


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8666</p> <p>Accredited to ISO 15189:2022</p>	<h3>County Durham and Darlington NHS Foundation Trust</h3> <p>Issue No: 013 Issue date: 27 February 2026</p>	
	<p>Laboratory Sciences University Hospital of North Durham Durham County Durham DH1 5TW</p>	<p>Contact: Mrs Rebecca Sedman Tel: +44 (0) 191 333 2116 E-Mail: rebecca.sedman@nhs.net Website: www.cddft.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Laboratory Sciences University Hospital of North Durham North Road Durham County Durham DH1 5TW</p> <p>Local contact Mrs Hazel Borthwick Joanne Lawson Jen Siddall Mrs Sharon Campbell</p>	<p>Clinical Biochemistry Haematology and Blood Transfusion Histopathology Non-gynae Cytology Microbiology</p>	A
<p>Address Laboratory Sciences Darlington Memorial Hospital Hollyhurst Road Darlington DL3 6HX</p> <p>Local contact Dr Laura Bernstone Mrs Sharon Campbell Nicola McKeague</p>	<p>Clinical Biochemistry Microbiology Haematology and Blood Transfusion</p>	B
<p>Address Mortuary University Hospital of North Durham North Road Durham County Durham DH1 5TW</p> <p>Local contact Jen Siddall</p>	<p>Mortuary Services (body receipt, storage and release)</p>	C
<p>Address Mortuary Darlington Memorial Hospital Hollyhurst Road Darlington Durham DI3 6HX</p> <p>Local contact Jen Siddall</p>	<p>Mortuary Services (body receipt, storage and release)</p>	D



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Site activities performed away from the locations listed above:

Location details		Activity
Address Shotley Bridge Hospital Shotley Bridge Consett DH8 0NB	Local Contact Joanne Lawson Tel: +44 (0)191 333 2628 Email: jlawson5@nhs.net	Management of Ward 4 blood fridge
Address Bishop Auckland Hospital Cockton Hill Road DL14 6AD	Local Contact Nicola McKeague Tel: +44 (0)1325 743686 Email nicola.mckeague@nhs.net	Management of laboratory-based blood fridge Specimen reception



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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 FLUIDS (cont'd)	<u>Immunoassay examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturers instructions for analysis using Siemens Advia Centaur XPT	
Serum	Cortisol	LP/PA/CB/CBIA012	B
	Digoxin	LP/PA/CB/CBIA013	B
	ELF assays (hyaluronic acid & TMP1)	LP/PA/CB/CBIA045	B
	Ferritin	LP/PA/CB/CBIA025	B
	Folate	LP/PA/CB/CBIA026	B
	FSH	LP/PA/CB/CBIA006	B
	FT3	LP/PA/CB/CBIA004	B
	FT4	LP/PA/CB/CBIA003	B
	hCG (Total)	LP/PA/CB/CBIA015	B
	LH	LP/PA/CB/CBIA007	B
	Macroprolactin Screen	Inc Polyethylene glycol pre-treatment	B
	NtproBNP	LP/PA/CB/CBIA020	
	Oestradiol	LP/PA/CB/CBIA41	B
	P3NP	LP/PA/CB/CBIA014	B
		LP/PA/CB/CBIA034	B
	Progesterone	LP/PA/CB/CBIA008	B
	Prolactin	LP/PA/CB/CBIA005	B
	PSA	LP/PA/CB/CBIA009	B
	SHBG	LP/ND/CB/CBIA038	B
	Testosterone	LP/PA/CB/CBIA011	B
	THIH(high sensitivity troponin)	LP/PA/CB/CBIA036	B
	TSH	LP/PA/CB/CBIA002	B
Serum	Vitamin B12	LP/PA/CB/CBIA027	B
	Free androgen index	By calculation	B
Serum	ELF Score	By calculation	B



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		
CSF	Xanthochromia	Uvikon spectrophotometry with reference to LP/PA/CB/CBSP028	A
	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturers instructions for analysis	
Serum	Serum Free Light Chains	Turbidimetry on Optilite Freelite kappa Free kit LK016.OPT	B
		Optilite Freelite lambda Free kit LK018. OPT	B
		LP/PA/IM/SOP037	



