


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	York and Scarborough Teaching Hospitals NHS Foundation Trust	
	Issue No: 006 Issue date: 12 November 2021	
	York Hospital Wigginton Road York North Yorkshire YO31 8HE	Contact: Elizabeth Fox Tel: +44 (0)1904 725163 E-Mail: Elizabeth.Fox@york.nhs.uk Website: www.yorkhospitals.nhs.uk/our-services/a-z-of-services/laboratory-medicine1
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
Address Microbiology Laboratory York Hospital Wigginton Road York North Yorkshire YO31 8HE	Local contact Elizabeth Fox	Microbiology Viral Serology Mycology
		Y

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Address Microbiology Laboratory Scarborough Hospital Woodlands Drive Scarborough YO12 6QL	Local contact Elizabeth Fox	Microbiology Limited serology
		S



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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 TISSUES AND FLUIDS	<u>Microbiological examinations for the purpose of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Whole Blood	Isolation of microorganisms of clinical significance	Becton Dickinson BACTEC FX continuous liquid culture monitoring system Gram film by light microscopy if positive Manual Subculture using pre-prepared media MB-SOP-BCULT	Y, S
Sputum, Pleural fluid, BAL	Isolation of microorganisms of clinical significance	Light Microscopy – Gram film as required Manual Culture using pre-prepared media MB-SOP-ROU-SPT	Y, S
Vaginal swabs Cervical swabs Urethral swabs	Isolation of microorganisms of clinical significance	Light microscopy - wet film only for <i>T vaginalis</i> Gram film for <i>B. vaginalis</i> Manual direct culture MB-SOP-GENITAL	Y, S



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Sputum, Pleural fluid, BAL	Isolation of Mycobacteria sp of clinical significance	UV Fluorescent microscopy using Auramine-Phenol stain MGIT BD BACTEC™ MGIT™ 960 Mycobacterial continuous Liquid culture monitoring system. Solid culture using non-acidified pyruvate LJ slopes MB-SOP-AFB-CUL	Y, S
Swabs Ear, nose, throat, eye	Isolation of microorganisms of clinical significance	Light Microscopy of Gram film Manual Culture onto chromogenic agar MB-SOP-ROU-EAR MB-SOP-ROU-EYE MB-SOP-ROU-MOUTH MB-SOP-ROU-NOSE MB-SOP-ROU-THRO	Y, S
Swabs from wounds	Isolation of microorganisms of clinical significance	Microscopy – Gram film if required Direct manual culture onto solid media and enrichment MB-SOP-AMC-ABS MB-SOP-AMC-ANID MB-SOP-AMC-SK&WS	Y, S



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
CSF Ascetic fluid Bone Joint fluid CAPD fluid	Isolation of microorganisms of clinical significance	Microscopy Manual cell count via Fast Read 102 Disposable Counting Chambers. Gram film Direct manual culture and enrichment using solid culture media and enriched soybean-casein digest broth (BD Bactec Peds Plus) and nutrient broth MB-SOP-AMC-FLUID MB-SOP-AMC-PDF MB-SOP-CSF MB-SOP-CSFCS	Y, S
Faeces	Isolation of microorganisms of clinical significance	Manual direct culture and enrichment for enteric pathogens MB-SOP-FAE-PAR MB-SOP-FAE-SU	Y, S
Faeces	Detection of Rotavirus antigen	Rotavirus antigen detection using Meridian Biosciences ImmunoCARD STAT – immunogold based horizontal lateral flow technology. MB-SOP-FAE-ROT	Y, S
Faeces	Detection of Norovirus Antigen	Norovirus antigen detection using Meridian Biosciences ImmunoCARD STAT – immunogold based horizontal lateral flow technology MB-SOP-FAE-NORO	Y, S



