


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>8755</p> <p>Accredited to ISO 15189:2012</p>	<h3>Nottingham University Hospitals NHS Trust</h3> <p>Issue No: 005    Issue date: 01 July 2021</p>	
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<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY FLUIDS AND TISSUES</b></p> <p>Aspirates Cellular and fluid material contained on swabs, cannulae, Faeces Fluids Genital samples Pus Samples from sterile sites Semen Tissues Respiratory samples</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation of micro-organisms of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):</p> <p>Manual inoculation followed by culture using SOPs:</p> <p>General Swabs D Bench – SOP PR 2058 Enteric SOP – SOP PR 2062 Genital Swab Methods SOP PR 2059 Special Bacteriology Methods SOP PR 2056 Investigation of samples for respiratory pathogens SOP PR2070</p>
<p>Whole blood</p>	<p>General isolation of micro-organisms of clinical significance</p>	<p>Automated culture using BacTec FX400 Blood Culture Method SOP PR 2057</p>
<p>Urine</p>	<p>Quantification of white and red blood cells, bacteria and epithelial cells</p>	<p>Automated urine analysis using Sysmex UF1000:</p>
<p>Urine</p>	<p>Isolation, identification and antibiotic susceptibility testing of microorganisms of clinical significance</p>	<p>MAST Uriplus Urine Methods SOP PR 2054</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMLs):
Cerebral fluid samples, CAPD fluids	Detection and quantification of white and red blood cells	Light Microscopy using a Fuchs Rosenthal and Kova counting chamber for counts and Differentiation of white blood cells using Toluidine blue stain or TURKs.: CSF Methods – SOP PR 2055, Special Bacteriology Methods – SOP PR 2056,
Swabs	Isolation and identification testing of microorganisms of clinical significance	
Respiratory samples	Isolation of MRSA	Manual culture using: MRSA Bench – SOP PR 2071
Urine	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.) and routine respiratory culture of clinical significance	Automated culture and microscopy (screening by fluorescent microscopy using Auramine stain, and ZN light microscopy on automated detection) using BD MGIT 960 and BD Bactec FX40; SOP PR2069 Investigation of specimens for respiratory pathogens PR2070
Pus		
Tissue		
Fluids		
CSF		
Skin, Nail	General isolation and characterisation of clinically significant fungi	Manual culture and fluorescent microscopy using calcofluor stain using SOP: PR 2060
Cultures isolated in house from the above	Identification of clinically significant bacteria	Biochemical profile determination using: Vitek 2 SOP PR 2057 Urine SOP PR 2054 Genital SOP PR 2059 Enteric SOP PR2062 General Swabs D Bench – SOP PR 2058
	Identification of clinically significant bacteria and fungi	Automated identification using the Bruker Maldi-ToF platform and SOP PR3362



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMLs):
Cultures isolated in house from the above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc diffusion and/or automated methods using EUCAST methodology, including Microscan Walkaway 96 Plus analyser: Antibiotic SOP PR2053 Blood Culture Identification Procedures PR2057 Genital SOP PR 2059 Enteric SOP PR2062
	Identification of clinically significant bacteria	General bacteriology SOP PR2058 Enteric SOP PR 2062 Special Bacteriology pr2056 Genital bench PR 2059 Respiratory bench PR 2069/2070 Blood cultures bench PR 2057 Mycology SOP PR 2060 Urines bench PR 2054
Cultures isolated in house from the above	Identification of Staphylococcal isolates	Prolex staph latex PR 2058
Cultures isolated in house from the above	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Strep grouping kit PR 2053, PR 2054, PR 2056, PR 2057, PR 2058, PR 2059
Cultures isolated in house from the above	Detection of <i>Salmonella</i> polyvalent 'O' (PSO) and <i>Salmonella</i> polyvalent 'H' (PSH); <i>Shigella</i> species; <i>Vibrio</i> species.	MAST agglutination using Enteric SOP PR 2062