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:	
Whole Blood: EDTA samples	Blood Grouping <ul style="list-style-type: none"> A B O Rhesus D status 	Automated Bio-Rad IH1000 blood transfusion analysers SOP: LP/PA/TR 9 Manual methods using DiaMed-ID Micro Typing system LP/PA/TR16	A/B
Whole Blood: EDTA samples	Antibody Screening Antibodies of the following systems: <ul style="list-style-type: none"> Rh- C,D,E,c,e, Kell- K,k, Duffy- Fya, Fyb MNSs- M,N,S,s Kidd- Jka, Jkb	Automated Bio-Rad IH1000 blood transfusion analysers SOP: LP/PA/TR 9 Manual methods using DiaMed-ID Micro Typing system LP/PA/TR16	A/B
	Antibody Screening Antibodies of the following systems: <ul style="list-style-type: none"> Rh- Cw Kell- Kpa Lutheran- Lua, Lewis- Lea, Leb P- P1	Automated Bio-Rad IH1000 blood transfusion analysers SOP: LP/PA/TR 9 Manual methods using DiaMed-ID Micro Typing system LP/PA/TR16	A/B
Whole Blood: EDTA samples	Antigen phenotyping C, c, E, e, K, Fya, Fyb, Jka, Jkb, M, N, S, s	Manual methods using DiaMed-ID Micro Typing system LP/PA/TR57	A/B
	C, c, E, e, K, Fya, Fyb, Jka, Jkb, M, N, S, s, Lea, Leb, P1, Kpa, Lua, Cw	Manual methods using DiaMed-ID Micro Typing system LP/PA/TR57	A/B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Whole Blood: EDTA samples (cont'd)	Antigen phenotyping (cont'd) c, C, e ,E, and K	Manual methods using DiaMed-ID Micro Typing system and DiaClon Rh-subgroups + K cards LP/PA/TR57	A/B
	<ul style="list-style-type: none"> • Diaclon Anti-Jka/Jkb, • Diaclon Anti-M/N, • Diaclon Anti-Fya/Fyb & ID Anti-Fya/Fyb test serum for phenotyping Fya, Fyb antigens, • Diaclon Anti-S/s & ID Anti-S/s test serum, • Biorad Seraclone Anti-s (MNS4) antisera, • Biorad Seraclone Anti-Fya (FY1) antisera, Biorad Seraclone Anti-Fyb (FY2) antisera	Manual methods using DiaMed-ID Micro Typing system LP/PA/TR57	A/B
	<ul style="list-style-type: none"> • Diaclon Anti-Lea/Leb, • Biorad Seraclone Anti-Kpa (KEL3) antisera, • Biorad Seraclone Anti-Lua (LU1) antisera, Biorad Seraclone Anti-Cw (RH8) antisera	Manual methods using DiaMed-ID Micro Typing system LP/PA/TR57	A/B
Whole Blood: EDTA samples	Kleihauer test for estimation of foeto-maternal haemorrhage	Clin Tech Shepherds Stain kit and Eosin stain SOP: LPPATR3	A/B
Whole Blood: EDTA samples	Crossmatch	SOP LPPATR58	A/B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Whole Blood: EDTA samples	Direct anti-globulin test, monospecific and polyspecific	SOP LPPATR 9	A/B
		Manual methods using DiaMed-ID Micro Typing system	A/B
		SOP LPPATR51	A/B
	<u>Coagulation examination activities for the purpose of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:	
Plasma (sodium citrate)	Blood Coagulation	ACL TOP 550 CTS	
	<ul style="list-style-type: none"> • PT • APTT • Clauss-Fibrinogen • Actin FS 	Optical clot detection Key SOPs LP/PA/HA/CO3 LP/PA/HA/CO2 LP/PA/HA/CO3	B B B B
Plasma (sodium citrate)	Blood Coagulation	ACL TOP 550 CTS	B
	INR	Optical clot detection	B
		SOP LP/PA/HA/CO26	
	D-Dimer	Latex enhanced immunoassay using Werfen D-Dimer HS500 kit	B
		SOP LP/PA/HA/CO32	
	Anti Xa Assay	LP/PA/HA/CO3	B
	Derived fibrinogen	Algorithm on ACL TOP 550 CTS SOP LP/PA/HA/CO1	B



