


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8368</b> Accredited to ISO 15189:2012	<b>The Newcastle Upon Tyne Hospitals NHS Foundation Trust</b>	
	Issue No: 010 Issue date: 15 March 2024	
	<b>Microbiology Department</b> Freeman Hospital Freeman Road Newcastle upon Tyne NE7 7DN	<b>Contact: Jennifer Collins</b> Tel: +44 (0)1912 336161 Fax: +44 (0)1912 231224 E-Mail: <a href="mailto:jennifer.collins24@nhs.net">jennifer.collins24@nhs.net</a> Website: <a href="http://www.newcastle-hospitals.org.uk">www.newcastle-hospitals.org.uk</a>

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
<b>Microbiology Department</b> Freeman Hospital Freeman Road Newcastle upon Tyne NE7 7DN	Jennifer Collins Microbiology Viral Serology	A

#### Site activities performed away from the locations listed above:

Location details	Activity	Location code
<b>North East Innovation Lab,</b> The Biosphere, Newcastle Helix, Drayman's Way, Newcastle upon Tyne, NE4 5BX	Jamie Burbeck Viral Molecular Techniques	B
<b>COVID -19 Testing Hot lab</b> Department of Blood Sciences Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Jennifer Collins Molecular Techniques	C



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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 BODY TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis</u>	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'.	A
Serum unless otherwise stated	HAV IgM	<b>Roche Modular Analytics E170 using ECLIA measurements:</b>  Elecsys Anti-HAV IgM BS-SOP-OP-Biochem-94 SEROLSOP032	A
	HBsAb *Detected/Not Detected and titre reported.	Elecsys Anti-HBs assay BS-SOP-OP-Biochem-81 SEROLSOP034	A
Serum/CSF	CMV IgG - Screening	Elecsys CMV IgG BS-SOP-OP-Biochem-88 SEROLSOP023	A
Serum/CSF	CMV IgM	Elecsys CMV IgM BS-SOP-OP-Biochem-91 SEROLSOP023	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Serum unless otherwise stated (cont'd)          Serum/CSF	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	<b>Roche Modular Analytics e411 using ECLIA measurements:</b>  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'.	A
	HBsAg - Screening	Elecsys HBsAg II BS-SOP-OP-Biochem-85 SEROLSOP034	A
	HCV Ab- screening	Elecsys Anti-HCV BS-SOP-OP-Biochem-80 SEROLSOP033	A
	HIV - Screening	Elecsys HIV combi PT BS-SOP-OP-Biochem-87	A



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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/CSF	Syphilis screening (detection of antibodies to Treponema pallidum)	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'.  Launch DS2 using DIA.PRO Diagnostics Syphilis IgM ELISA. SEROLSOP005	A
Serum	ASOT *Titre reported	Roche Modular analytics C702 - COBAS ASLO assay-immunoturbidometric BS-SOP-OP-Biochem-84 SEROLSOP024	A



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Serum	HBeAg	<b>Roche E411 using ECLIA measurements:</b>  Elecsys HBeAg assay BS-SOP-OP-Biochem-86 SEROLSOP034	A
	HBeAb	Elecsys Anti-HBe assay BS-SOP-OP-Biochem-83 SEROLSOP020	A
	Rubella IgM	Elecsys Rubella IgM BS-SOP-OP-Biochem-93 SEROLSOP012	A
Serum	HAV IgG	<b>DiaSorin Liaison XL analyser using CLIA measurement:</b>  Anti-HAV SEROLSOP032 SEROLSOP016	A
	HIV Ag/Ab	SEROLSOP030	A



