


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9560</p> <p>Accredited to ISO 15189:2022</p>	<p>Mersey and West Lancashire Teaching Hospitals NHS Trust</p> <p>Issue No: 018 Issue date: 12 May 2026</p>	
	<p>Pathology Department Warrington Hospital Lovely Lane Warrington WA5 1QG United Kingdom</p>	<p>Contact: Victoria Williamson Tel: +44 (0)1925 275592 E-Mail: victoria.williamson8@nhs.net Website: www.whh.nhs.uk/ServiceCatInfo.asp?id=31</p>

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
<p>Address Pathology Department Warrington Hospital Lovely Lane Warrington WA5 1QG</p> <p>Local contact Victoria Williamson Tel: +44(0)1925 275592</p>	<p>Histology Haematology Blood Transfusion Biochemistry Microbiology Virology Immunology Mortuary: Storage and release of bodies Hospital and Coronial Post-mortems Retrieval of tissue from Post-mortem</p>	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Address Halton Hospital Hospital Way Runcorn WA7 2DA</p> <p>Local contact Victoria Williamson Tel: +44(0)1925 275592</p>	<p>Biochemistry Haematology Blood Transfusion Mortuary: Storage and release of bodies</p>	B



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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 BODY TISSUE and FLUIDS</p> <p>Cytology samples: CSF, urine, general body fluids, bronchial brushings, EBUS, FNA</p>	<p><u>Cytological examination activities for the purposes of clinical diagnosis</u></p> <p>Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities.</p>	<p>In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:</p> <p>In-house documented procedures using:</p> <p>Slide Preparation using VWR megastar 600 Centrifuge</p> <p>ThermoFisher Cytospin: HCNG-1</p> <p>Production of agar cell block: HC-NG-1</p> <p>PAP Staining using Lecia autostainer: HCCU-1</p> <p>Diff Quick staining: HC-NG-1</p>	<p>A</p>



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HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Tissue samples: Formalin fixed paraffin embedded (FFPE), fresh and frozen.	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination supported by: Histology cut-up Using manual methods. SOP: HC-CO-47 Dissection of small specimens using manual methods. SOP: HC-CU29 Dissection of large spec using manual methods. SOP: HC-PA-2, HC-PA-7, HC-PA-8, HC-PA-14, HC-PA-33, HC-PA-38, HC-PA-47, HC-PA-53 Tissue Processing using Thermofisher Excelsior AS. SOP: HC-CU-14	A
Formalin fixed paraffin embedded (FFPE), fresh and frozen tissue samples	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination supported by: (cont'd) Embedding using Thermofisher Histostars. SOP: HC-BS-12 Section Cutting using Leica Histocore Multicut microtomes. SOP: HC-BS-12 Automated H&E staining by Sakura autostainer and cover-slipper using SOP HC-BS-12	A
Formalin fixed paraffin embedded (FFPE), fresh and frozen tissue samples	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Decalcification using Faxitron HC-CU-31	A



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HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Stained FFPE slides/ Cytology prepared slides	Morphological assessment/interpretation and diagnosis of Histological and Cytological specimens	Microscopy using a range of consultant grade microscopes with Medical Reporting via MOLIS AP LIMS software using SOP HC-CO-45	A
Formalin-fixed paraffin embedded tissue slides	Demonstration of:	Special Tinctorial Histochemical Staining Methods SOP Manual techniques	A
	Basophilic and eosinophilic structures	Routine H&E staining using a manual method SOP: HC-SS-11	A
	Acid mucins	Alcian Blue Technique using a manual method. SOP: HC-SS-4	A
	Acid and Neutral mucins	Alcian Blue – Periodic Acid-Schiff ± Diastase using a manual method. SOP HC-SS-4	A
	Bacteria	Gram Stain using a manual method. SOP: HC-SS-9	A
	Connective tissue	Van Gieson using a manual method. SOP: HC-SS-22	A
	Fungi or Pneumocystis	Grocott Methenamine using a manual method. SOP: HC-SS-10	A
	Glycogen and mucins	PAS ± Diastase using a manual method. SOP: HC-SS-4	A
	Haemosiderin	Perl's Prussian Blue Stain using a manual method. SOP: HC-SS-18	A
	Inclusion bodies/ reticulin	Orcein (Shikata) Stain using a manual method. SOP: HC-SS-20	A
	Mast cells	Toluidine Blue using a manual method. SOP: HC-SS-21	A



