

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Accredited to
ISO 15189:2012

Newcastle Upon Tyne Hospitals NHS Foundation Trust

Issue No: 003 Issue date: 30 November 2018

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUES AND FLUIDS Serum unless otherwise stated	<u>Serological examination activities for the purpose of clinical diagnosis</u> HAV IgM HBsAg - Screening HBcAb - Screening HBsAb *Detected/Not Detected and titre reported. HCV ab- screening Rubella IgG - Screening	Roche Modular Analytics E411 using ECLIA measurements: Elecsys Anti-HAV IgM BS-SOP-OP-Biochem-94 SEROLSOP032 Elecsys HBsAg II BS-SOP-OP-Biochem-85 SEROLSOP034 Elecsys Anti-HBc BS-SOP-OP-Biochem-82 SEROLSOP034 Elecsys Anti-HBs assay BS-SOP-OP-Biochem-81 SEROLSOP034 Elecsys Anti-HCV BS-SOP-OP-Biochem-80 SEROLSOP033 Elecsys Rubella IgG BS-SOP-OP-Biochem-89 SEROLSOP021
Serum/CSF	CMV IgG - Screening	Elecsys CMV IgG BS-SOP-OP-Biochem-88 SEROLSOP023
Serum/CSF	CMV IgM	Elecsys CMV IgM BS-SOP-OP-Biochem-91 SEROLSOP023



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	
Serum unless otherwise stated (cont'd)		Roche Modular Analytics E411 using ECLIA measurements:
Serum/CSF	Syphilis screening (detection of antibodies to Treponema pallidum)	Elecsys Syphilis. ECLIA SEROLSOP005 SEROLSOP013
	HIV - Screening	Elecsys HIV combi PT BS-SOP-OP-Biochem-87 SEROLSOP030
	Toxoplasma IgG	Elecsys Toxo IgG BS-SOP-OP-Biochem-90 SEROLSOP024
	ASOT *Titre reported	Roche Modular analytics -COBAS ASLO assay-immunoturbidometric BS-SOP-OP-Biochem-84 SEROLSOP024
Serum		Roche Modular Analytics E411 using ECLIA measurements:
	HBeAg	Elecsys HBeAg assay BS-SOP-OP-Biochem-86 SEROLSOP034
	HBeAb	Elecsys Anti-HBe assay BS-SOP-OP-Biochem-83 SEROLSOP020
	Rubella IgM	Elecsys Rubella IgM BS-SOP-OP-Biochem-93 SEROLSOP012



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Serum (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u> HAV IgG Parvovirus IgG Parvovirus IgM EBNA IgG EBV VCA IgM EBV VCA IgG Lyme Disease IgG Lyme Disease IgM Measles IgG Measles IgM	DiaSorin Liaison XL analyser using CLIA measurement: Anti-HAV SEROLSOP032 SEROLSOP016 Biotrin Parvovirus B19 IgG SEROLSOP016 SEROLSOP024 Biotrin Parvovirus B19 IgM SEROLSOP016 SEROLSOP024 EBNA IgG SEROLSOP023 SEROLSOP016 EBV VCA IgM SEROLSOP023 SEROLSOP016 EBV VCA IgG SEROLSOP023 SEROLSOP016 Borrelia IgG SEROLSOP024 SEROLSOP016 Borrelia IgM II SEROLSOP024 SEROLSOP016 Measles IgG SEROLSOP021 SEROLSOP016 Measles IgM SEROLSOP021 SEROLSOP016



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Serum (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	DiaSorin Liaison XL analyser using CLIA measurement
	VZV IgG	VZV IgG SEROLSOP016 SEROLSOP017
	VZV IgM	VZV IgM SEROLSOP016 SEROLSOP017
	Herpes IgG	HSV 1/ 2 IgG SEROLSOP016 SEROLSOP017
	Herpes IgM	HSV 1/ 2 IgM SEROLSOP016 SEROLSOP017
	Mumps IgG	Platelia Mumps IgG SEROLSOP021 SEROLSOP026
	Mumps IgM	Platelia Mumps IgM SEROLSOP021 SEROLSOP026
	HTLV I/II	HTLV I/II SEROLSOP009
Serum		BioMerieux mini VIDAS using ELFA measurement:
	HBsAg - Confirmation	HBsAg Ultra SEROLSOP012 SEROLSOP034
	HBcAb - Confirmation	Anti-HBc Total II SEROLSOP012 SEROLSOP034
	Rubella IgG - Confirmation	RUBIgG II SEROLSOP012