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:	
Whole Blood (EDTA)	Screening test for Glucose 6 phosphate dehydrogenase deficiency	Trinity Biotech kit, visual qualitative fluorescence SOP LP/PA/HA37	A
Bone marrow aspirate slides	Reporting of normal and abnormal morphologies	Manual MGG stain LP/PA/HA/63	A/B
Whole blood (EDTA)	Identification of normal and abnormal morphologies including WBC differential count	Manual MGG Manual microscopy Key SOPs LP/PA/HA7 LP/PA/HA61 LP/PA/HA63	A/B A/B A/B A/B
Whole Blood EDTA	Malaria screening for: P. falciparum P. vivax P. ovale P. malariae	Thick and thin films Fields stain and manual microscopy Binax Now immunochromatographic test Key SOPs LP/PA/HA/13 LP/PA/HA1	A/B A/B A/B A/B
Whole blood EDTA	ESR	Vitech Interliner Key SOPs LP/PA/HA17 LP/PA/HA22	A
	ESR	Manual method – Westergreen tube method on half hour tikme with 1-hour conversion algorithm, on board	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Serum	Measurement of: Anticardiolipin IgG/IgM antibodies	Launch Diagnostics Dynex DS2 analyser (ELISA) LP/PA/HA129	A
	Intrinsic Factor Antibodies	LP/PA/HA130	A
Whole Blood (EDTA)	Detection of haemoglobin S (Hb-S),	Clintech Solubility test kit SOP LP/PA/HA19	A



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<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue.</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>AFOS Ventilated Tables</p> <p>Specimen dissection – CP/PA/CP/SOP4 LP/PA/HP/SOP26 TO /SOP 33 LP/PA/HP/SOP35 AND /SOP36 LP/PA/HP/SOP40 LP/PA/HP/SOP42 TO /SOP44 LP/PA/HP/SOP134</p> <p>Tissue Sampling LP/PA/HP/SOP98</p> <p>Specimen Decalcification Decalcification & the determination of end point using Ammonium Oxalate test.</p> <p>LP/PA/HP/SOP113</p> <p>Tissue processing using VIP Tissue processors</p> <p>LP/PA/HP/SOP106</p> <p>Manual Tissue Embedding Sakura Tissue-Tec 6 LP/PA/HP/SOP3</p> <p>Tissue Sectioning Using Leica Microtomes</p> <p>LP/PA/HP/SOP104</p>	<p>A (unless otherwise stated)</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A (unless otherwise stated)
Tissue for frozen sections		Cryotomy Intra-operative Frozen sections Using Leica Cryostat LP/PA/HP/SOP20	
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides		Pathologist reporting procedures CP/PA/CP/SOP6 CP/PA/CP/SOP8 CP/PA/CP/SOP16	
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining For the detection of:		
	Basophilic and eosinophilic structures	Routine morphological staining Prisma automatic using: LP/PA/HP/SOP102 Haematoxylin and Eosin (H & E) stains LP/PA/HP/SOP65 Frozen Section Staining (Rapid H&E) LP/PA/HP/SOP17	
Trephine on glass slides	Basophilic and eosinophilic structures	Haematoxylin and Eosin (H & E) stains LP/PA/HP/SOP65	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A (unless otherwise stated)
FFPE slides	Special stains for the detection of:	Documented in-house procedures for manual special stains	
	Connective tissue	Van Gieson method LP/PA/HP/SOP66	
	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) LP/PA/HP/SOP68	
	Reticulin fibres	Gordon & Sweets method LP/PA/HP/SOP69	
	Elastic fibres	Modified Weigert LP/PA/HP/SOP70	
	Acid and Neutral Mucopolysaccharides	Alcian Blue/PAS LP/PA/HP/SOP71	
	Carbohydrates and mucins	Period acid Schiff's (with and without diastase) LP/PA/HP/SOP72	
	Amyloid	Improved Congo red LP/PA/HP/SOP73	
	Amyloid	Sirius Red LP/PA/HP/SOP74	
	Gram positive and negative microorganisms	Grams method LP/PA/HP/SOP75	
	Helicobacter/Microorganisms	Giemsa stain LP/PA/HP/SOP77	
	Acid Alcohol Fast Atypical Mycobacterium (Tubercle bacilli)	Ziehl Neelsen LP/PA/HP/SOP78	
	Haemosiderin and ferric iron	Perls Prussian Blue LP/PA/HP/SOP79	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A (unless otherwise stated)
FFPE slides (cont'd)	Special stains for the detection of: Melanin bleached Mast cells Atypical Mycobacterium (M. leprae)	Documented in-house procedures for manual special stains Melanin Bleach LP/PA/HP/SOP81 Toluidine Blue LP/PA/HP/SOP82 Wade Fite LP/PA/HP/SOP85	
FFPE slides	<u>Immunohistochemistry to detect the following:</u> Epithelial cells Differential diagnosis-malignant mesothelioma /adenocarcinoma Epithelial cell types Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas T cells in mantle zone T and B cells -leukaemia Childhood ALL, follicular lymphoma B cells lymphoma Reed Sternberg cells, Hodgkins Endothelial cells, malignancy	Dako Omnis Immuno Stainer and LP/PA/HP/SOP24 AE1/AE3 BCL2 BerEP4 CALRETININ CD3 CD5 CD10 CD20 CD30 CD31	A (unless otherwise stated)