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Formalin-fixed paraffin embedded tissue slides (cont'd)	Demonstration of: (cont'd)	Special Tinctorial Histochemical Staining Methods SOP Manual techniques	A
	Melanin	Masson Fontana using a manual method. SOP: HC-SS-13	A
	M Tuberculosis	Ziehl Neelsen (ZN) using a manual method. SOP: HC-SS-24	A
	Reticulin Fibres	Gordon and Sweet Stain using a manual method. SOP: HC-SS-19	A
	Elastin	Miller's Elastic Van Gieson using a manual method. SOP: HC-SS-16	A
Formalin-fixed paraffin embedded tissue slides	Immunohistochemistry for the detection of:	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra Plus SOP: HC-IM-17 and HC-IM-18; incorporating the following antibodies: -	A
	Squamous epithelium, follicular epithelia in thyroid, epithelia and mesothelium in small and large bowel	34Be12 (HMWCK)	A
	Smooth Muscle, soft tissue tumour such as leiomyosarcomas	Actin (SMA)	A
	Follicular and diffused large cell lymphomas from reactive lymph nodes	BCL-2	A
	Diffuse large B cell lymphomas and Burkitt's lymphoma and Reed Sternberg cells in Hodgkin's disease	BCL-6	A



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HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra Plus SOP: HC-IM-17 and HC-IM-18; incorporating the following antibodies: -	A
	Epithelial Cells of the Colon.	BerEP4	A
	Luminal cells of fallopian tubes, Ovarian epithelial malignancies	CA125	A
	Classification of mesothelial cells and malignant mesothelioma of the epithelial type	Calretinin	A
	Adenocarcinoma of intestinal origin	CDX2	A
	Normal and neoplastic T cells from thymocytes to mature T cells	CD3	A
	Inducer T cells both normal and neoplastic	CD4	A
	T cell lymphomas and mantle cell lymphoma	CD5	A
	All germinal centre cells – tonsil Renal cell carcinoma	CD10	A
	Granulocytes, Reed-Sternberg cells.	CD15	A
	B cells	CD20	A



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HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra Plus SOP: HC-IM-17 and HC-IM-18; incorporating the following antibodies: -	A
	Small B cell lymphocytic lymphoma.	CD23	A
	Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells	CD30	A
	Endothelial cells. Benign and malignant vascular disorders	CD31	A
	Leucocyte differentiation	CD34	A
	All Leucocytes	CD45 (LCA)	A
	Neural / neuroendocrine tissue and natural killer cells	CD56	A
	Macrophages	CD68	A
	Adenocarcinoma	CEA	A
	Neuroendocrine cells	Chromogranin A	A
	Glandular and stratified squamous epithelium	CK (AE/AE3)	A
	Myoepithelial cells of the prostate / breast. Squamous cell carcinoma	CK5/6	A



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HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra Plus SOP: HC-IM-17 and HC-IM-18; incorporating the following antibodies: -	A
	Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell	CK7	A
	Epithelial cells	CK8/18	A
	Basal cell marker	CK14	A
	Columnar cell epithelium	CK20	A
	Smooth and striated muscle tumours	Desmin	A
	Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast	E-Cadherin	A
	Variety of normal and neoplastic epithelia	EMA	A
	Oestrogen receptors breast carcinoma	ER	A
	CerbNeu protein	HER2	A
	Melanoma cells	HMB-45	A
	Melanoma	Melan A	A
	Proliferating cells in germinal B cells	MIB-1 (Ki67)	A