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Serum (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	BioMerieux mini VIDAS using ELFA measurement:
	HBcIgM	HBc IgM II SEROLSOP034 SEROLSOP012
	CMV IgG - Confirmation	CMV IgG SEROLSOP012
	CMV IgG Avidity	CMV IgG Avidity II SEROLSOP012 SEROLSOP023
	HIV - Confirmation	HIV DUO, HIVP24 II, Immunocomb II HIV 1 & 2, Alere BiSpot SEROLSOP012 SEROLSOP035
	Toxoplasma IgM	Toxo IgM SEROLSOP012 SEROLSOP024
Serum unless otherwise stated		BioRad Evolis Twinplus analyser using ELISA:
	HCV ab/ag - Confirmation	Monolisa Anti-HCV PLUS SEROLSOP013 SEROLSOP033
	Mycoplasma IgM	Platelia M. pneumonia IgM SEROLSOP024 SEROLSOP013
Serum/BAL	Galactomannan	Platelia Aspergillus EIA SEROLSOP013
	H.pylori Antibody	Platelia H. pylori IgG SEROLSOP028 SEROLSOP01
	Hepatitis E IgG	Fortress Diagnostics HEV IgG SEROLSOP032



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	
Serum unless otherwise stated (cont'd)	Hepatitis E IgM	BioRad Evolis Twinplus analyser using ELISA: Fortress Diagnostics - HEV IgM SEROLSOP032
Serum	HCV Ag	Abbott Architect (ECLIA): Abbott HCV Ag SEROLSOP033
Serum unless otherwise stated	Antibiotic assay Amikacin, Gentamicin, Tobramycin, Vancomycin	Roche Integra analyser using Fluorescent polarisation: SEROLSOP014
	Syphilis Confirmation (IgM to Treponema pallidum)	BioRad Evolis Twinplus - Syphilis IgM-ELISA SEROLSOP005 SEROLSOP013
	TPPA titre	Fujirebio Inc Serodia TPPA-Particle agglutination SEROLSOP005
	RPR titre	Launch Diagnostics ASI RPR- Manual assay agglutination
Urine samples	Legionella Ag	Trinity Biotech - Bartels ELISA Legionella Urinary Antigen SEROLSOP030
Serum/CSF	Cryptococcal Ag	Immy Latex-Cryptococcus antigen-latex agglutination SEROLSOP031
Urine	Pneumococcal Ag	Binax NOW Streptococcus pneumonia antigen card. - immunochromatography SEROLSOP015



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	
Serum	HIV confirmation	Biorad Geenius- Immunochromatography SEROLSOP012SEROLSOP035
Faeces	Faecal Ag tests for H.pylori	OXOID Amplified IDEIA Hp StAR - ELISA SEROLSOP028
HUMAN TISSUE AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Swabs (various sites including Wound /Ear/ Eye/ Throat etc.), Tissue Samples (multiple types non-respiratory tract).	Isolation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods MICROSOP054 MICROSOP065
Sputum, BAL, NPS, ETS, cough swabs, tissue and fluid samples (e.g. pleural fluids/biopsy and other respiratory tract fluids and tissues)	Isolation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods MICROSOP005 MICROSOP052 MICROSOP053 MICROSOP075
Blood	Isolation of microorganisms of clinical significance	Blood culture with automated detection of positive growth Biomérieux BacT/Alert MICROSOP060



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Intravascular IV lines	Isolation of microorganisms of clinical significance	Standard bacteriological culture, identification and microscopy methods MICROSOP066
Stool samples	Enteric sample culture and sensitivity testing for Salmonella, Shigella, <i>E.coli</i> 0157, Campylobacter, Vibrio, Yersinia, other food poisoning organisms	Standard bacteriological culture, identification and microscopy methods MICROSOP058
Stool samples	Carbapenemase Producing Enterobacteria Screening	Manual culture using E&O Colorex mSuperCarba agar MICRODOC320
Rectal swabs	Testing for Rotavirus and Adenovirus antigens	Coris Bio-Concept Combi-strip-Immuno-chromatographic MICROSOP058 MICROSOP077
Stool, urine samples, liver abscesses	Detection of Ova, Cysts and parasites (OCP)	Microscopic examination either direct and/or faecal concentration DIASYS Midi Parasep faecal parasite concentrator. Examination for ova and cysts of human parasites. MICROSOP071
Stool samples	Detection of <i>Clostridium difficile</i> glutamate dehydrogenase and Toxins A & B	Biomerieux GDH kit :VIDAS-antigen detection MICROSOP074 Biomerieux <i>C.difficile</i> toxin kit: VIDAS MICROSOP074
Stool samples	Confirmation of <i>C.difficile</i> positives.	PCR using Cepheid GeneXpert, Xpert® <i>C. difficile</i> kit. MICROSOP074
Stool Samples	Detection of Norovirus DNA	PCR using Cepheid GeneXpert MICRODOC223