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HUMAN BODY TISSUE (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Dako Omnis Immuno Stainer and LP/PA/HP/SOP24	A (unless otherwise stated)
FFPE slides (cont'd)	Vascular epithelium	CD34	
	B & T cells	CD45	
	Neuroectodermal cells	CD56	
	Macrophages	CD68	
	B cells	CD79	
	GIST tumours	CD117 (c-kit)	
	Carcinoid/metastatic Adenocarcinoma differentiation	CDX2	
	Epithelial malignancy	CEA (MONO)	
	Epithelial malignancy	CEA (POLY)	
	Neuroendocrine cells	CHROMOGRANIN	
	Epithelial cells	CK-PAN	
	Prostatic basal cells	CK-34BE12	
	Epithelial neoplasms	CK5/6	
	Differentiating primary/metastatic pulmonary adenocarcinoma	CK7	
	Differentiating primary/metastatic pulmonary adenocarcinoma	CK20	
	Lymphatic endothelium	D2-40	
	Smooth and striated muscle	DESMIN	
	Epithelial cell Ca	E-CADHERIN	
	Epithelial cell	EMA	



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HUMAN BODY TISSUE (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Dako Omnis Immuno Stainer and LP/PA/HP/SOP24	A (unless otherwise stated)
	Oestrogen receptor - breast	OESTROGEN RECEPTOR	
	Melanoma panel marker	HMB45	
	Proliferating cells	KI67	
	Melanoma panel marker	MELAN A	
	Germ cell tumour	OCT3/4	
	Transcription factor kidney, thyroid	PAX-8	
	Cervical Ca	P16	
	Tumour suppressor	P53	
	Benign/malignant prostate tumour	P63	
	Progesterone receptor breast	Progesterone Receptor	
	Prostate neoplasms	Prostate Specific Antigen (Poly)	
	Melanoma panel marker	S100	
	Smooth muscle	SMA	
	Smooth muscle myosin	SMMhc	
	Neuroendocrine cells	SYNAPTOPHYSIN	
	Thyroid/lung	TTF1	
	Mesenchymal cells	VIMENTIN	
	Renal tumours, mesothelioma	WT-1	



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Slides as prepared above</p>	<p><u>Morphological assessment and interpretation/diagnosis</u></p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Interpretive microscopy:</p> <p>Microscopes:</p> <ul style="list-style-type: none"> - Nikon & Nikon Eclipse - Olympus BH2 - Leica <p>Key SOP's:</p> <ul style="list-style-type: none"> - Pathologist reporting <p>CP/PA/CP/SOP6 CP/PA/CP/SOP8</p>	<p>A (unless otherwise stated)</p>