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HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra Plus SOP: HC-IM-17 and HC-IM-18; incorporating the following antibodies: -	A
	Breast carcinoma	Progesterone	A
	Prostate secretory and ductal epithelium	PSA	A
	Malignant change in cervical epithelium, HPV	P16	A
	Expression in squamous, urothelial, myoepithelial / basal cell differentiation	P40	A
	Tumour suppress protein	P53	A
	Epithelial neoplasms	GATA 3	A
	Prostate basal cells, glandular epithelium	P63	A
	Schwann cells, adipocytes, cartilage	S100	A
	Islets of Langerhans cells	Synaptophysin	A
	Lymphomas in lung and thyroid.	TTF-1	A
	Cells of mesenchymal origin	Vimentin	A
	Helicobacter pylori		A
FFPE Tissue Sections	Digital Reporting of Histology Section Images	UFC Phillips Digital Scanner and IMS Software SOP: HC-DIG-1, HC-DIG-2	A



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HUMAN BODY FLUIDS as specified below:	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Whole Blood	Full Blood Count and differential leucocyte count (Hgb, RCC, WCC, PLTS, Hct, MCV, MCH, MCHC Neutrophils, lymphocytes, monocytes, eosinophils, basophils)	Automated Sysmex XN9000 Track system containing 2 x XN20 & 1 x XN10 Analysers. SOPs: H021, H024, H061	A
	Reticulocyte count	Sysmex XN550 Analyser SOPs H414, H418, H419, H420, H422	B
		Automated Sysmex 2 x XN20 Track system Analyser. SOP: H021	A
	Normal/abnormal morphologies and WBC differential	Sysmex SP50 Automated Slide-maker /Stainer and DI60 digital morphology SOPs: H060, H054, H070, H053	A
		Manual staining using MGG SOP:H071	A
	Erythrocyte Sedimentation Rate	Starrsed Interliner FRL Analyser SOP: H004, H005, H006, H007 Manual: Sediplast ESR (Westergren) SOP: H008	A
	Detection of Heterophile antibody	Clearview IM II Glandular Fever Screening Kit SOP: H029	A
Detection and speciation of malaria parasites; - Plasmodium vivax - Plasmodium falciparum - Plasmodium ovale - Plasmodium malariae - Plasmodium knowlesi	Manual staining using Field's stains and light microscopy. SOP: H033, H070	A	



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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Whole blood	Malaria Antigen Screening for detection of: - Plasmodium falciparum and pan-detection of: - Plasmodium falciparum - Plasmodium malariae - Plasmodium ovale - Plasmodium vivax	CareStart™ RPYDTEST – Malaria Antigen Screening Test SOP: H031	A
Bone marrow	Bone marrow assessment for the detection of abnormal cell types, morphology and numbers	Sysmex SP50 Automated Slide-maker /Stainer and light microscopy. SOP's: H050, H054, H060	A
Bone Marrow/urine	Detection of iron	Perl's stain and light microscopy SOP: H035	A
Plasma	Routine Coagulation (PT/APTT/Fibrinogen/D-Dimer/Thrombin Time, INR, APTT ratio, Coagulation correction tests)	Sysmex CS5100 Automated Coagulation Analyser (Warrington) & Sysmex CS2500 Automated Analyser (Halton) SOPs: H203, H206, H207, H208, H210, H211, H212, H213, H218, H239	A, B
Plasma	PT/APTT	Manual techniques using Siemens reagents SOP H206, H208	A, B
Plasma	Specialist Coagulation (Factor Xa)	Sysmex CS5100 Automated Coagulation Analyser SOPs: H215	A
Plasma	Thrombophilia Screening (ATIII, Protein C, Protein S, APCR, Lupus Screen)	Sysmex CS5100 Automated Coagulation Analyser SOPs: H220, H222, H223, H224, H225 & H226	A



