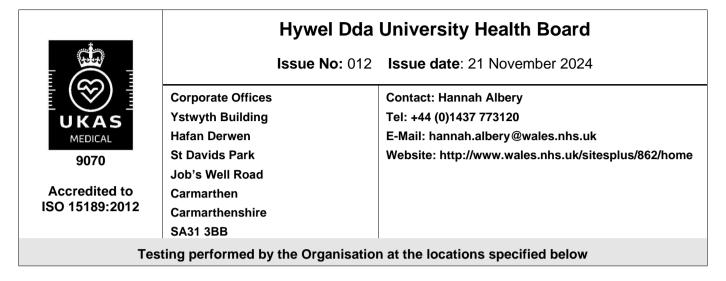
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations		Activities	Location code
Address Pathology Department Withybush General Hospital Fishguard Road Haverfordwest Pembrokeshire SA6 12PZ	Local contact Hannah Albery Tel: +44 (0)1437 773120 E-Mail: hannah.albery@wales.nhs.uk	Biochemistry Haematology Blood Transfusion Blood storage and issue Microbiology Phlebotomy	WGH
Prince Philip Hospital Bryngwyn Mawr Dafen Llaneli Carmarthenshire SA14 8QF	Hannah Albery Tel: +44 (0)1437 773120 E-Mail: hannah.albery@wales.nhs.uk	Biochemistry Haematology Blood Transfusion Phlebotomy	PPH

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UKAS MEDICAL 9070 Accredited to ISO 15189:2012	Hywel Dda University Health Board Issue No: 0012 Issue date: 21 November 2024
	Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

Location details	Activity
Withybush General Hospital Haverfordwest Pembrokeshire SA6 12PZ	Phlebotomy service
Prince Philip Hospital Bryngwyn Mawr Dafen Llanelli Carmarthenshire SA14 8QF	Phlebotomy service
Amman Valley Hospital Folan Road Glanamman SA18 2BQ	Phlebotomy service



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Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

	Type of test/Properties		Location
Materials/Products tested	measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Code
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis	Standard specifications/ Equipment/Techniques used Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using colorimetry LPBIO618 Roche Cobas 8000	
Serum/Plasma	Acetaminophen (paracetamol)	Cambridge Life Sciences assay kit Enzymatic using aryl acylamidase	WGH, PPH
	Alkaline phosphatase		WGH, PPH
	Conjugated bilirubin		WGH
	Magnesium		WGH, PPH
Plasma	Fructosamine		PPH
	Total Protein		WGH, PPH
	Total bilirubin	Diazo method	WGH, PPH
Serum/Plasma/Urine	Albumin		WGH, PPH
	Creatinine	Jaffe method	WGH, PPH
Serum	Iron		WGH, PPH
	Lithium		WGH, PPH
CSF	Lactate		WGH, PPH
Plasma	Lactate		WGH, PPH



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using Electrochemiluminescence (competition or sandwich)	
Serum	Digoxin	LPBIO618 Roche Cobas 8000	WGH, PPH
	CEA		PPH
Serum/Plasma	Vitamin B12		WGH, PPH
	Cortisol		WGH, PPH
	Folate		WGH, PPH
	Free T4		WGH, PPH
	Free T3		WGH, PPH
	Ferritin		WGH, PPH
	FSH		WGH, PPH
	LH		WGH, PPH
	βhCG		WGH, PPH
	Prolactin		WGH, PPH
	PSA		WGH, PPH



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using enzymatic methods	
Serum/Plasma	тѕн	LPBIO618 Roche Cobas 8000	WGH, PPH
	Troponin T		WGH, PPH
	AFP		РРН
	РТН		WGH,
	Triglyceride		WGH, PPH
	Glucose		WGH, PPH
	Cholesterol		WGH, PPH
	Gamma Glutamyl Transferase		WGH, PPH
	HDL		WGH, PPH
Plasma	Alcohol		WGH, PPH
	Ammonia		WGH, PPH
Serum/Plasma/	Amylase		WGH, PPH
Serum	Uric Acid		WGH PPH
CSF	Glucose		WGH, PPH
Serum	Gentamicin		WGH, PPH



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using immunoturbidimetric methods	
Serum	Transferrin	LPBIO618 Roche Cobas 8000	WGH, PPH
	B2-microglobulin		WGH
	CA 125		WGH, PPH
	CA 15-3		PPH
	CA19-9		РРН
	Anti-TPO antibodies		РРН
	Total IgE		PPH
Serum/Plasma	α1-antitrypsin		WGH
	СЗ		WGH
	C4		WGH
	CRP		WGH, PPH
	Immunoglobulin A		WGH, PPH
	Immunoglobulin G		WGH, PPH
	Immunoglobulin M		WGH, PPH
	Rheumatoid factor		WGH, PPH