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HUMAN BODY FLUIDS	<u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions based on Thinprep Genesis equipment and SOP's	A (unless otherwise stated)
Fine needle aspirations (various sites) Serous effusions (pleural, ascitic, pericardial) Respiratory fluids and brushings Urine Gastrointestinal brushings Cyst Fluids Synovial Fluid CSF Peritoneal washings	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	ThinPrep Genesis – LP/PA/CY/SOP27 Cytocentrifugation – LP/PA/CY/SOP26 Use of Leica Autostainer – LP/PA/CY/SOP15 Sputum Prep – LP/PA/CY/SOP32 Bronchial Brushings LP/PA/CY/SOP29 Bronchioalveolar Lavage- LP/PA/CY/SOP32 Serous Fluid/Cyst Prep – LP/PA/CY/SOP35 Breast FNA – LP/PA/CY/SOP36 Urine Prep – LP/PA/CY/SOP37 CSF Prep – LP/PA/CY/SOP38 Diff Quick Staining – LP/PA/CY/SOP42 ThinPrep 2000 – LP/PA/CY/SOP27 Joint Fluids – CYPR009 LP/PA/CY/SOP39 Thrombin Cell CLOT Prep – LP/PA/CY/SOP28	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fine needle aspirations (various sites) Serous effusions (pleural, ascitic, pericardial) Respiratory fluids and brushings Urine Gastrointestinal brushings Cyst Fluids Synovial Fluid CSF Peritoneal washings</p>	<p><u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions based on Thinprep Genesis equipment and SOP's</p> <p>Miscellaneous endoscopic brushings – LP/PA/CY/SOP29</p> <p>EBUS sample preparation – LP/PA/CY/SOP92 Diff Quick Staining – LP/PA/CY/SOP42</p>	<p>A (unless otherwise stated)</p>