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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme, as defined in the as defined in the July 2018 Sickle cell and Thalassaemia screening programme: laboratory QA evidence requirements (testing identified by *)	
Whole blood	Identification and quantitation of Haemoglobin/haemoglobin variants*	Haemoglobinopathy screening by Automated HPLC using TOSOH G8 SOPs: H303, H313, H314, H315, H316, H317, H318 & H319	A
Whole blood	Sickle Cell Screen (HbS)	Qualitative solubility test for detection of the presence of HbS in human blood using Streck Sickledex Kit. SOP H308	A



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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Whole Blood	Blood group/phenotype and antibody screen A, B, O and AB groups Rh groups, antigens-; C, c, D, E, e, Kell blood group system, antigens: K	Automated Ortho Vision Analyser SOPs: T139, T140 & T141	A
	Blood group/phenotype and antibody screen A, B, O and AB groups Rh groups, antigens-; C, c, D, E, e, Kell blood group system, antigens: K	Manual using Ortho Biovue technique and Ortho Biovue pipette and Workstation. SOPs: T076, T018, T019, T020	A, B
Blood (Plasma)	Antibody identification • Rh blood group system, antigens: C,c,D,E,e • Kell blood group system, antigens: K • Kidd blood group system, antigens: Jka, Jkb, • Duffy blood group system, antigens: Fya, Fyb, • MNS blood group system, antigens: M, N, S, s, • Lewis blood group system, antigens: Lea,Leb • Lutheran blood group system, antigens: Lua, Lub • P blood group system, antigens: P1	Automated Ortho Vision Analyser SOPs: T023, T123	A



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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood (Plasma)	Antibody identification <ul style="list-style-type: none"> • Rh groups, antigens: C, c, D, E, e, • Kell blood group system, antigens: K • Kidd blood group system, antigens: Jka, Jkb, • Duffy blood group system, antigens: Fya, Fyb, • MNS blood group system, antigens: M, N, S, s, • Lewis blood group system, antigens: Lea, Leb • Lutheran blood group system, antigens: Lua, Lub • P blood group system, antigens: P1 	Manual using Ortho Biovue technique and Ortho Biovue pipette and Workstation. SOPs: T023, T018, T123, T142	A, B
Whole Blood (Recipient and donor)	Cross match (compatibility testing of patient's plasma with donor red cells) associated provision of blood /blood components.	Automated Ortho Vision Analyser SOP: T028	A
Whole Blood (Recipient and donor)	Cross matching (Compatibility testing of patient's plasma with donor red cells) associated provision of blood /blood components.	Manual using Ortho Biovue technique and Ortho Biovue pipette and Workstation. – SOPs T028, T018, T142	A, B



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Whole Blood (Recipient and donor)	Measurement of Foetal Hb in maternal blood for FMH determination	Guest Medical Foetal Red Cell Detection Kit (Kleihauer) SOP: T059	A
Whole Blood (Recipient and donor)	Neonatal Serology including blood grouping A, B, O and AB groups, Rh groups & provision of blood /blood components	Ortho Vision Analyser SOPs: T139, T140 & T141	A
Whole Blood (Recipient and donor)	Direct Antiglobulin	Ortho Vision Analyser (Automated) – SOP T057, T139, T140 & T141 Manual using Ortho Biovue technique and Ortho Biovue pipette and Workstation – SOPs T028, T018, T019, T020	A, B



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<p>HUMAN TISSUES AND FLUIDS as specified below:</p> <p>Aspirates Cellular and Fluid material contained on swabs Cannulae Corneal Scrapes/Contact lens fluid Faeces Fluids Genital Samples Pus Samples from sterile sites Tissues Urine CSF</p> <p>Whole Blood</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p>General isolation of micro-organisms of clinical significance</p> <p>General isolation of micro-organisms of clinical significance</p>	<p>In house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMI's)</p> <p>Manual inoculation (SOP MF131 – Inoculation of culture media for bacteriology) followed by culture using SOPs: MF49 – sterile sites MF50 – cannulae MF51 – skin/superficial soft tissue MF57 – faeces MF83 – bacterial eye infections MF136 – genital tract MF86 – MRSA screen MF88 – urine MF90 – CSF MF107 – respiratory samples MF110 – pus and exudates MF111 – Orthopaedic tissue MF127 – Ear MF128 – Paranasal sinuses MF129 – Superficial mouth MF130 - Throat</p> <p>Automated blood culture using the BacTAlert analyser. SOP's: ME2 – Blood Culture registration MF26 – Sepsis and systemic or disseminated infections</p>	<p>A</p> <p>A</p>



