


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9325</p> <p>Accredited to ISO 15189:2012</p>	<p>Cambridge Clinical Laboratories Ltd</p> <p>Issue No: 012 Issue date: 05 September 2022</p>	
	<p>Park House Winship Road Milton Cambridge Cambridgeshire CB24 6BQ</p>	<p>Contact: Mike Morel / Jennie Oates Tel: +44 (0) 1223 395486 E-Mail: quality@camclinlabs.co.uk Website: www.camclinlabs.co.uk</p>
<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
HUMAN BODY FLUIDS AND TISSUES	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	In house methods in conjunction with manufacturer's instructions:
FFPE		DNA extraction using Cobas DNA sample preparation kit using : CLP-179
DNA	Detection of: BRAF Mutation (V600E)	RT-PCR using Cobas 4800 BRAF V600 Mutation Test using : Roche Cobas Z480 and CLP-182
DNA	Detection of: EGFR mutation	RT-PCR using Cobas EGFR Mutation Test v2 Using : Roche Cobas Z480 and CLP-192
Whole blood	Extraction of DNA for the purposes of testing below	DNA extraction using Roche MagNA Pure 24 (MP24) CLP-193
Plasma	Extraction of RNA for the purposes of testing below	RNA extraction using Biomerieux NucliSENS EasyMAG CLP-137



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>DNA extracted using above procedure</p> <p>Viral RNA extracted using above procedure</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of: HLA B*57:01</p> <p>Analysis of:</p> <p>HIV PR-RT (Protease and Reverse transcriptase)</p> <p>HIV V3</p> <p>HIV Integrase</p>	<p>In house methods in conjunction with manufacturer's instructions:</p> <p>In house PCR assay and gel electrophoresis and sequencing data analysis using: CLP-151 CLP-172 CLP-173 CLP-175 Sequencing performed at an external ISO 15189:2012 accredited laboratory.</p> <p>In house PCR assay and gel electrophoresis and sequencing data analysis via the Stanford University HIV Drug resistance database using: CLP-135 CLP-138 CLP-139 CLP-140</p> <p>CLP-141</p> <p>CLP-184 Sequencing performed at an external ISO 15189:2012 accredited laboratory.</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Oropharyngeal and nasopharyngeal swabs</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) with target genes E and N</p>	<p>In house methods in conjunction with manufacturer's instructions:</p> <p>Documented in house methods including DHSC requirements for private providers of Covid-19 testing, to include:</p> <ul style="list-style-type: none"> • General Population Testing <p>RNA Extraction using either of the following:</p> <ul style="list-style-type: none"> • Zymo Quick RNA Viral Kit, CLP-195 • Himedia Inst NX Mag96 Automated Nucleic Acid Extractor System CLP-196 <p>PCR by VirPath Nonacus QPCR kit, CLP-199, using Roche LC480ii and z480 Realtime PCR amplification platforms</p>
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