


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8913</p> <p>Accredited to ISO 15189:2012</p>	<h3>Northern Care Alliance NHS Foundation Trust</h3> <p>Issue No: 005 Issue date: 30 May 2022</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Swabs from wounds, ulcers, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, faeces, sterile fluids, pus,</p>	<p><u>Microbiology examinations for the purposes of clinical diagnosis</u></p> <p>Isolation and identification of microorganisms of clinical significance</p>	<p>In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.</p> <p>Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs</p> <p>MC-SOP-21 SPECIMEN PREPARATION / PLATING OUT MC-SOP-12 CSF MC-SOP-15 ENTERIC SECTION MC-SOP-25 STERILE FLUIDS MC-SOP-123 INVESTIGATION OF BILE MC-SOP-20 GENITAL SWABS MC-SOP- 40 SPUTUM & BRONCHIAL ASPIRATE MC-SOP-24 EAR SWABS MC-SOP-26 EYE SWABS MC-SOP-27 CORNEAL SCRAPES MC-SOP-30 MOUTH SWABS MC-SOP-185 NASAL SAMPLES MC-SOP-32 THROAT SWABS MC-SOP-33 PERNASAL SWABS MC-SOP-36 ADMISSION SCREENING, ITU SURVEILLANCE & WARD OUTBREAKS MC-SOP-120 INVESTIGATION OF TISSUE & BONE SPECIMENS MC-SOP-163 ORTHOPAEDIC IMPLANTS AND PROSTHETIC JOINTS MC-SOP-28 ABSCESS & DEEP WOUND SWABS MC-SOP-29 SKIN & SUPERFICIAL WOUND SWABS MC-SOP-39 IV CANNULAE & ASSOCIATED SPECIMENS</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.
Swabs from wounds, ulcers, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, faeces, sterile fluids, pus cont'd	Isolation and identification of microorganisms of clinical significance (cont'd)	Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs MC-SOP-38 H.PYLORI & CULTURE OF GASTRIC BIOPSIES MC-SOP-36 ADMISSION SCREENING, ITU SURVEILLANCE & WARD OUTBREAKS
Sputum and lower respiratory tract specimens, tissues, fluids	Isolation of Mycobacterium species	Becton Dickinson MGIT automated continuous growth system using SOP MC-SOP-41 Manual culture using LJ slopes and SOP MC-SOP-41
	Detection of Mycobacterium species	Manual staining using phenol auramine and fluorescence microscopy, MC-SOP-41
	Detection of mycobacterial and fungal growth	Becton Dickinson FX40 semi-automated blood culture system using MC-SOP-162
Serum, CSF	Detection of cryptococcal antigen	IMMY latex agglutination test and IMMY Cryptococcal lateral flow using MC-SOP-84
Sterile fluids	Cell count and differential cell count	Kova slide and SOP MC-SOP-12, MC-SOP-25
CSF	Cell count and differential cell count	C-CHIP Haemocytometer MC-SOP-12
Bacterial culture, body fluids and tissues	Identification of Gram positive and negative bacteria	Manual Gram staining technique using SOP MC-SOP-13



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.
Vaginal swabs	Detection of Trichomonas vaginalis and clue cells	Staining slides using acridine orange and fluorescence microscopy using MC-SOP-020
Blood	Detection of bacterial growth	bioMerieux Virtuo semi-automated blood culture system using MC-SOP-14
Faeces	Detection of oocysts of Cryptosporidium.	Automated and manual staining using Polystainer and fluorescence microscopy, SOP MC-SOP-127
Faeces	Detection of ova, cysts and parasites	Parasep faecal concentration method using MC-SOP-127
Faeces, sellotape slide, anal swab	Detection of parasites, cysts and ova	Light microscopy using direct slide preparation of faecal suspension and MC-SOP-127
Bacterial isolate	Determination of Antimicrobial Susceptibility of bacteria	EUCAST disc diffusion method MC-SOP-174 E-Test gradient strips measured manually MC-SOP-176
	Detection of carbapenemases	MC-SOP-128 Micronaut broth MIC MC-SOP-199
Yeast isolate	Determination of Antimicrobial Susceptibility of yeasts	E-Test gradient strips measured manually MC-SOP-176 Micronaut broth MIC MC-SOP-141
		Automated method using bioMerieux Vitek 2XL instrument and MC-SOP-42, MC-SOP-141