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<p>HUMAN TISSUES AND FLUIDS</p> <p>Routine sample types:</p> <p>Aspirates Cellular and fluid material contained on swabs, catheter tips and intra-uterine contraceptive devices Fluids Genital samples</p> <p>Pus Samples from sterile sites Semen Tissue Urine Bone Surgical Implants Sputum Bronchoalveolar lavage/aspirate Respiratory samples Nasopharyngeal secretions Nasal secretions</p> <p>Cultures isolated in-house from all samples listed above.</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation of microorganisms of clinical significance</p> <p>Manual culture methods using various solid agar media</p> <p>Identification of microorganism of clinical significance.</p>	<p>Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>LP/PA/MB/EXAM5 LP/PA/MB/EXAM4 LP/PA/MB/EXAM21 LP/PA/MB/EXAM7 LP/PA/MP/EXAM19 LP/PA/MB/EXAM18 LP/PA/MB/EXAM15</p> <p>Maldi Biotyper MBT Compass IVD Matrix Assisted Laser Desorption/Ionisation Time of Flight Mass Spectrometry LP/PA/MB/EXAM30 LP/PA/MB/EQUIP37 and</p> <p>Conventional identification methods including biochemical, latex agglutinations: LP/PA/MB/KIT4 LP/PA/MB/KIT2</p>	<p>A (unless otherwise stated)</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:	A (unless otherwise stated)
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual culture using chromogenic selective solid agar media using: LP/PA/MB/EXAM3	
Blood and fluids from sterile sites	Isolation of microorganisms of clinical significance	Liquid media culture using automated continuous monitoring system: BD BACTEC Fx Blood Culture analyser using manufacturer's instruction and: LP/PA/MB/EQUIP26 LP/PA/MB/EXAM2	
Fluids: Ascitic fluid Joint fluids Cerebrospinal fluid (CSF) Pus Drain fluids Peritoneal fluid Continual Peritoneal Ambulatory Dialysis Wound Bile	Isolation of microorganisms of clinical significance	Manual culture methods using various solid agar media: LP/PA/MB/EXAM18 LP/PA/MB/EXAM3	
Intra-ocular fluid Corneal scrapes	Isolation of microorganisms of clinical significance	Manual culture methods using various solid agar media: LP/PA/MB/EXAM26	
Cellular and fluid material contained on swabs	Screening for Carbapenemase-producing Enterobacteriaceae (CPE)	Manual culture using chromogenic selective solid agar media using: LP/PA/MB/EXAM22	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:	A (unless otherwise stated)
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: <i>Campylobacter</i> spp. <i>Clostridium difficile</i> <i>Escherichia coli</i> O157 <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp.	Manual culture methods using various solid agar media: LP/PA/MB/EXAM6 LP/PA/MB/EXAM21	
Cultures isolated in-house from all samples listed above	Identification of Staphylococcal isolates	Bio-rad Pastorex Staph Plus LP/PA/MB/KIT6	
Cultures isolated in-house from all samples listed above	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Streptococcal Grouping kit. LP/PA/MB/KIT7	
	Detection of Salmonella polyvalent 'O' (PSO) and Salmonella polyvalent 'H' (PSH); Shigella species	Oxoid agglutination sera LP/PA/MB/KIT79 LP/PA/MB/KIT80	
	Identification of E. coli O157	Oxoid E.coli O157 Latex Test LP/PA/MB/KIT9	
	Antimicrobial susceptibility testing of clinically significant bacteria	Manual (EUCAST) by disc diffusion and gradient MIC using SOPs: LP/PA/MB/EXAM23 LP/PA/MB/KIT14	
Fluids Tissues Pus Cerebrospinal fluid Ascitic fluid Genital swabs	Detection, identification and semi-quantification of: White blood cells Bacterial cells Yeast cells and fungal hyphae Clue cells	Direct examination using staining techniques and light microscopy and Gram staining. LP/PA/MB/EQUIP14 LP/PA/MB/KIT33	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:	A (unless otherwise stated)
Cerebrospinal fluid Ascitic fluids	White blood cell type differential	Direct examination using staining techniques and light microscopy and Gram and Methylene blue staining. LP/PA/MB/EQUIP14 LP/PA/MB/KIT33	
	Quantification of white and red blood cells.	Direct manual microscopy using light microscopy: LP/PA/MB/EQUIP14 LP/PA/MB/EXAM18 LP/PA/MB/EXAM3 LP/PA/MB/EXAM25	
Urine	Quantification of white blood cells and epithelial cells. Detection and characterisation of urinary casts	Automated microscopy: 1Q200 Sprint urine analyser using manufacturer's instructions and LP/PA/MB/EQUIP25 Direct examination using light microscopy and LP/PA/MB/EQUIP14 SOP: LP/PA/MB/EQUIP25 (contingency)	
Faeces	Detection of ova, cysts and parasites	Concentration using midi-parasep concentrator and examination of deposit by light microscopy following manufacturer's instructions and LP/PA/MB/EQUIP14 SOP: LP/PA/MB/EXAM11	