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Faeces	Detection of presence of Faecal Ova, Cysts and Parasites	Detection of faecal parasites using Apacor Midi Parasep faecal parasite concentrator and light microscopy MB-SOP-FAE-PAR	Y, S
Faeces	Detection of <i>Clostridium difficile</i> Toxin A and B and glutamate dehydrogenase antigen	Alere C.DIFF QUIK CHEK COMPLETE rapid membrane EIA MB-SOP-HDHTOXXRAPID	Y, S
Faeces	Detection of <i>Clostridium difficile</i> toxin gene	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y, S
Tips IUCD Contact lens	Foreign objects Bacterial & fungal pathogens	Microscopy – gram film if required Direct manual culture and enrichment MB-SOP-ROU-TIPS	Y, S
Tissue	Isolation of microorganisms of clinical significance	Microscopy - Gram Direct manual culture and enrichment MB-SOP-AMC-TIS	Y, S
Bacterial cultures	Antimicrobial susceptibility testing (AST)	EUCAST methodology & interpretive breakpoints using: Manual disc diffusion Gradient MIC MB-SOP-TES-ABS E-TEST using concentration gradient strips manufactured by BioMerieux to provide measurement of MIC. MB-SOP-TES-ABS	Y, S



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Bacterial cultures	Antibiotic resistance testing 1. Carbapenemase producing Enterobacteriaceae 2. Detection of bacteria with ESBL 3. Vancomycin Resistant Enterococci	BioMerieux pre-poured chromID®CARB SMART screening agar. KPC + MBL Confirm ID kit (Rosco). For identification of Metallo-β-lactamases and KPC enzymes (Class A). Neo-Rapid CARB Kit 98024 Oxoid pre-poured Brilliance ESBL screening agar. MASTDISCS ID AmpC and ESBL detection discs. Rosco ESBL discs MB-SOP-TES-CARB MB-SOP-TES-ESBL MB-SOP-TES-VRE	Y, S
Skin Hair Nails	Isolation and presumptive identification of fungi of clinical significance	Microscopy following treatment with Potassium hydroxide. Fluorescent microscopy using Fluorescent Brightener Light microscopy of fungal cultures using Lactophenol Blue Manual inoculation and culture using solid agar MB-SOP-MYCOL	Y
Swabs	Screening for microorganisms of clinical significance - MRSA/MSSA screens	Manual inoculation and culture, single and bi-plate MB-SOP-MRSA/MSSA	Y, S



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Yeast cells & fungal hyphae Granular, hyaline & cellular casts	Cell count – UF1000I Sysmex flow cytometer Culture - Primary UTI opaque. Direct sensitivity testing on pre-poured Oxoid Muller Hinton agar MB-SOP-UR-MCS	Y, S
Bacterial & fungal isolates cultured in-house from the above	Isolation of microorganisms of clinical significance Identification/ Biological classification	BioMerieux VITEK MS isolate ID system utilises Matrix-assisted laser desorption ionization–time of flight mass spectrometry (MALDI-TOF MS) technology - spectroscopy MB-SOP-TES-VITEK MB-SOP-MALDI	Y
Nasopharyngeal aspiration and swabs	Detection of Respiratory Syncytial Virus	Meridian Bioscience Inc. TRU RSV-Rapid qualitative lateral flow for detection of RSV antigen MB-SOP-TRURSV	Y, S
Decontaminated Sputum and untreated sputum	Confirmation of presence of <i>Mycobacterium tuberculosis</i>	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y
Urine, endocervical swabs, Vaginal swabs in Roche PCR media	Confirmation of presence of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i>	Cepheid GeneXpert IV – multiplex rapid real-time PCR MB-SOP-PCR-GX	Y



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions	
Urine	Detection of <i>Legionella pneumophila</i> serogroup 1 antigen	Lateral flow membrane chromatographic test MB-SOP-UR-BINAX	Y, S
Urine	Detection of <i>Streptococcus pneumoniae</i> antigen	Lateral flow membrane chromatographic test MB-SOP-UR-BINAX	Y, S
Faeces	Detection of <i>Helicobacter pylori</i> antigens	Pro-Lab Diagnostics Proflow rapid membrane immunoassay MB-SOP-FAE-PYLORI	Y