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Skin/Nail	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic and microscopic examination (stained and unstained) SOP: MF117 – Dermatological specimens for superficial mycosis	A
Urine	Quantification of White Blood Cells, Red Blood Cells and Bacteria	Sysmex UF 5000 – Flow cytometry using automated urine analysers x2 SOP's: MF88 – Urine Culture (including automated cell count and manual culture where required)	A
Aspirates Corneal Scrapes Eyes Fluids Tissues	<u>Microscopy</u> Detection of Bacteria, Yeast cells and fungal hyphae	Microscopic examination using: MF114 – Staining Procedures	A
Cerebral Fluid Samples	Quantification of white blood cells and red blood cells	Microscopic examination using: MF90 – CSF	A
Faeces	Detection of ova, cysts and parasites	Unstained direct microscopic examination and formol ether faecal concentration and microscopic examination using: MF41 – Investigation of specimens other than blood for parasites	A



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<p>HUMAN TISSUES AND FLUIDS as specified below: (cont'd)</p> <p>Ascitic Fluid</p> <p>Genital Tract</p> <p>Cultures isolated in-house from all samples previously listed.</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Microscopy</u> (cont'd)</p> <p>Investigation for Spontaneous Bacterial Peritonitis Quantification and differential of white blood cells</p> <p>Examination of genital specimens for the presence of Gonococci, Yeast, Bacterial vaginosis</p> <p>Identification of microorganisms of clinical significance</p>	<p>In house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMI's)</p> <p>Microscopic examination using: SOP: MF59 – Specimen Culture: Fluids from normally sterile sites</p> <p>Gram stained microscopic examination by manual methods or semi -automated method using Polystainer using SOP: MF126</p> <p>Manual and/or automated methods using: VITEK MS (Matrix-Assisted Laser Desorption/Ionisation) using SOPs: MF121 – VITEK MS MF122 – VITEK MS instrument management</p> <p>VITEK 2 Compact (x2) using colorimetric reactions from individual wells containing test substrate.</p> <p>SOP's: MF46 – Automated organism identification</p> <p>MF118 – VITEK 2 Compact instrument management</p>	<p>A</p> <p>A</p> <p>A</p>



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<p>HUMAN TISSUES AND FLUIDS as specified below: (cont'd)</p> <p>Bacterial cultures isolated in-house from all samples previously listed:</p> <p>Enterobacteriaceae isolates from urine only</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Antibiotic Sensitivity Testing of clinically significant bacteria</p>	<p>In house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMI's)</p> <p>Manual and/or automated antimicrobial susceptibility testing by EUCAST guidelines</p> <p>VITEK 2 Compact (x2)—analysis of microbial growth in microwells with varying concentration of antibiotic</p> <p>VITEK XL – analysis of microbial growth in microwells with varying concentration of antibiotic</p> <p>SOP: MF46 – Vitek 2 systems (Compact and XL)-Automated Organism Identification and Antibiotic Sensitivity testing.</p> <p>Manual techniques using SOPs: MF120 – Antibiotic Sensitivity Testing: manual disc diffusion and MIC MF29 – Carbapenemase producers MF62 – Detection of ESBL's</p>	<p>A</p>