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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 (cont'd)	Parvovirus IgG	Biotrin Parvovirus B19 IgG SEROLSOP016 SEROLSOP024	A
	Parvovirus IgM	Biotrin Parvovirus B19 IgM SEROLSOP016 SEROLSOP024	A
	EBNA IgG	EBNA IgG SEROLSOP023 SEROLSOP016	A
	EBV VCA IgM	EBV VCA IgM SEROLSOP023 SEROLSOP016	A
	EBV VCA IgG	EBV VCA IgG SEROLSOP023 SEROLSOP016	A
Serum (cont'd)		<b>DiaSorin Liaison XL analyser using CLIA measurement</b>	
	Lyme Disease IgG	Borrelia IgG SEROLSOP024 SEROLSOP016	A
	Lyme Disease IgM	Borrelia IgM II SEROLSOP024 SEROLSOP016	A
	Measles IgG	Measles IgG SEROLSOP021 SEROLSOP016	A
	Measles IgM	Measles IgM SEROLSOP021 SEROLSOP016	A
	VZV IgG	VZV IgG SEROLSOP016 SEROLSOP017	A



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



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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)	HBcIgM	HBc IgM II SEROLSOP034 SEROLSOP012	A
	CMV IgG - Confirmation	CMV IgG SEROLSOP012 SEROLSOP075	A
	CMV IgG Avidity	CMV IgG Avidity II SEROLSOP012 SEROLSOP075	A
	Toxoplasma IgM	Toxo IgM SEROLSOP012 SEROLSOP024	A
	Mycoplasma IgM	Launch DS2 using Virion/Serion Mycoplasma IgM ELISA. SEROLSOP061, SEROLSO067	A
	H.pylori Antibody	Launch DS2 using Premier H pylori ELISA. SEROLSOP061, assay SEROLSOP068.	A
	Hepatitis E IgG	Launch DS2 using Fortress Diagnostics ELISA. SEROLSOP061, assay SEROLSOP040	A





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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u> (cont'd)		
Serum unless otherwise stated	Hepatitis E IgM	<b>Launch DS2 analyser using ELISA:</b>  Launch DS2 using Fortress Diagnostics ELISA. SEROLSOP061, assay SEROLSOP040	A
Serum unless otherwise stated	Antibiotic assay Amikacin, Gentamicin, Tobramycin, Vancomycin	<b>Roche Integra analyser using Fluorescent polarisation:</b> SEROLSOP014	A
	TPPA titre	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'.  Fujirebio Inc Serodia TPPA-Particle agglutination SEROLSOP005	A
	RPR titre	Launch Diagnostics ASI RPR- Manual assay agglutination	A
Urine samples	Legionella Ag	Manual assay (Immunochromatography) using Meridian TRU Legionella Ag assay SEROLSOP070	A
Serum/CSF	Cryptococcal Ag	Immy Latex-Cryptococcus antigen-latex agglutination SEROLSOP031	A



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<b>HUMAN BODY TISSUE AND FLUIDS (cont'd)</b>	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>		
Urine	Pneumococcal Ag	Manual assay (Immunochromatography) using Meridian TRUStr. pneumo Ag assay SEROLSOP071	A
BAL induced sputum	Detection of <i>Pneumocystis jirovecii</i>	Easymag/MagNAPure, ABI7500 fast. PCR SOP039	A
Serum	HIV confirmation	Biorad Geenius-Immunochromatography SEROLSOP012SEROLSOP035	A
Faeces	Faecal Ag tests for H.pylori	Launch DS2 EIA using Premier Platinum HPSA Plus SEROLSOP028 (assay) SEROLSOP-61	A
<b>HUMAN TISSUE AND FLUIDS</b>	<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	A
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	A
Blood	Isolation of microorganisms of clinical significance	Blood culture with automated detection of positive growth Biomerieux BacT/Alert MICROSOP060	A A



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	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	A
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	A
Rectal swabs	Carbapenemase Producing Enterobacteria Screening	Manual culture using E&O Colorex mSuperCarba agar MICRODOC320	A
Stool	Testing for Rotavirus and Adenovirus antigens	Coris Bio-Concept Combi-strip-Immuno-chromatographic MICROSOP058 MICROSOP077	A
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	A