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HUMAN BODY FLUIDS	<u>Serological examinations for investigation for immunity and markers of infectious disease</u>	In-house documented methods following manufacturers' instructions	
Serum	Qualitative detection of Hep B surface antigen VZV IgG Toxoplasma IgG/IgM Measles IgG Lyme Disease IgG Lyme Disease IgM	BioMerieux VIDAS30, automated bench top immuno-analyser based on Enzyme Linked Fluorescent Assay (ELFA) presence technology. SE-SOP-HEPB SE-SOP-HBL SE-SOP-LYME SE-SOP-TOXGM SE-SOP-VZV SE-SOP-VIDAS	Y
Upper respiratory tract specimens from specimen types :-: Nose swabs Throat swabs Nasopharyngeal secretions Nasopharyngeal aspirates	Syndromic Qualitative detection of winter respiratory viruses Adenovirus Corona Virus (229E, HKU1, NL63, OC43) Human Metapneumovirus Rhino/enterovirus Influenza virus A (H1, H1-2009, H3) Influenza virus B Parainfluenza virus 1-4 Respiratory Syncytial Virus A/B <i>Chlamydia pneumoniae</i> <i>Mycoplasma pneumoniae</i>	GenMark Eplex closed system Molecular Analyser (using multiplex rapid real-time PCR) MB-SOP-PCR-EPLEX	Y, S



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HUMAN BODY FLUIDS	<u>Serological examinations for investigation for immunity and markers of infectious disease (cont'd)</u>	In-house documented methods following manufacturers' instructions (cont'd)	
Serum	Qualitative detection of: HIV Ag/Ab Combo - HIV p24 antigen and HIV-1 /HIV-2. Anti-HBc II Anti-HBc IgM HAVAb-IgM HBeAg HBsAg Qualitative II Anti-HCV HBeAg EBV EBNA-1 IgG EBV VCAG EBV VCAM CMV IgG CMV IgM Syphilis TP Quantitative detection of: AHBs iVancomycin iGent Rubella IgG	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy screening programme: laboratory Quality Assurance evidence requirements for antenatal screening'. Architect i2000SR fully automated immunoassay system utilising Chemiluminescent microparticle immunoassay (CMIA)	Y
<u>Serum tube from EDTA tubes</u>	<u>SARS-CoV-2 IgM & IgG</u>	SE-SOP-HAVM SE-SOP-CMV SE-SOP-GENT SE-SOP-VANC SE-SOP-HBEAG SE-SOP-HEPB SE-SOP-HEPC SE-SOP-HIV SE-SOP-MEASLES SE-SOP-RUB SE-SOP-STS SE-SOP-EBV	Y
Nose and Throat swabs, sputum, nasopharyngeal aspirates, tracheal aspirates and pleural aspirates in VTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, N2 and E gene targets	<u>Elecsys SARS-COV-2 kit using Roche Cobas e801 CB-SOP-ACOV2</u> Cepheid Gene Xpert: using Real time Polymerase Chain Reaction (RT-PCR) Sars-CoV-2 RNA PCR (SMB-SOP-Covid-19 V01)	Y, S S, Y



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HUMAN BODY FLUIDS	<u>Serological examinations for investigation for immunity and markers of infectious disease (cont'd)</u>	In-house documented methods following manufacturers' instructions (cont'd)	
Nose and Throat swabs, sputum, nasopharyngeal aspirates, tracheal aspirates and pleural aspirates in VTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically Orf1a/b gene targets	Aus Diagnostics High-Plex 24 System using Multiplexed Tandem Polymerase Chain Reaction (MT-PCR) (MB-SOP-PCR-Covid -19)	Y
Nose and Throat swabs, sputum, nasopharyngeal aspirates, tracheal aspirates and pleural aspirates in VTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically Orf1a/b gene targets	Hologic Panther using TMA (target Mediated Amplification) and DKA (Dual Kinetic Assay) (MB-SOP-PCR-Panther -Covid19)	Y
Nose and Throat swabs, sputum, nasopharyngeal aspirates, tracheal aspirates and pleural aspirates in VTM	Detection and differentiation of lineage β -betacoronavirus (β - β CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically N2 and E gene targets	GenMark ePlex using Real time Polymerase Chain Reaction (RT-PCR) (MB-SOP-PCR-EPLEX)	S
Blood	Quantification of Chlamydia trachomatis rRNA Neisseria gonorrhoeae rRNA	Roche COBAS 4800 system for real-time PCR based amplification Roche COBAS X- 480 –fully automated multi-channel pipetting system for sample preparation extraction, purification and preparation of target nucleic acid for PCR analysis Roche COBAS Z-480 rapid thermal block cycler with integrated real-time detection capability. Simultaneous detection on 4 detection channels for multiplex real-time PCR assays PCR MB-SOP-PCR-CTNG MB-SOP-PCR-GX	Y
END			