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HUMAN TISSUES AND FLUIDS as specified below: (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMI's)	
Faeces	<u>Immunoassays</u> Detection of C.difficile GDH/Toxin A and B	Detection of GDH and toxins A and B using the TechLab® C.Diff Quik Chek Complete rapid membrane enzyme immunoassay. SOP:MF35 – C.difficile toxin testing in faecal specimens.	A
Urine	Detection of Pneumococcal urinary antigen	The qualitative detection of Streptococcus pneumoniae antigen in urine using an immunochromatographic assay – BinaxNOW. SOP: MV2 – Detection of pneumococcal antigen	A
Urine	Detection of legionella pneumophila serogroup 1 urinary antigen	The qualitative detection of Legionella pneumophila serogroup 1 antigen in urine specimens using a rapid immunochromatographic assay using BinaxNOW SOP: MV26	A



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HUMAN TISSUES AND FLUIDS as specified below: (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures following UK Health Security Agency (UKHSA) SMI's	
	<u>Infectious Disease tests</u>	Documented in-housed methods to meet the requirements of the of Infectious Diseases in Pregnancy Screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy Screening Programme: laboratory QA evidence requirements'	A
Serum	Hepatitis A IgM HBsAg HIV Ab/Ag (combo) Anti-HBs HB Core Ab (Total) HCV ab Rubella IgG Syphilis total Ab	Immunoassay using Siemens Advia Centaur analysers (Biochemistry) SOP: MV4/MV5/MV6/MV7/MV8/MV12	A
Serum	Detection of specific antibodies <ul style="list-style-type: none"> • CMV IgG and IgM • EBV EBNA IgG • EBV VCA/EA IgG • EBV VCA IgM • Measles IgG Varicella Zoster IgG	ELFA (Enzyme Fluorescent Assay) by VIDAS 3 Immuno-analyser using SOP: MV3/MV9/MV10/M24	A
	<u>Miscellaneous activities for the purpose of clinical diagnosis</u>		
Joint Fluids	Detection of crystals for diagnosis of gout and pseudo gout: <ul style="list-style-type: none"> • Monosodium urate Calcium pyrophosphate	Polarised light microscopy SOP: MF49 – Specimen culture: Fluids from normally sterile sites	A



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HUMAN TISSUES AND FLUIDS as specified below: (cont'd)	<u>Molecular Examination activities for the purpose of clinical diagnosis</u>	In house documented procedures following UK Health Security Agency (UKHSA) SMI's	
MRSA Screens (Nasal swabs)	Detection of MRSA	Real-time PCR by the GeneXpert (Cepheid) analyser: SOP: MF59	A
Faeces	Detection of genes for C. difficile toxin b/binary toxin	Real-time PCR by the GeneXpert (Cepheid) analyser SOP: MF35	A
Faeces	Detection of Norovirus	SOP:MF144	A
Rectal Swabs	Detection of Carbapenemase encoding genes blaVIM, blaNDM, blaOXA, blaKPC and blaIMP	Xpert Carba-R assay SOP: MF143	A
CSF	Detection of multiple target sites: <ul style="list-style-type: none"> • Neisseria meningitidis • Streptococcus pneumoniae • Haemophilus influenza • Enterovirus • HSV1 and 2 • Varicella Zoster Human Parechovirus	Qualitative multiplexed nucleic acid test by FilmArray (Bio Fire) ME panel using SOP: MF124	A



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<p>HUMAN SAMPLES AND TISSUES</p> <p>Serum/Plasma</p> <p>Serum/Plasma</p>	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis</u></p> <p><u>Renal Profile</u></p> <p>Sodium</p> <p>Potassium</p> <p>Chloride</p> <p>CO2</p> <p>Urea</p> <p>Creatinine</p> <p><u>Liver Profile</u></p> <p>Total Bilirubin</p> <p>Direct Bilirubin</p> <p>AST</p> <p>ALT</p> <p>GGT</p> <p>ALP</p> <p>Total protein</p> <p>Albumin</p>	<p>In-house documented procedures</p> <p>Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37</p> <p>Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37</p>	<p>A</p> <p>A</p>



