


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9003 Accredited to ISO 15189:2022</p>	Imperial College of Science, Technology and Medicine operating as Imperial College London	
	Issue No: 015 Issue date: 28 March 2025	
	Molecular Diagnostics Unit Room I.2.3 2nd Floor, Lift Bank D Chelsea & Westminster Hospital 369 Fulham Road, London SW10 9NH	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 at the above address only		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 proviral load	Manual extraction, real-time QPCR using BioRad CFX
	HTLV 1&2 proviral detection and genotyping	SOP MDU0400 In-house method for assaying HTLV-1 provirus load
		Nsted PCR with gel electrophoresis visualisation using ABI GeneAmp 9700 and SureCycler 8800
		MDU0406 - Manual extraction, digestion using restriction enzyme, visualisation using gel electrophoresis



9003

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Issue No: 015 Issue date: 28 March 2025

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Plasma (EDTA)</p>	<p><u>Molecular virology examination activities for the purposes of clinical diagnosis</u></p> <p>Genotyping and detection of mutations in the NS3, NS5a, and NS5b genes of HCV associated with reduced susceptibility to anti-HCV direct acting agents.</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods:</p> <p>Manual RNA extraction, reverse transcribed PCR amplification using, ABI GeneAmp 9700 thermocycler, SureCycler 8800.</p> <p>SOP MDU1001 HCV NS3 Resistance testing,</p> <p>MDU1002 HCV NS5b Resistance testing,</p> <p>MDU1004 HCV NS5a Resistance testing.</p> <p>Next Generation Sequencing using Illumina MiSeq platform: SOP MDU0312 Operation of the Illumina MiSeq Next Generation Sequencer</p> <p>SOP MDU0316 Operation of the Illumina iSeq Next Generation</p> <p>MDU0314 MiSeq Sample Library Preparation using Illumina Nextera XT kit</p> <p>Reporting SOP MDU 1003 Reporting and storage of HCV resistance results</p>
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