


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9003 Accredited to ISO 15189:2012	Imperial College of Science, Technology and Medicine operating as Imperial College London	
	Issue No: 011 Issue date: 13 September 2021	
	Molecular Diagnostics Unit Imperial College London St.Mary's Campus 4th Floor Wright-Fleming Building, Norfolk Place London W2 1PG	Contact: Anjna Badhan Tel: +44 (0)20 7594 3917 E-Mail: anjna.badhan@imperial.ac.uk Website: http://www.imperial.ac.uk/medicine/molecular-diagnostic-unit/
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 Molecular Diagnostics Unit Imperial College London St.Mary's Campus 4 th Floor Wright-Fleming Building, Norfolk Place London W2 1PG	Local contact Anjna Badhan	Molecular virology	MDU
Address Flowers Building, South Kensington Imperial College Campus, London SW7 5NH	Local contact Smita Chauhan	Molecular virology	Flowers



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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 FLUIDS	<u>Molecular virology examination activities for the purposes of clinical diagnosis</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods:	
Whole blood (EDTA) and CSF	HTLV 1 & 2 viral load and genotyping	Manual extraction, real-time QPCR using BioRad CFX Connect thermocycler, ABI GeneAmp 9700 thermocycler, SureCycler 8800. SOP MDU0400 In-house method for assaying HTLV-1 provirus load	MDU
Plasma (EDTA) and CSF	Detection of mutations in the integrase and protease-RT genes of HIV-1 associated with reduced susceptibility to anti- HIV drugs	Manual RNA extraction, reverse transcribed PCR amplification using, ABI GeneAmp 9700 thermocycler, SureCycler 8800. SOP MDU0311 In-house PCR amplification and sequencing of HIV-1 protease/RT Next Generation Sequencing using Illumina MiSeq platform. SOP MDU0312 Operation of the Illumina MiSeq Next Generation Sequencer, SOP MDU0316 Operation of the Illumina iSeq Next Generation MDU0314 MiSeq Sample Library Preparation using Illumina Nextera XT kit Reporting SOP MDU 0302 Reporting and storage of HIV-1 resistance results	MDU



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HUMAN BODY FLUIDS	<u>Molecular virology examination activities for the purposes of clinical diagnosis</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods:	MDU
Plasma (EDTA)	Genotyping and detection of mutations in the NS3, NS5a, and NS5b genes of HCV associated with reduced susceptibility to anti-HCV direct acting agents.	Manual RNA extraction, reverse transcribed PCR amplification using, ABI GeneAmp 9700 thermocycler, SureCycler 8800. SOP MDU1001 HCV NS3 Resistance testing, MDU1002 HCV NS5b Resistance testing, MDU1004 HCV NS5a Resistance testing. Next Generation Sequencing using Illumina MiSeq platform. SOP MDU0312 Operation of the Illumina MiSeq Next Generation Sequencer, SOP MDU0316 Operation of the Illumina iSeq Next Generation MDU0314 MiSeq Sample Library Preparation using Illumina Nextera XT kit Reporting SOP MDU 1003 Reporting and storage of HCV resistance results	
Samples self-collected. Combined Nasopharyngeal and Oropharyngeal swab in viral transport medium or Cobas medium	Screening for SARS-CoV-2 RNA (COVID-19); specific gene sequence E Screening for SARS-CoV-2 RNA (COVID-19); specific gene sequence N1 for: General Population testing	Documented in house methods including DHSC minimum standards for private providers of COVID-19 General Population In-house QPCR using manual spin column with Qiagen viral RNA kit or using the Felix automated extraction handling platform with Analytika Jena or Promega Maxwell HT Viral TNA kit. Detection uses ThermoFisher Taqman Fast virus one step Master Mix with primer and probes and BioRad CFX thermocycler. SOP MDU 0803	MDU, Flowers



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HUMAN BODY FLUIDS	<p><u>Molecular virology examination activities for the purposes of clinical diagnosis</u></p> <p>Serology examination activities for the purposes of clinical diagnosis</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods:</p>	
Serum or plasma from venous blood (EDTA)	Detection of SARS-CoV-2 (COVID-19) S1 antibodies	SOP MDU 0805 manual in-house ELISA using Spectra Max M2 reader	MDU
END			