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Skin hair and nail samples. Respiratory samples, tissue and fluids including CSF samples, swabs. Oesophageal brushings.	Identification of Fungi of clinical significance and Fungal susceptibility testing.	Microscopy and standard fungal culture methods. MICROSOP050
Urine Samples	Urine cell counts, culture and identification of microorganisms of clinical significance	Instrumentation Laboratories IQ Sprint Analyser. Using Biomerieux Chromogenic CPSE agar MICROSOP018 MICROSOP063
Nose, Throat, Perineal, Wound Swabs, Fluid Samples	<i>Staph.aureus</i> screening and chromogenic culture for MRSA	E&O Colorex chromogenic S.aureus and Biomerieux Chrome ID MRSA MICROSOP059 MICRODOC198
CSF Fluids (non-respiratory tract)	Quantitative cell counts, Bacteriological culture and identification of microorganisms of clinical significance	Quantitative cell counts - KOVA slides. Standard bacteriological culture, identification and microscopy methods MICROSOP051 MICROSOP056
Bacterial isolates/ Direct samples from Blood Cultures	Bacterial Identification	Bruker MALDI-TOF MICROSOP076
Bacterial isolates from samples listed above	Susceptibility testing	By disc diffusion - EUCAST Testing and Zone sizes MICROSOP068 MICROSOP072
Bacterial Isolates	Rapid detection of MRSA	MIC: Oxoid M.I.C.E strips MICROSOP068 Alere - MRSA PBP2a- Latex agglutination MICROSOP036



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Streptococcal isolates	Identification of Streptococcal Groups A, B, C, D, F, G	Oxoid Strep Grouping- Latex agglutination MICROSOP034
Bacterial Isolates	Rapid detection of <i>Streptococcus pneumoniae</i> Mycobacteriology	Wellcogen S.pneumo Ag Kit – Latex agglutination MICRODOC321
HUMAN TISSUE AND FLUIDS (cont'd)	<u>Mycobacterial examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Respiratory samples, Fluids, CSF, tissue, bone Marrow, Blood, urine	Identification of Acid Fast Bacilli (AFB)	Auramine Phenol stain using Fluorescent microscopy methodology and Olympus microscope TB SOP 004, 005, 009
Respiratory samples, Fluids, CSF, tissue, bone Marrow, Blood, urine	Isolation and presumptive identification of Mycobacterial species	Manual Culture using LJ and Kirschner culture media- TB SOP 002, 004, 005, 006 and 044
Respiratory samples, Fluids, CSF, tissue, bone Marrow,	Isolation and presumptive identification of Mycobacterial species	Liquid media using BD TB MGIT TBSOP045 and 046
Blood	Interferon Gamma	Launch DS2 using Quantiferon Tb gold plus kit (Qiagen)
Respiratory samples	Detection of: Mycobacterium Tuberculosis rpoB gene mutation for Rifampicin resistance	TBSOP008 Cepheid Gene Xpert using Real time PCR: TBSOP024



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HUMAN TISSUE AND FLUIDS	<u>Molecular biology examination activities for the purpose of clinical diagnosis</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Respiratory samples	FluA H5 and H7 H1N1 Oseltamir resistance H275Y mutation	ABI 7500 taqman using in house assays and realtime PCR: PCRSOP020 and 024 PCRSOP022
Swabs Pernasal swabs	Measles RNA Bordatella pertussis ptxP and 15481 genes	PCRSOP002 PCRSOP001
CSF, EDTA, Tissue	HHV 6 DNA	PCRSOP008
Respiratory Samples	Flu A H3 H1N1 typing	Luminex using H1/H3 duplex and EAV singleplex assays PCRSOP028
	Flu B RSV A RSV B Parainfluenza type 1-4 hMPV Rhinovirus Enterovirus Adenovirus	Luminex Magpix system using NxTAG respiratory pathogen panel using RT-PCR PCRSOP027
Faeces	Enteric pathogen panel to detect genetic sequences on the following: Adenovirus Norovirus Astrovirus Rotavirus Sapovirus	Roche Flow system using Roche light cycler and the TIB Gastro kit: PCRSOP003and 016 PCRSOP007



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CSF, swabs, stool	Enterovirus Paraechovirus	Roche Flow system using Roche light cyclers and the FTD viral meningitis kit: PCRSOP006
Lesion swabs/skin swabs	HSV1 HSV2 VZV	Roche Flow system using Roche light cyclers and the FTD vesicular rash kit: PCRSOP005
Whole blood, urine, CSF	Adenovirus CMV EBV	Roche Flow system using Roche light cyclers and the FTD ACE quantitative kit: PCRSOP004
Urine, genital swabs	N.Gonorrhoeae	Roche Flow system using Roche light cyclers and the FTD N.gonorrhoeae confirmation kit: PCRSOP031
Blood, CSF, Swabs, tissue	HHV6	Roche Flow system using Roche light cyclers and in-house assay PCRSOP008
Serum/ plasma	Quantification of: HIV-1 specific sequences HBV DNA HCV DNA	Roche Cobas 6800 using NAAT technology for the following assays: In house assay and SEROLSOP030 Roche kit and SEROLSOP034 Roche kit and SEROLSOP033
Urine, vaginal, cervical, throat and rectal	Chlamydia trachomatis N.gonorrhoea	Combination and standalone assays using Cobas CT/NG kit and PCRSOP030
Plasma	HCV genotyping	Roche Cobas 4800 using NAAT technology for the following assays: Roche kit and PCRSOP025
END		