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using other measurement principles listed below LPBIO618 Roche Cobas 8000	
Serum/Plasma	Aspartate aminotransferase	UV absorbance	WGH, PPH
	Alanine aminotransferase	UV absorbance	WGH, PPH
	Creatine kinase	UV absorbance	WGH, PPH
	Bicarbonate (ECO2)	UV absorbance	WGH, PPH
	Lactate dehydrogenase	UV absorbance	WGH, PPH
	Salicylate	UV absorbance	WGH, PPH
Serum/Plasma	Chloride	Ion selective electrodes	WGH, PPH
Serum/Plasma/Urine	BUN/Urea Blood/Urea/Nitrogen	Kinetic test with urease and glutamate hydrogenase	WGH, PPH
Serum/Plasma	Calcium	Photometrical	WGH, PPH
Serum/Plasma/Urine	Potassium	Ion-selective electrodes	WGH, PPH
Serum/Plasma	Phosphate	Molybdate UV	WGH, PPH
Serum/Plasma/Urine	Sodium	Ion-selective electrodes	WGH, PPH
Urine	Total Protein	Turbidimetric	WGH, PPH



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using other measurement principles listed below LPBIO618 Roche Cobas 8000	
CSF	Protein	Turbidimetric	WGH, PPH
Serum	Vancomycin	KIMS	WGH, PPH
Serum/Plasma/Urine	Creatinine Clearance	Calculation	WGH, PPH
	Adjusted calcium	Calculation	WGH, PPH
	Calculated globulins	Calculation	WGH, PPH
Serum	eGFR	Calculation	WGH, PPH
Serum/Plasma	non-HDL Cholesterol	Calculation	WGH, PPH
Serum	Transferrin Saturation	Calculation	WGH, PPH
Serum	LDL Cholesterol	Calculation	WGH, PPH
Urine	Albumin/ Creatinine Ratio	Calculation	WGH, PPH
Urine	Protein/ Creatinine Ratio	Calculation	WGH, PPH
Serum	Serum Ascites Albumin Gradient (SAAG)	Calculation	WGH, PPH
Serum	Cholesterol/ HDL Cholesterol Ratio	Calculation	WGH, PPH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Roche 8000 (c702 and e602 modules) using other measurement principles listed below LPBIO618 Roche Cobas 8000	
Urine	Creatinine Output	Calculation	WGH, PPH
Urine	Potassium Output	Calculation	WGH, PPH
Urine	Protein Output	Calculation	WGH, PPH
Urine	Sodium	Calculation	WGH, PPH
Urine	Urea Output	Calculation	WGH, PPH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis	
Whole Blood (Arterial)	Blood Gases:	Radiometer ABL Flex Plus Blood Gas Analyser LPBIO Radiometer ABL 90 Flex Plus Blood Gas Analyser	WGH, PPH
	pO2	Optical	
	Glucose Lactate	Amperometric	
	ctHb sO2 FO2Hb FCOHb FHHb FMetHb FHbF	Spectrophotometry	
	pH pCO2 Potassium Sodium Calcium	Potentiometric	
	H+ Bicarbonate Total CO2 Base Excess Standard bicarbonate	Derived	



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Serum/Urine	Osmolality	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Vitech Scientific Advanced Osmo1 single sample Micro-Osmometer	WGH, PPH
		Using freezing point depression measurement.	
		LPBIO631 Advanced Micro- osmometer	
Serum/Urine	Detection and identification of abnormal protein bands.	SEBIA Hydrasys 2 Electrophoresis and immunoprecipitation	WGH
		LPBIO038 Sebia Hydrasys for Electrophoresis and Immunofixation	
Urine	Bence Jones Protein Output	Calculated test	WGH
Serum	Detection and identification of abnormal protein bands	Sebia Capillarys 3 Octa Capillary by electrophoresis and immunotyping LPBIO046	WGH
Whole blood (EDTA)	HbA1c	Tosoh G8 analyser using HPLC	WGH, PPH
		LPBIO621 TOSOH G8 HbA1c analyser	FFN
Serum	Quantification of kappa and lambda free light chains	Automated immunoassay using kits produced by the Binding Site on the Optilite analyser	WGH
		LPBIO45	
	Kappa (Ϗ)/Lambda (λ) ratio	By Calculation	WGH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purpose of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
EDTA Plasma	Qualitative detection of infectious mononucleosis IgM heterophile antibodies	Clearview IM II test kit Qualitative lateral flow immunoassay LPHAE604 Infectious Mononucleosis	WGH, PPH
Whole blood (EDTA)	Sickle cell screening – Haemoglobin S	Streck Sickledex test kit (Blood) Qualitative solubility LPHAE610 Sickle screening: Sickledex testing Kit	WGH, PPH
Blood films	Detection of <i>Plasmodium</i> spp.	Stained blood films (Combination of routine 'Modified Wrights' and Giemsa	WGH, PPH
	Detection of Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium falciparum,</i> <i>Plasmodium Malariae,</i> <i>Plasmodium Ovale,</i> <i>Plasmodium vivax</i>	CareStart Malaria Rapydtest Kit LPHAE600 Laboratory detection of malarial parasites	
Whole blood (EDTA)	Full blood count • Haemoglobin • White cell count • Red cell count • Platelets • HCT • MCV • MCH • MCHC • Differential Reticulocytes	Siemens Advia 2120i analyser Using spectrophotometry, impedance, and flow cytometry measurement. LPHAE607 Siemens Advia 2120i Full Blood Count Analyser	WGH