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
Serum/Plasma	<u>Bone Profile</u> ALP Inorganic Phosphate Calcium Total protein Albumin	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<u>Haematinics</u> Iron Transferrin	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<u>Lipids</u> Cholesterol Triglycerides HDL Cholesterol	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<u>General Toxicology</u> Paracetamol Salicylate Ethanol	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
Serum/Plasma	<u>Therapeutic drug Monitoring (TDM)</u> Digoxin Theophylline Phenytoin Carbamazepine Valproate	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<u>Inflammatory Investigations</u> C-Reactive protein Rheumatoid Factor Uric Acid	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<u>Diabetic Tests</u> Glucose	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
	<u>Proteins</u>		
Serum/Plasma	Total Protein	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
	Albumin		
	IgA		
	IgG		
	IgM		
	C3		
	C4		
	<u>General Chemistry</u>		
Serum/Plasma	Amylase	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Plasma (lithium/heparin)	Ammonia		
	Bile Acid		
	CK		
	Magnesium		
Serum/Plasma	Lithium	spectrophotometry	
Serum/Plasma	LDH	spectrophotometry	



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<p>HUMAN SAMPLES AND TISSUES (cont'd)</p> <p>Serum/plasma</p>	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <ul style="list-style-type: none"> • Adjusted calcium • Cholesterol: HDL cholesterol ratio • Non HDL cholesterol • LDL Cholesterol • Globulins • Anion Gap • Indirect bilirubin • Estimated GFR • AKI • Iron Saturation <p>Total Iron Binding capacity</p> <p><u>Urine Analysis</u></p>	<p>In-house documented procedures</p> <p>Calculated parameters: results obtained from analysis of assays on Advia1800/Advia XPT using SOP B-DOC318</p>	<p>A</p>
<p>Urine</p>	<p>Micro albumin</p> <p>Calcium</p> <p>Creatinine (Enzymatic)</p> <p>Potassium</p> <p>Sodium</p> <p>Phosphate</p> <p>Protein</p> <p>Urea</p> <p>Uric acid</p>	<p>Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37</p>	<p>A</p>



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures	
Urine	<p><u>Urine Analysis</u> (cont'd)</p> <ul style="list-style-type: none"> • Albumin Creatinine Ratio • Protein Creatinine Ratio • Creatinine Clearance • Calcium creatinine ratio 	Calculated Parameters: results obtained from analysis of assays on Advia1800/Advia XPT using SOP B-DOC318	A
	<p><u>CSF Analysis</u></p> <p>Protein</p> <p>Glucose</p>	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<p><u>Fertility tests</u></p> <p>FSH</p> <p>LH</p> <p>Prolactin</p> <p>Estradiol</p> <p>Testosterone</p> <p>Progesterone</p> <p>HCG</p>	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
	<u>Thyroid Function</u>		
Serum/Plasma	FT3	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A
	FT4		
	TSH		
	TPO		
	<u>Oncology tests</u>		
Serum/Plasma	CEA	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A
	CA125		
	PSA		
	AFP		
	CA-19-9		
	<u>Investigation of anaemia</u>		
Serum/Plasma	Vitamin B12	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A
	Folate		
	Ferritin		
	<u>Adrenal Function</u>		
Serum/Plasma	Cortisol	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
Serum/Plasma	<u>Cardiovascular tests</u> Troponin I High sensitivity	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A
Serum/Plasma	PTH	Siemens Advia Centaur XPT chemiluminescence SOPs BIO24, BIO114, B-Doc37	A
	P3NP		A
	NT – Pro BNP Vitamin D		A
	Procalcitonin		A
Serum/Plasma	<u>Allergy & Autoimmunity</u> CTD screen (IgG)	Phadia 250 analyser SOP BIO73	A
	IgA TTG		
	MPO/PR3		
	Total IgE		
Serum	Anti-CCP by detection of specific IgG		
	Specific allergens		



