehydes	SOP Periodic Acid-Schiff (PAS) Stain CPWI 0002P	
	Diastase Digestion PAS	SOP Diastase Digestion-PAS CPWI 0002E	
	Haemosiderin & ferric salts	SOP Perl's Prussian Blue CPWI 0002 R	
	Type IV collagen fibres (Reticulin)	SOP Gordon & Sweet Reticulin Stain CPWI0002Q	
	Sirius Red	SOP Sirius Red CPWI 0002S	
	Mast cells	SOP Toluidine Blue for Mast Cells CPWI 0002T	
	<i>Mycobacterium tuberculosis</i>	SOP Ziehl Neelsen Stain CPWI 0002U	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue	Detection of the following: Hepatocellular carcinomas, yolk sac tumours Epithelial marker T-cell lymphocytes Broad reactivity with epithelial cells. Mesothelial cells are negative Expressed in normal endometrial glands, ovary and cervix. Expressed in ovarian carcinoma Medullary thyroid tumour marker	<u>Immunohistochemistry</u> Automated methods using: Immunohistochemistry General Procedure CPSOP0101 – Histology Slides , SOP Bond Computer Procedure CPWI 0101D, SOP Bond Maintenance Schedule CPWI 0101E and: Leica Bond III and the following antibodies: Alpha Fetoprotein (AFP) Alpha-Methylacyl-CoA-Racemase (AMACR) Bcl-2 Epithelial Antigen (Ber-EP4) CA125 Calcitonin	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd) Useful in differentiating malignant mesothelioma from adenocarcinomas (in particular of the lung). Also used to differentiate adrenal cortical neoplasms from pheochromocytomas	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Calretinin	
	Liver: Malignant vs Benign, Pleura: Adenocarcinoma vs Mesothelioma, Carcinomas, HCC	Carcinoembryonic Antigen (CEA)	
	Preferred marker for T-cells. A polyclonal pan T antibody, but occasional T-cell neoplasms	CD3	
	Mantle cell lymphomas	CD5	
	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	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (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	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) CD15	
	Pan B-cell marker, also some Reed-Sternberg (RS) cells. Preferred marker for B-cells	CD20	
	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	
	Endothelial cells but also expressed on human lymphoid and myelopoetic progenitor cells. Useful to identify vascular tumours and characterise leukaemias	CD34	
	All lymphoid cells, variable reaction with macrophages, histiocytes, monocytes. Myeloid cells are unreactive	CD45 (Leucocyte Common Antigen)	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd) A cell adhesion molecule expressed by most neuroectodermal-derived tissues and their tumours. Also labels NK cells	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) CD56 (N-CAM)	
	Macrophages, myeloid cells and histiocytes and their derived neoplasms	CD68	
	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	
	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	CD138	
	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	