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HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Whole blood (EDTA)	Full blood count Haemoglobin White cell count Red cell count Platelets HCT MCV MCH MCHC Differential Reticulocytes 	Siemens Advia 2120i analyser Using spectrophotometry, impedance, and flow cytometry measurement. LPHAE607 Siemens Advia 2120i Full Blood Count Analyser	PPH
Blood films	Reporting of normal and abnormal morphologies	Automated Siemens Haematek stainer using modified Wrights stain pack Manual light microscopy LPHAE601 Preparation and staining of blood films LPHAE140 Examination and reporting of blood films	WGH PPH
Whole blood (EDTA)	ESR	Sediplus S2000 automated reader Using sedimentation measurement LPHAE106 Performance of ESR tests Vesmatic 30 Automated ESR Reader by sedimentation	WGH
		LPHAE609 Automated ESR	PPH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis (</u> cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Bone Marrow aspirates	Detection of morphological changes of clinical significance	Automated Siemens Haematek stainer using Modified Wrights stain pack	WGH
		Manual light microscopy LPHAE109 Laboratory procedures for dealing with bone marrows LPHAE Examination and reporting of blood films	
Bone Marrow aspirates	Detection of morphological changes of clinical significance	Automated Siemens Haematek stainer using modified Wrights stain pack Manual light microscopy LPHAE608 Bone marrows	РРН
Citrated plasma	Coagulation • aPTT • PT	Sysmex TCoag KC1. Semi-automated coagulation analyser	WGH
		Using mechanical clot detection LPHAE138 Use of KC1 Coag Analyser	
Citrated plasma	Coagulation APTT PT INR D-Dimer Fibrinogen Lupus anticoagulant Factor assays (VIII) Anti-Xa	Werfen ACLTOP 350 LPHAE611	WGH
Citrated plasma	Coagulation • aPTT • PT • INR • D-Dimer • Fibrinogen	Werfen ACLTOP 350 LPHAE611	РРН



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Whole blood (EDTA)	Kleihauer test for Foetomaternal haemorrhage	Guest Medical foetal red cell detection kit Acid elution technique LPBTR600 Kleihauer	WGH
Whole blood (EDTA)		Ortho Clinical Diagnostics BioVue Vision and Ortho Workstation	WGH PPH
		LPBTR604 LPBTR605	
	Blood grouping and typing by identification of the following antigens		WGH PPH
	Group A, B, D and c		
	Screening and identification of the antibodies against the following antigens: D, E, e, C, c, K, k, Fya, Fyb, Jk(a), Jk(b), S, S, M, N, P1, Le(a) and Le(b)		WGH PPH



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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using Ortho Clinical Diagnostics Vision and Ortho Workstation	
Whole blood (EDTA)	Red cell antigen phenotyping for the following:	Manual serological Haemagglutination	WGH
	Le(a), Le(b), Fy(a), Fy(b), M, S, s, C, c, E, e, Jk(a), Jk(b)	Automated serological haemagglutination	PPH
		LPBTR104 Red cell typing LPBTR907 Red cell phenotyping LPBTR604 Ortho Clinical Diagnostics: Ortho Vision SOP LPBTR605 Ortho Clinical Diagnostics: Ortho Workstation SOP	
Whole blood (EDTA)	Cross-match	LPBTR604 Ortho Clinical Diagnostics LPBTR605 Ortho Clinical Diagnostics: Ortho Workstation	WGH PPH
Whole blood (EDTA)	Direct Antiglobulin Test	LPBTR604 Ortho Clinical Diagnostics: Ortho Vision SOP LPBTR605 Ortho Clinical Diagnostics: Ortho Workstation	WGH PPH