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMLs):
Cultures isolated in house from the above	Identification of <i>E. coli</i> O157	<i>E.col</i> O157 Oxoid Latex Test using: Enteric SOP PR 2062
Cultures isolated in house from the above	Identification of <i>Campylobacter</i> species and <i>Yersinia</i> species	Light microscopy and Carbol Fuchsin stain using: SOP PR 2062
Faeces	Detection of ova, cysts and parasites (OCP)	Concentration and light microscopic examination using Parasep method: Enteric SOP PR2062
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Fluorescent microscopy (Auramine stain) using: Enteric SOP PR2062
Faeces	Detection of <i>C. difficile</i> GDH antigen	Dynex DS2 (EIA): DS2 SOP – PR 2051
Faeces	Detection of <i>C. difficile</i> toxin A & B	Dynex DS2 (EIA): Enteric SOP PR2062
Faeces	Detection of Rotavirus and Adenovirus antigen	Biokit Biorapid ROTA-ADENO kit Enteric SOP – PR 2062



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant Using Siemens Centaur XPT
Plasma Serum	<u>Detection of:</u> HIV Ag/Ab Hepatitis C Antibody Syphilis HBsAg Anti-HBs Anti-HBc IgM antibody Anti-HBc total antibody HBeAg antibody Anti-HBe antibody Hepatitis A IgM antibody Hepatitis A total antibody Rubella IgM antibody Rubella IgG antibody	SOP – PR 3027
Clotted Blood, Plasma, Serum	<u>Detection of:</u>  CMV IgM CMV IgG CMV IgG Avidity EBV IgM EBV VCA IgG EBV EBNA IgG <i>Toxoplasma</i> IgG VZV IgG Parvovirus IgM Parvovirus IgG Measles IgG HTLV I/II IgG <i>Borrelia</i> IgG Mumps IgG	Documented in house methods incorporating manufacturers' instructions where relevant Using Diasorin Liaison XL  SOP – PR 3028



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of confirmation of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant
Clotted Blood	HBsAg,  HIV Ag/Ab,  VZV IgG,  Borrelia IgG/IgM,  Mumps IgG	Using the BioMerieux VIDAS 3 – Enzyme Immunoassay VIDAS 3 – SOP – PR 3380
Lithium heparin plasma	Procalcitonin  Detection of HCV Ag/Ab  Detection of HEV IgG, HEV IgM  Detection of H.pylori IgG  Syphilis IgM	Automated ELISA using Dynex DS2 analyser and EIA HCV Antigen/Antibody Combo EIA SOP-PR2097  Automated ELISA using Dynex DS2 analyser and EIA DS2 System manual (PR2051), HEV IgG and IgM EIA Standard Operating Procedure (PR3151)  Automated ELISA using Dynex DS2 analyser and EIA Helicobacter pylori IgG (PR2095)  Automated ELISA using Dynex DS2 analyser and EIA DS2 System manual (PR2051), Treponema IgM (PR3149)