Pus/fluids	Detection of ova, cysts and parasites	Direct preparations observed using light microscopy following LP/PA/MB/EQUIP14 SOP: LP/PA/MB/EXAM11	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:	A (unless otherwise stated)
Perianal Swab	Detection of <i>E.vermicularis</i> ova and larvae	Concentration using centrifugation and examination of deposit using light microscopy following LP/PA/MB/EQUIP14 SOP: LP/PA/MB/EXAM11	
Urine	Detection of <i>Schistosoma spp</i>	Concentration using centrifugation and examination of deposit using light microscopy following LP/PA/MB/EQUIP14 SOP: LP/PA/MB/EXAM11	
Faeces	Detection of <i>Cryptosporidia spp</i> and <i>Cyclospora spp</i>	Fluorescent microscopy using an auramine phenol stain and confirmation using a Ziehl Neelsen staining and light microscopy following LP/PA/MB/EQUIP14 SOP: LP/PA/MB/EXAM11	
Cellular and fluid material contained on swabs (genital)	Detection of <i>Trichomonas vaginalis</i>	Culture using liquid broth media and examination with light microscopy following SOP: LP/PA/MB/EXAM7	
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopy examination using: LP/PA/MB/EXAM5	
Skin Nail hair	Isolation and identification of clinically significant dermatophyte fungi.	Direct microscopy of KOH digested samples and culture on selective solid agar media using SOP: LP/PA/MB/EXAM9	
Faeces	Detection of toxigenic <i>Clostridium difficile</i> GDH antigen	Lateral flow chromatograph for detection of GDH antigen (Pro-lab) using manufacturer's instructions and SOP: LP/PA/MB/KIT11	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:	A (unless otherwise stated)
Faeces	Detection of toxigenic <i>Clostridium difficile</i> Toxin A&B	Enzyme linked fluorescent immunoassay (ELFA) for detection of toxin A&B using a mini-Vidas (Biomerieux) following manufacturer's instructions and SOP: LP/PA/MB/KIT8 Cepheid GeneXpert real time PCR with manufacturer's instructions and LP/PA/MB/EQUIP30	
Faeces	Gene detection for Toxin A&B of toxigenic <i>Clostridium difficile</i>	SOP: LP/PA/MB/KIT22	
Throat swab Nasal swab Throat/nasal swab Nasopharyngeal secretions	Detection of RSV and Influenza A & B	SOP: LP/PA/MB/KIT24	
Nasal swab Groin swab	Detection of Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	LP/PA/MB/KIT23	
Nasal and throat swab	Detection of RSV and Influenza A & B	CEPHEID Xpert Xpress x16 real time PCR with manufacturer's instructions and LP/PA/MB/EQUIP30	
Swabs & NPA	SARS-CoV-2, Flu, RSV	LP/PA/MB/KIT72	
Swab & Culture	CPE	LP/PA/MB/KIT57	
Faeces	Detection of Rota Virus and Adenovirus	Lateral flow immunochromatograph Certest for Rotavirus and Adenovirus antigens using manufacturer's instructions and SOP LP/PA/MB/KIT12	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:	A (unless otherwise stated)
Faeces	Detection of Norovirus	Lateral flow immunochromatograph (r- Biopharm) for Norovirus antigen using manufacturer's instructions and SOP LP/PA/MB/KIT10	
	<u>Serological examination activities for the purposes of clinical diagnosis</u>	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the current version of "Infectious diseases in pregnancy screening: laboratory QA evidence requirements"	A (unless otherwise stated)
Serum	Detection of: Hep B surface Ag Hep C Ab HIVp24 Ag HIV 1 &HIV 2 Ab	Manufacturer's instructions for Biomerieux Mini Vidas analyser, Enzyme linked fluorescent immunoassay (ELFA) and SOP's LP/PA/MB/EQUIP31	
Serum	Determination of Anti-Streptolysin O titre	Manual test (Biokit) following manufacturer's instructions and LP/PA/MB/KIT15	
Serum	Detection of: Hep B surface Antigen Hep C Antibody HIVp24 Antigen HIV 1 &HIV 2 Antibody	Manufacturer's instructions for Biomerieux Mini Vidas 30 analyser, Enzyme linked fluorescent immunoassay (ELFA) and SOP's LP/PA/MB/EQUIP34 LP/PA/MB/EQUIP31	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the current version of "Infectious diseases in pregnancy screening: laboratory QA evidence requirements"	A (unless otherwise stated)
Serum	Varicella Zoster IgG Rubella IgG Measles IgG Hep B core antibody Hep A IgM Hep A total antibody	LP/PA/MB/KIT 34 LP/PA/MB/KIT 36 LP/PA/MB/KIT 35 LP/PA/MB/KIT 37 LP/PA/MB/KIT 38 LP/PA/MB/KIT 39	
	Detection of: HIVp24 Antigen HIV 1 & HIV 2 Antibody Treponema Pallidum (syphilis) antibody Hep B surface Antigen Hep B surface Antibody Hep C Antibody	Manufacturer's instructions for Siemens Advia Centaur XPT analyser and SOP's LP/PA/CB/CBAU301 LP/PA/MB/KIT 40 LP/PA/MB/KIT 41 LP/PA/MB/KIT 42 LP/PA/MB/KIT 43 LP/PA/MB/KIT 44	
Swab & Urine	Chlamydia, Gonorrhoea and HSV 1&2	Transcription mediated amplification and RTPCR using Hologic Panther LP/PA/MB/EXAM37 LP/PA/MB/KIT68 LP/PA/MB/KIT69 LP/PA/MB/KIT70 LP/PA/MB/KIT71	
END			