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Stool samples	Detection of <i>Clostridium difficile</i> glutamate dehydrogenase and Toxins A & B	Biomerieux GDH kit :VIDAS-antigen detection MICROSOP074	A
Stool samples	Confirmation of <i>C.difficile</i> positives.	Biomerieux <i>C.difficile</i> toxin kit: VIDAS MICROSOP074	A
Stool Samples	Detection of Norovirus DNA	PCR using Cepheid GeneXpert, Xpert® <i>C. difficile</i> kit. MICROSOP074	A
		PCR using Cepheid GeneXpert MICRODOC223	A



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	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	A
Urine Samples	Urine cell counts, culture and identification of microorganisms of clinical significance	Instrumentation Laboratories IQ200 Sprint Analyser. Using Biomerieux Chromogenic CPSE agar MICROSOP018 MICROSOP063	A
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	A
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	A
Bacterial isolates/ Direct samples from Blood Cultures	Bacterial Identification	Bruker MALDI-TOF MICROSOP076	A
Bacterial isolates from samples listed above	Susceptibility testing	By disc diffusion - EUCAST Testing and Zone sizes MICROSOP068 MICROSOP072	A
Bacterial Isolates	Rapid detection of MRSA	BioRad Pastorex - MRSA PBP2a– Latex agglutination MICROSOP036	A



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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	A
	Mycobacteriology	Auramine Phenol stain using Fluorescent microscopy methodology and Olympus microscope	A
Respiratory samples, Fluids, CSF, tissue, bone Marrow, Blood, urine	Identification of Acid Fast Bacilli (AFB)	TB SOP 004, 005, 009	A
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	A
Respiratory samples, Fluids, CSF, tissue, bone Marrow,	Isolation and presumptive identification of Mycobacterial species	Liquid media using BD TB MGIT TBSOP045 and 046	A
		Launch DS2 using Quantiferon Tb gold plus kit (Qiagen)	A
Blood	Interferon Gamma	TBSOP008	A
	Detection of:	Cepheid Gene Xpert using Real time PCR:	
Respiratory samples	Mycobacterium Tuberculosis rpoB gene mutation for Rifampicin resistance	TBSOP024	A
Clinical isolates of HG2 Mycobacteria	Mycobacterial sensitivity test	TREK Sensititre trays (Thermofisher). TBSOP049.	A



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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)	
		ABI 7500 taqman using in house assays and realtime PCR:	A
Respiratory samples	FluA H5 and H7 H1N1 Oseltamivir resistance H275Y mutation	PCRSOP020 and 024 PCRSOP022	A A
Swabs	Measles RNA	PCRSOP002	A
Pernasal swabs	Bordetella pertussis ptxP and 15481 genes	PCRSOP001	A
CSF, EDTA, Tissue, blood	HHV 6 DNA	PCRSOP008	A
Sputum, viral nasal swabs, viral throat swabs	Viral respiratory panel for detection of Flu A H1 and H3 subtypes	TIB LightMix Modular RT-PCR, Roche Flow. PCRSOP028	A
Sputum, viral nasal swabs, viral throat swabs	Viral respiratory panel for detection of: Flu A Flu B RSV Parainfluenza 1-4 HMPV Rhinovirus Adenovirus	TIB LightMix Modular RT-PCR, Roche Flow. PCRSOP003	A
	Flu A 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	A



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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)	
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: PCR SOP003 and 016 PCR SOP007	A
CSF, swabs, stool	Enterovirus Paraechovirus	Roche Flow system using Roche light cycler and the FTD viral meningitis kit: PCR SOP006	A A
Lesion swabs/skin swabs, CSF	HSV1 HSV2 VZV	Roche Flow system using Roche light cycler and the FTD vesicular rash kit: PCR SOP045	A A A
Whole blood, urine, CSF, tissues, respiratory samples	Adenovirus CMV EBV	Roche Flow system using Roche light cycler and the FTD ACE quantitative kit: PCR SOP004	A A A