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue (cont'd)</p>	<p><u>Histopathology</u> (cont'd)</p> <p>Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)</p> <p>Detection of the following: (cont'd)</p> <p>Endocrine cells, neuroendocrine cells and their derived tumours</p> <p>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</p> <p>Intermediate filament protein expressed in simple, complex, transitional, ductal and glandular epithelium. Useful in distinguishing metastatic breast and colonic adenocarcinomas</p> <p>Basal and myoepithelial cells of human complex epithelia</p> <p>G I tract epithelium</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>Immunohistochemistry</u> (Automated Leica Bond III, cont'd)</p> <p>Chromogranin A</p> <p>Cytokeratin 5 (CK5)</p> <p>Cytokeratin 7 (CK7)</p> <p>Cytokeratin 17 (CK17)</p> <p>Cytokeratin 19 (CK19)</p>	<p>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (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) Reacts with gastric and intestinal epithelium, urothelium and Merkel cells. Useful in distinguishing between GI tract and breast adenocarcinomas Epithelial differentiation, Small round blue cell tumours, Specific soft tissue tumour Differential diagnosis: Carcinoma vs non- epithelial tumour Cytokeratins 1,5,10, and 14 Reacts with CMV infected cells 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 Transmembrane cell adhesion molecule in epithelial cells. Useful in identifying lobular breast carcinomas	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Cytokeratin 20 (CK20) Cytokeratin (AE1/AE3) Cytokeratin (CAM5.2) Cytokeratin High MWt (34betaE12) Cytomegalovirus (CMV) Desmin E-cadherin	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd) 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	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Epithelial Membrane Antigen (EMA)	
	Blood pro-enzyme that reacts with platelets, megakaryocytes, macrophages, dermal dendritic cells, and fibroblast-like mesenchymal or histiocytic cells. Useful in identifying dermatofibromas and malignancies	Factor VIII (Von Willebrand Factor)	
	Positive on membrane of mesothelial cells. Some adenocarcinomas are positive but show cytoplasmic staining	HBME-1 (Mesothelial Cell)	
	Epidermal growth factor receptor overexpression in adenocarcinomas of breast and GI tract origin. This is used for predicting the response to anti-EGFR treatment	HER2	
	Reacts with HSV Type1 infected cells	Herpes Simplex Virus Type 1 (HSV)	
	Melanocytic Lesions, PEComa, Adrenal tumours	HMB-45 (melanosome)	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd)	
	Germ cell tumour marker	Human Chorionic Gonadotrophin (hCG)	
	Polyclonal light chains of kappa type	Kappa	
	Ki-67 Protein	Ki-67 Antigen	
	Polyclonal light chains of lambda type	Lambda	
	Melanoma marker	Melan A	
	Smooth muscle	Myosin Heavy Chain Smooth Muscle (MHC-SM)	
	Neuroendocrine marker	Neurone Specific Enolase (NSE)	
	Oestrogen Receptor	ER	
	Nuclei and/or cytoplasm of carcinoma cells. Mutated in many tumours. Indicated in HPV infected cells	P16	
	Nuclei of tumour cells. A tumour suppressor gene. Overexpressed in many tumours	p53	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd) 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	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) p63	
	Confirming Uro-genital, Gynae tumours. Thyroid	PAX8	
	Germ cell tumour marker	Placental Alkaline Phosphatase (PLAP)	
	Breast tumour marker	Progesterone Receptor (PR)	
	Reacts with secretory and ductal epithelium in normal & neoplastic tissue	Prostatic Specific Antigen (PSA)	
	Melanoma and nerve cell marker	S100	
	Smooth muscle cells	Smooth Muscle Actin	
	Endocrine cells, neuroendocrine cells and their derived tumours	Synaptophysin	
	Positive in thyroid epithelium, thyroid tumours & follicular adenoma	Thyroglobulin	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue (cont'd)	Detection of the following: (cont'd) Thyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumours Vimentin intermediate filament Wilm's and mesothelioma tumour marker	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Thyroid Transcription Factor (TTF-1) Vimentin WT1	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	<u>Microscopy (qualitative analysis)</u> In-house procedures: Reporting Results in Cellular Pathology CPSOP 0003	



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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	A
Serum (unless stated otherwise)		Automated using the Roche Cobas c702 module photometric assay CBSOP 0201.1	
and Urine, Fluids, CSF	Albumin		
Plasma	Alcohol		
	ALP		
	ALT		
Plasma	Amikacin		
and Urine	Ammonia		
	Amylase		
	AST		
and Urine	Beta-hydroxybutyrate		
	Bicarbonate		
and Fluids	Bile Acids		
	Bilirubin (total)		
	C3 Complement		
	C4 Complement		
and Urine	Calcium		
	Carbamazepine		
and Urine	Chloride		
	Cholesterol		
and Fluids	Conjugated Bilirubin		
	Creatine Kinase		
	Creatinine (enzymatic)		
and Urine, Fluids	Creatinine (jaffe)		
	CRP		
	Digoxin		
	Gamma-glutamyl-transferase		
and Urine, Fluids, CSF,	Gentamycin		
Plasma	Glucose		
	HDL Cholesterol		
	Immunoglobulin A		
	Immunoglobulin G		
	Immunoglobulin M		
and Fluids, CSF	Iron		
	Lactate Dehydrogenase		
	Lithium		