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.
Bacterial or yeast isolate (cont'd)	Identification of bacteria and yeasts	Automated method of biochemical testing using bioMerieux Vitek XL instrument and MC-SOP-13 Maldi-tof method using bioMerieux Vitek MS instrument and MC-SOP-152 Manual methods using biochemical or antigen/antibody detection: API, Pro-lab Staphylococcal latex, Pro-lab Streptococcal latex, Rosco Diagnostica Diatab, , Oxoid Dry Spot Pneumo, oxidase, catalase., MC-SOP-13
Urine	Quantitation of white and red blood cells, epithelial cells, casts, bacteria	Sysmex UF5000 instrument using flow cytometry and MC-SOP-206 Manual method using microplate and inverted microscopy MC-SOP-16
Urine	Isolation and identification of microorganisms of clinical significance	Manual culture using MC-SOP 16 Urine analysis
Urine	Qualitative detection of Legionella pneumophila serotype 1 and pneumococcal antigen	Binax NOW immunochromatographic assay, MS-SOP-19
Urine	Detection of HCG(pregnancy test)	SureStep chromatographic immunoassay, MC-SOP-18



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.
Serum	Qualitative measurement of the following: Hepatitis A IgG and IgM antibody Anti-Hepatitis B antibody Hepatitis B surface antigen* Hepatitis B core antibody Hepatitis B core IgM Hepatitis B e antibody Hepatitis B e antigen Hepatitis C antibody HIV 1&2 antibody and p24 antigen* Rubella IgG antibody CMV IgG and IgM antibody Epstein Barr IgG, IgM and EBNA Treponema antibody*	Documented in-house methods to meet the requirements of the IDPS screening programme(s) as defined in the July 2018 'Infectious diseases in pregnancy screening: Laboratory QC evidence requirements (relevant tests marked with *) Abbott Architect i2000 using chemiluminescence and MC-SOP-45
Serum	Qualitative measurement of the following: Mumps IgG antibody Rubella IgM antibody Varicella zoster IgG antibody Toxoplasma total antibody Measles IgG antibody HIV Ab/Ag Hepatitis B surface antigen Hepatitis B core antigen Hepatitis C antibody Hepatitis E IgG & IgM antibodies	bioMerieux Vidas immunoassay analyser and MC-SOP-95
Serum	Qualitative measurement of HIV 1&2 antibody and p24 antigen	Biorad Geenius immunochromatographic test using MC-SOP-151
Faeces	Qualitative detection of Glutamate dehydrogenase (GDH) for the presence of C difficile and Helicobacter pylori antigen	Sysmex DS2 analyser using immunoassay and MC-SOP-102



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.
Faeces	Qualitative detection of C.difficile toxin A & B	Techlab immunochromatographic assay (lateral flow) using MC-SOP-146
Serum, plasma	Detection of the following viral DNA/RNA: Hepatitis B viral load Hepatitis C viral load Hepatitis C genotype HIV viral load	Abbott m2000sp (nucleic acid preparation) and Abbott m2000rt (real time PCR) platforms using MC-SOP-103
Faeces	Detection of the following enteric viral nucleic acid targets: Astrovirus, Sapovirus, adenovirus, norovirus I and II and rotavirus	Automated extraction using the MT-PREP and multiplexed tandem PCR using the AusDiagnostics High-Plex, MC-SOP-201, MC-SOP-202
Nasal swabs, throat swabs, nasopharyngeal aspirates	Molecular detection of 12 respiratory pathogen nucleic acid targets Influenza A Influenza B RSV Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4 Metapneumovirus Adenovirus Mycoplasma pneumoniae Bordetella spp Bordetella pertussis	Automated extraction using the MT-PREP and Multiplexed tandem PCR using the AusDiagnostics High Plex. MC-SOP-201 and MC-SOP-202
CSF and swabs in viral transport media	Molecular detection of 6 viral nucleic acid targets HSV 1 HSV 2 VZV Adenovirus Enterovirus Parechovirus	Automated extraction using the MT-PREP and Multiplexed tandem PCR using the AusDiagnostics High Plex. MC-SOP-201 and MC-SOP-202



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and UKHSA SMIs as relevant.
Urethral swabs, endocervical swabs, vulvo-vaginal swabs, rectal swabs eye swabs, throat swabs	Qualitative molecular detection of C trachomatis and N. gonorrhoeae.	Hologic Tigris analyser using transcription mediated amplification and MC-SOP-46
Faeces	Detection of C difficile toxin gene TcdB	Cepheid GeneXpertanalyser using MC-SOP-146
Nose swabs and throat swabs in viral transport medium or saline	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: SARS-CoV-2a (ORF1 gene) and SARS-CoV-2b (ORF8 gene).	Documented in-house methods for DNA / RNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions: Automated extraction using the MT-PREP and Multiplexed tandem PCR using AusDiagnostics Highplex MC-SOP-201 and 202
Nose swabs and throat swabs in viral transport medium or saline	Detection of SARS CoV-2 (COVID-19) virus RNA specific gene sequences; RdRp and N	Real time PCR using Abbott m2000 sp/rt and RealTime SARS-CoV-2 assay MC-SOP-103
END		