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Blood, CSF, Swabs, tissue	HHV6	Roche Flow system using Roche light cycler and in-house assay PCRSOP008	A
Serum/ plasma	Quantification of: HIV-1 specific sequences	Roche Cobas 6800 using NAAT technology for the following assays:	A
Urine, swabs	HBV RNA HCV RNA Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG)	In house assay and SEROLSOP030 Roche kit and SEROLSOP034 Roche kit and SEROLSOP033 Roche kit and PCRSOP032 PCRSOP030	A A A A
HUMAN TISSUES AND FLUIDS			
Dried blood spots	HCV RNA detection	RT-PCR in house assay, easymag, ABI7500 PCRSOP017	A



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Nose and throat swabs in VTM/UTM	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 Orf1a/b gene targets	Roche Cobas 6800 using cobas® SARS-CoV-2 RT-PCR  PCRSOP048	A
Nose and throat swabs in VTM/UTM		Kingfisher Extraction Platform (for use with the Altona assay) (Omega BioTek MagBind viral DNA/RNA 96 kit), Altona RealStar SARS-CoV-2 test kit. PCRSOP053.	A
Nose and throat swabs in VTM/UTM, respiratory secretions, Endotracheal secretions (ETS), Nasopharyngeal secretions (NPS), sputum, Bronchoalveolar lavage (BAL), respiratory swabs.	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	Roche FLOW system 2 using Altona RealStar RT-PCR Assay (PSU + MagNA Pure 96 with Viral NA SV kit + LC480 thermocycler).  PCRSOP051	A
Nose and throat swabs in VTM/UTM, respiratory secretions, Endotracheal secretions (ETS), Nasopharyngeal secretions (NPS), sputum, Bronchoalveolar lavage (BAL), respiratory swabs.	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	Applied Biosystems 7500/7500 FAST PCR Platform using Altona RealStar RT-PCR Assay using specified extraction robots (MagNA Pure 96 or Biomerieux NucliSENS easyMAG)  PCRSOP050	A
Serum	Detection of SARS-CoV-2 total antibodies	Elecsys® Anti-SARS-CoV-2 assay on the Roche cobas® e411 serology analyser	C



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Throat swabs, nose swabs, NT swabs, NPS, ETS and BAL in VTM	Respiratory pathogen (RP2) detection targets Adenovirus, Coronavirus [220E, HKU, NL3,OC43], SARS-CoV-2, MERS, hMPV, Rhino/enterovirus, Influenza A [H1, H3, H1-2009], Influenza B, Parainfluenza 1, 2, 3, 4, RSV, <i>Bordetella parapertussis</i> , <i>Bordetella pertussis</i> , <i>Chlamydia pneumoniae</i> , <i>Mycoplasma pneumoniae</i>	BioFire Film Array RPP2.1 on BioFire Torch analyser. PCRSOP058	A
Nose/Throat Swab in VTM	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 N2 gene targets	RT-PCR Assay using Cepheid Gene Xpert PCRSOP055	A
Upper respiratory samples	Detection of SARS-CoV-2 RNA	Thermo Fisher Scientific KingFisher Apex system. Applied Biosystems TaqPath COVID-19 kit INNOVSOP010 INNOVSOP011 INNOVSOP012	B



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## Schedule of Accreditation

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### The Newcastle Upon Tyne Hospitals NHS Foundation Trust

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Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Nose/Throat Swab in VTM	Detection and differentiation of lineage $\beta$ -betacoronavirus ( $\beta$ - $\beta$ CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, Orf and N2 gene targets	Diagnostics for the World - Samba II analyser. SARS COV2 test. LAB-MED-RCOV-SOP002	C
Nose/Throat Swab in VTM, Throat Swab, BAL in VTM	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 N2 gene targets, Also, Flu/RSV respiratory viruses, Flu A+B	RT-PCR Multiplex Assay (Influenza A/B/RSV/SAR-CoV-2) using Cepheid Gene Xpert LAB-MED-RCOV-SOP003. PCRSOP055 PCRSOP059	A, C
END			