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HUMAN BODY TISSUES/FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Whole blood	Isolation of microorganisms of clinical significance	Automated culture using Bactec Fx WBSOP037 LPMIC010	WGH
CSF, Ear Swabs, Eye Swabs, Faeces, Fluids, Genital Swabs, Nasal, Oral & Throat Swabs, Neonatal Screening Swabs, Pernasal Swabs, Pus, Sputum, BAL & associated specimens, Tissues & Biopsies, Wound Swabs, Bone & Prosthetic Joint samples	Isolation, identification and antimicrobial sensitivity testing of bacterial isolates of clinical significance	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) Manual culture on a variety of agar plates. Bacterial identification using manual biochemical methods Susceptibility testing using EUCAST methodology WBSOP027, LPMIC012 WBSOP001, LPMIC013 LPMIC014 WBSOP002, LPMIC015 WBSOP002, LPMIC015 WBSOP025, WBSOP026, LPMIC018 WBSOP028, LPMIC020 WBSOP009, LPMIC020 WBSOP009, LPMIC023 WBSOP005, WBSOP004, WBSOP005, LPMIC025 WBSOP005, LPMIC026 LPMIC027 WBSOP041, LPMIC030 WBSOP057, LPMIC031 WBSOP017, LPMIC032	WGH
Swabs/Urines	Screening for Methicillin- Resistant Staphylococcus aureus (MRSA)	Manual culture using chromogenic media WBSOP029, LPMIC022	WGH
Settle Plates Contact Plates Broths	Isolation and identification of microorganisms	Examination of Pharmacy samples	WGH



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HUMAN BODY TISSUES/FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Urine	Detection and quantification of red blood cells, white blood cells, epithelial cells, casts, yeasts, parasites, cysteine crystals and sperm <u>Parasitology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u>	Manual Microscopy WBSOP014, LPMIC028	WGH
Faeces	Detection and identification of ova, cysts and parasites	Manual concentration method using ParaSep kit. Light microscopy.	WGH
	Detection and identification of cryptosporidium and Giardia	LPMIC016 Manual wet prep for Giardia Auramine stain for Cryptosporidium Light microscopy.	WGH
	Mycology examination activities for the purpose of clinical diagnosis	LPMIC016	
Skin, hair and nails	General isolation and characterisation of fungi and yeasts of clinical significance	Manual culture and microscopy method using documented in- house procedures WBSOP039, LPMIC019	WGH



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HUMAN BODY TISSUES/FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Faeces	Detection of Helicobacter pylori antigen	Manual method: Proflow (Prolab) membrane immunoassay kit	WGH
		WBSOP006, LPMIC021	
Faeces	Detection of Rotavirus/Adenovirus	RIDA QUICK Rotavirus/Adenovirus Combi (Immunochromatographic) LPMIC039	WGH
Faeces	Detection of Clostridium difficile GDH and Toxin (A&B)	RIDA QUICK C. Diff GDH and toxins A&B (Immunochromatographic) WBSOP010, LPMIC040	WGH
		LPMIC047	
Urine	Detection of Streptococcus pneumonia antigen	Diagnostica Immuview rapid lateral flow kit LPMIC036	WGH
Urine	Detection of Legionella pneumophila antigen	Diagnostica Immuview rapid lateral flow kit LPMIC036	WGH
Serum	Detection of: HIV Hepatitis B surface antigen Hepatitis C antibody Hepatitis B antibody	Cobas e411 Immunoassay – sandwich principle LPMIC086 Roche Cobas e411 SOP: LPBIO630 v1 (Infinity middleware); LPMIC086 v3;	WGH



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HUMAN BODY TISSUES/FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	WGH
Throat Swab	Molecular detection of Flu A, Flu B, RSV & SARS-CoV-2	PCR using the Cepheid GeneXpert LPMIC084 Cepheid Xpert Xpress Flu A, Flu B, RSV & SARS-CoV-2	WGH
Throat swab	Molecular detection of respiratory pathogens Adenovirus Coronavirus 229E Coronavirus NL63 Coronavirus OC43 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A virus, including subtypes H1, H3, H1-2009 Influenza B virus Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Respiratory syncytial virus Bordetella parapertussis Bordetella pertussis Chlamydia pneumoniae Mycoplasma pneumoniae	PCR using Biofire LPMIC078 Molecular testing for Respiratory pathogens using Biofire FilmArray Torch	WGH



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HUMAN BODY TISSUES/FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions for analysis using:	
Faeces	Molecular detection of Clostridioides difficile	PCR using the Cepheid GeneXpert LPMIC085 Clostridioides difficile PCR	WGH
Swabs Urine	Molecular detection of MRSA & CPO	PCR using the Cepheid GeneXpert LPMIC022 Screening Specimens	WGH
Faeces	Molecular detection of Norovirus	PCR using the Cepheid GeneXpert LPMIC083 Norovirus PCR	WGH
END			