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless stated otherwise) (cont'd)</p> <p>and Urine</p> <p>Urine, Fluids, CSF</p> <p>Urine, Fluids, CSF</p> <p>and Urine</p> <p>and Urine, Fluids</p> <p>and Urine, Fluids</p> <p>and Urine, Fluids</p> <p>and Urine, Fluids</p> <p>Plasma</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Magnesium</p> <p>Micro total Protein</p> <p>Microalbumin</p> <p>Paracetamol</p> <p>Phenytoin</p> <p>Phosphate</p> <p>Protein</p> <p>Rheumatoid Factor</p> <p>Salicylate</p> <p>Theophylline</p> <p>Tobramycin</p> <p>Transferrin</p> <p>Triglyceride</p> <p>Urate</p> <p>Urea</p> <p>Vancomycin</p> <p>Chloride</p> <p>Potassium</p> <p>Sodium</p> <p>Alpha-feto protein</p> <p>Anti-TPO</p> <p>BNP</p> <p>CA125</p> <p>CA199</p> <p>CEA</p> <p>Cortisol</p> <p>Ferritin</p> <p>FSH</p> <p>FT3</p> <p>FT4</p> <p>HCG</p> <p>LH</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Automated using the Roche Cobas c702 module photometric assay CBSOP 0201.1</p> <p>Automated using the Roche Cobas ISE module using ion selective electrodes CBSOP 0201.1</p> <p>Automated using the Roche Cobas e602 module using electrochemiluminescence CBSOP 0201.1</p>	<p>A</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	A
Serum (unless stated otherwise)	Oestradiol Progesterone Prolactin PSA PTH Serum Folate SHBG Testosterone Troponin T TSH Vitamin B12	Automated using the Roche Cobas e602 module using electrochemiluminescence CBSOP 0201.1	A
	pH pCO2 K+ Na+ Cl- cLac pO2 ctHb sO2 FO2Hb 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
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	
	HbA1C	Menarini HB 9210 Boron Affinity CBSOP 0219.1	



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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	A
Sweat	Chloride Conductivity	Wescor Chlorocheck Model 3400 using LI-BIO-SwtWcrSOP and measurement principle stated: Coulometric Conductivity	
Serum	<u>Immunological examinations for the purpose of clinical diagnosis</u> Total IgE 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)	Enzyme-linked fluorescence using in-house procedures: ISOP 0015 in conjunction with manufacturer's instructions using: ImmunoCAP 250	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless stated otherwise) (cont'd)</p>	<p><u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Specific IgE (cont'd):</p> <p>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) IgA Tissue Transglutaminase Antibodies Cyclic Citrullinate Peptide (CCP) Antibodies IgG and IgM Cardiolipin Antibodies CTD (ANA) Screen dsDNA Antibodies</p> <p>Detection of 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 Histomes Ribosomal P-protein</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Enzyme-linked fluorescence using ISOP 0015 in conjunction with manufacturer's instructions using:</p> <p>ImmunoCAP 250</p> <p>EuroImmuno ANA Profile-3 Immunoblot assay ISOP0017</p>	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	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 EuroBlotMaster procedures ISOP0016, ISOP0016A and EuroImmuno Myositis Antigens Profile 3 Kit	
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 Diseases Kit	
Serum	Hep-2 ANA	INOVA NovaLite Hep-2 ANA Kit by Immunofluorescence ISOP0002, ISOP0002A	
Serum	Vitamin D	IDS iSYS Chemiluminescence assay ISOP0027A	
Faeces	Faecal Calprotectin	Dynex DS2 Buhlmann Calprotectin ELISA assay LP-BIO-SOPCalp	
Serum	Serum protein electrophoresis, Paraprotein levels Immunotyping	Sebia Capillarys 2 analyser using Capillary zone electrophoresis and Immunosubtraction: LI-BIO-SOPSebCp2	
Urine	Urine protein electrophoresis Urine protein immunofixation		
Serum, Plasma	Detection of cryoglobulin	Manual screening for Cryoglobulinaemia LI-BIO-SOPCryo	



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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	A
Urine	Total protein Glucose Ketones Urobilinogen Bilirubin Nitrites Erythrocytes/haemoglobin pH	Combur 9 Dip stick testing strips using: ISOP0029	
Whole Blood	<u>Provision of Point of Care testing in accordance with ISO 22870: 2016 related to the following:</u> Glucose	Electrical detection of enzyme reaction on test strip using Roche Accu-Chek Inform II and procedure PTSOP 0007	B,C,D,E, F
	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	B



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END			

Hospital Wards, Clinics and Outpatients Luton & Dunstable University Hospital NHS Trust Site - as above		B
	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 Assessment Unit	X	
Respiratory Nurses	X	
SCBU ITU (NICU 1)	X	x
St Marys Care Unit	X	
Surgical Arrivals (Ward 21)	X	



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Surgical Outpatients	X	
Surgical Short Stay Unit	X	
Surgical Short Stay Unit Recovery 3	X	
Theatres - Gynaecology	X	
Theatres 1 to 6	X	
Hospital Wards, Clinics and Outpatients Luton & Dunstable University Hospital NHS Trust Site - as above		B
	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



8212
Accredited to
ISO 15189:2012

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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Bedfordshire Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 August 2021

Testing performed by the Organisation at the locations specified

Ward 6	X	
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Off site POCT as listed	
Site	Roche AccuChek Inform II
C	X
D	X
E	X
F	X