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Plasma Serum	Detection of Mycoplasma IgM	Automated ELISA using Dynex DS2 and EIA Mycoplasma IgM EIA (PR2096)
	Confirmation of the presence of HIV 1 and 2 Ab	Geenius HIV 1/2 Confirmatory Assay - (PR3145)
Urine	Detection of Legionella Antigen	Automated ELISA using Dynex DS2 analyser and EIA DS2 Legionella Antigen EIA (PR2092);  And kit Binax Legionella NOW (PR2093)
Urine, CSF	Detection of streptococcus pneumoniae antigen	Binax NOW Streptococcus pneumoniae (PR2094)
Clotted or EDTA Blood	Confirmation of syphilis	Rapid Plasma Reagin (RPR) Kit (PR2099)  Treponema pallidum Particle Agglutination (TPPA) (PR2100)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:
Urine, Endocervical swab, vaginal swab	Detection of  <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i> , Trichomonan vaginalis and Mycoplasma genitalium	Alinity m using methods as listed below and PR3729 NUH Microbiology Alinity m SOP:  STI assay using PCR technology with homogenous real-time fluorescence detection
Plasma, serum	HIV-1 RNA	RT-PCR
Plasma, serum	HCV RNA	RT-PCR
Plasma, serum	HBV RNA	RT-PCR
Throat Swab, BAL, Bronchial Aspirates, NPA	Detection of respiratory viruses	BioMerieux easyMAG Nucleic Acid Extraction by EasyMAG (PR2080) PR2958 AusDiagnostics High-Plex system SOP
CSF, Throat Swabs, Whole Blood, Faeces, skin swabs	Detection of neurological viruses Herpes simplex virus 1 (Human herpes virus 1; all strains) Herpes simplex virus 2 (Human herpes virus 2; all strains) Varicella zoster virus (Human herpes virus 3; all strains) Adenovirus group B, C and E (Includes groups B, C, E and some A, D; excludes hAdV 21) Enterovirus (types A, B, C and D) Parechovirus (types 1-8)	BioMerieux easyMAG Nucleic Acid Extraction by EasyMAG (PR2080) PR2958 AusDiagnostics High-Plex system SOP





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Serum	Quantitation of CMV	BioMerieux easyMAG Nucleic Acid Extraction by EasyMAG (PR2080) Quantitative RT-PCR using Applied Biosystems ABI 7500 CMV PCR (PR2083)
Serum	Quantitation of EBV	BioMerieux easyMAG Nucleic Acid Extraction by EasyMAG (PR2080) Quantitative RT-PCR -Applied Biosystems ABI 7500 EBV PCR (PR2102)
Throat and Nasal Swabs in Viral Transport Medium (VTM), Bronchoalveolar Lavage (BAL), Bronchial Aspirates and Nasopharyngeal Aspirates (NPA)	Detection and differentiation of lineage $\beta$ -betacoronavirus ( $\beta$ - $\beta$ CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, E and S gene targets	RealStar SARS-CoV-2 RT-PCR - Manual test using BioMerieux NucliSENS easyMAG extraction and Applied Biosystems 7500 Real Time PCR (PR2080)
Nasopharyngeal, Throat and Nasal Swabs in Viral Transport Medium (VTM) and Nasopharyngeal Aspirates	Detection and differentiation of lineage $\beta$ -betacoronavirus ( $\beta$ - $\beta$ CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, E and S gene targets	RealStar SARS-CoV-2 RT-PCR - Automated test using the AltoStar AM16 platform with AltoStar Purification Kit 1.5 and AltoStar internal Control 1.5 on the Bio-Rad CFX96 Real Time PCR system (PR3721)
Nasopharyngeal, Throat and Nasal Swabs in Viral Transport Medium (VTM) Bronchioalveolar lavage (BAL) Endotracheal secretions (ETS) Sputum	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences E and N2	Using the Cepheid GeneXpert System GX-XVI-16 module using PR3569 and specific methodologies/kits as below  Rapid, real-time RT-PCR using the Xpert Xpress SARS-CoV-2 rapid molecular test



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Endocervical swab, vaginal swab, urine, rectal, conjunctival and pharyngeal swabs	Detection of DNA from Neisseria gonorrhoeae	Real time PCR with Xpert CT/NG kit
Faeces, rectal swabs	Detection of C.difficile DNA	Real time PCR with Xpert C.difficile
	Detection of Flu and RSV RNA	Reverse transcription real-time PCR using Xpert Xpress Flu/RSV kit
	Detection of Norovirus RNA	Reverse transcription real-time PCR using Xpert Norovirus kit
Bacterial isolates from samples as indicated above.	Detection of PVL-positive staphylococcal isolates	Applied Biosystems 2720 thermal cycler PCR for Staphylococci isolates (PR2087)
END		