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HUMAN SAMPLES AND TISSUES (cont'd)	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Allergy & Autoimmunity</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens:</p>	In-house documented procedures	
Serum/Plasma	<p>Food panel:</p> <ul style="list-style-type: none"> • Egg White • Cow's milk • Cod fish • Wheat • Soybean • Peanut 	Phadia 250 analyser SOP BIO73	A
Serum/Plasma	<p>Nut panel:</p> <ul style="list-style-type: none"> • Peanut • Hazelnut • Brazil nut • Almond • Coconut 	Phadia 250 analyser SOP BIO73	A
Serum/Plasma	<p>Individual Allergens:</p> <ul style="list-style-type: none"> • Timothy Grass Pollen • House Dust Mite • Common Silver Birch • Aspergillus fumigatus • Cat • Dog • Rabbit epithelium • Egg Yolk • Gluten • Cashew • Walnut • Pecan • Pistachio 	Phadia 250 analyser SOP BIO73	A



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures	
Serum/Plasma	Allergy & Autoimmunity (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)		
	Mould panel:		
	<ul style="list-style-type: none"> • Penicillium chrysogenum • Cladosporium herbarum • Aspergillus fumigatus • Candida albicans • Alternaria alternate • Setomelanomma rostrata 	Phadia 250 analyser SOP BIO73	A
Faeces	Calprotectin	Phadia 250 analyser SOP BIO73	A
Urine	Identification of urine free light chains	Helena SAS V8 Analyser using agarose gel electrophoresis method SOP BIO36	A
Serum	Identification and quantification of paraprotein bands in serum	Helena SAS V8 Analyser using CZE and immunodisplacement SOP BIO 35	A
Urine	Pregnancy Diagnosis Test - Human chorionic gonadotrophin (hCG)	The SureStep One Step hCG Pregnancy Test is a qualitative immunoassay. SOP BIO3	A
Blood	Arterial Blood Gases:		
	<ul style="list-style-type: none"> • pH • pCO₂ • pO₂ • HCO₃ • Base Excess • O₂ saturation • Lactate • Haematocrit • Haemoglobin • Carboxyhaemoglobin • Methaemoglobin 	Siemens RAPIDPoint 500 Blood Gas Analyser SOP BIO104, Bio105	A



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures	
Serum, Urine	Osmolality	Osmo 1osmometer SOP BIO45	A
Serum/Plasma	Macroprolactin	PEG precipitation SOP BIO48 Siemens Advia Centaur XPT chemiluminescence SOPs BIO48, BIO143, B-Doc37	A
Blood	HbA1c	Sebia Capillary3 Tera analyser using Capillary Zone Electrophoresis (CZE) SOP BIO133	A
CSF	Xanthochromia	Spectrophotometry using Hitachi Spectrophotometer UV-Vis 2910 SOP BIO59	A
	<u>Renal Profile</u>		
Serum/Plasma	Sodium	Siemens Advia 1800 photometric and turbidimetric. SOPs BIO138, B-Doc37	B
	Potassium		
	Urea		
	Creatinine (Enzymatic)		
	Chloride		
	Zinc		



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
Serum/Plasma	<u>Liver Profile</u> Total bilirubin AST ALT GGT ALP Total protein Albumin	Siemens Advia 1800 photometric and turbidimetric. SOPs BIO138, B-Doc37	B
Serum/Plasma	<u>Bone Profile</u> ALP Inorganic Phosphate Calcium Total protein Albumin	Siemens Advia 1800 photometric and turbidimetric. SOPs BIO138, B-Doc37	B
Serum/Plasma	<u>Diabetic Tests</u> Glucose	Siemens Atellica CH photometric and turbidimetric. SOPs BIO138, B-Doc37	B



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures	
Serum/Plasma	<u>Inflammatory investigation</u> CRP	Siemens Atellica CH photometric and turbidimetric. SOPs BIO 138, B-Doc37	B
Serum/plasma	Adjusted calcium Globulins Estimated GFR AKI	Calculated parameters: results obtained from analysis of assays on Atellica CH using SOP B-DOC318	B
Faeces	FIT - Faecal immunochemical testing – quantitative measurement of haemoglobin	OC Sensor iO analyser SOPs BIO130, B-Doc417, B-Doc419	A
END			