


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>	Mersey and West Lancashire Teaching Hospitals NHS Trust	
	Issue No: 017 Issue date: 01 April 2026	
	Pathology Department Warrington Hospital Lovely Lane Warrington WA5 1QG United Kingdom	Contact: Victoria Williamson Tel: +44 (0)1925 275592 E-Mail: victoria.williamson8@nhs.net Website: www.whh.nhs.uk/ServiceCatInfo.asp?id=31

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>	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	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>	Biochemistry Haematology Blood Transfusion Mortuary: Storage and release of bodies	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
HUMAN BODY TISSUE and FLUIDS Tissue samples: Formalin fixed paraffin embedded (FFPE), fresh and frozen.	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: 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
Tissue samples: Formalin fixed paraffin embedded (FFPE).	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis (cont'd)	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 Leica autostainer and cover-slipper using SOP HC-BS-7	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
	Helicobacter	Giemsa Stain using a manual method. SOP: HC-SS-8	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



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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)	Demonstration of: (cont'd)	Special Tinctorial Histochemical Staining Methods SOP Manual techniques	A
	Mast cells	Toluidine Blue using a manual method. SOP: HC-SS-21	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



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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
	Diffuse large B cell lymphomas and Burkitt's lymphoma and Reed Sternberg cells in Hodgkin's disease	BCL-6	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



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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
	Granulocytes, Reed-Sternberg cells.	CD15	A
	B cells	CD20	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



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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
	Myoepithelial cells of the prostate / breast. Squamous cell carcinoma	CK5/6	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



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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
	Proliferating cells in germinal B cells	MIB-1 (Ki67)	A
	Breast carcinoma	Progesterone	A
	Prostate secretory and ductal epithelium	PSA	A
	Malignant change in cervical epithelium, HPV	P16	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
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
		Sysmex XN550 Analyser SOPs H414, H418, H419, H420, H422	B
	Reticulocyte count	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,	



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Whole blood	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
	Malaria Antigen Screening for detection of: - Plasmodium falciparum and pan-detection of: - Plasmodium falciparum - Plasmodium malariae - Plasmodium ovale - Plasmodium vivax	CareStart™ ROPYDTEST – 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



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Plasma	Specialist Coagulation (Factor Xa)	Symex CS5100 Automated Coagulation Analyser SOPs: H215	A
Plasma	Thrombophilia Screening (ATIII, Protein C, Protein S, APCR, Lupus Screen)	Symex CS5100 Automated Coagulation Analyser SOPs: H220, H222, H223, H224, H225 & H226	A
		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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<p>HUMAN BODY FLUIDS as specified below: (cont'd)</p> <p>Whole Blood</p> <p>Blood (Plasma)</p>	<p><u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u></p> <p>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</p> <p>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</p> <p>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</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Automated Ortho Vision Analyser SOPs: T139, T140 & T141</p> <p>Manual using Ortho Biovue technique and Ortho Biovue pipette and Workstation. SOPs: T076, T018, T019, T020</p> <p>Automated Ortho Vision Analyser SOPs: T023, T123</p>	<p>A</p> <p>A, B</p> <p>A</p>



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



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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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HUMAN SAMPLES AND TISSUES	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures	
Serum/Plasma	<u>Renal Profile</u> Sodium Potassium Chloride CO2 Urea Creatinine	Siemens Advia Chemistry XPT by photometric and turbidimetric. SOPs BIO106, Bio 90, B-Doc37	A
Serum/Plasma	<u>Liver Profile</u> Total Bilirubin Direct Bilirubin AST ALT GGT ALP Total protein Albumin	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</u> (cont'd)	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		
	Alpha -1- Antitrypsin		
	<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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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	<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 Total Iron Binding capacity	Calculated parameters: results obtained from analysis of assays on Advia1800/Advia XPT using SOP B-DOC318	A
Urine	<u>Urine Analysis</u> Micro albumin Calcium Creatinine (Enzymatic) Potassium Sodium Phosphate Protein Urea Uric acid	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</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		A
	Vitamin D		A
	Procalcitonin		A
Serum/Plasma	<u>Allergy & Autoimmunity</u> CTD screen (IgG)	Phadia 250 analyser SOP BIO73	A
	IgA TTG		
	MPO/PR3		
	aGBM		
	Total IgE		
Serum	Anti-CCP by detection of specific IgG		
	Specific allergens		



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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: Food panel: <ul style="list-style-type: none"> • Egg White • Cow's milk • Cod fish • Wheat • Soybean • Peanut 	Phadia 250 analyser SOP BIO73	A
Serum/Plasma	Nut panel: <ul style="list-style-type: none"> • Peanut • Hazelnut • Brazil nut • Almond • Coconut 	Phadia 250 analyser SOP BIO73	A
Serum/Plasma	Individual Allergens: <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: 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 (cont'd)</u>	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
Serum/Plasma	<u>Renal Profile</u> Sodium Potassium Urea Creatinine (Enzymatic) Chloride Zinc	Siemens Advia 1800 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 (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 (cont'd)</u>	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/Advia XPT 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			