


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>22188 Accredited to ISO 15189:2012</p>	<h3>Yourgene Health UK Limited</h3> <p>Issue No: 001 Issue date: 31 August 2021</p>	
	<p>Citylabs 1.0 Nelson Street Manchester M13 9NQ</p>	<p>Contact: Tahir Patel Tel: +44 (0)161 669 8122 E-Mail: tahir.patel@yourgene-health.com Email: info@yourgene-health.com Website: https://www.yourgene-health.com/</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
<p>HUMAN BODY FLUIDS</p> <p>Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) swabs and nasal swabs in inactivating viral transport media</p> <p>Samples self-collected or collected by a Provider accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and who is listed on the DHSC Approved Lists for General Population and/or Test to Release (5 day) testing and/or Day 2 and day 8 tests for international arrivals</p> <p>Nucleic Acid extracts</p>	<p>Virology examination procedures for the purposes of clinical diagnosis</p> <p>Detection of SARS-CoV-2 (COVID-19) gene markers (E and N genes)</p> <p>For:</p> <p>General Population Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods or antigen POCT</p> <p>Test to Release 5 Day Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods</p> <p>2 and 8 Day testing for international arrivals Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods</p>	<p>Documented in house methods including DHSC requirements for private providers of COVID-19 testing, to include:</p> <p>Automated sample handling using Tecan Yourgene SP150 (WI15-0001a) Automated nucleic acid extraction using Molgen PurePrep Pathogen Workflow (WI15-0001b) with PurePrep 96.</p> <p>Automated handling using SciClone G3 (96 and 384-well format) (WI15-0001d) Real Time PCR thermal cycler Thermofisher QuantStudio5 (384 well plate) (WI15-0001f) Real-Time PCR (including reverse transcription) using Clarigene™ SARS-CoV-2 CE-IVD assay.</p>



22188
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Yourgene Health UK Limited
Issue No: 001 Issue date: 31 August 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Virology examination procedures for the purposes of clinical diagnosis	Documented in house methods including DHSC requirements for private providers of Covid-19 testing, to include:
Nucleic Acid extracts	Detection of SARS-CoV-2 (COVID-19) gene markers (ORF1ab, N and S genes) For: General Population Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods or antigen POCT Test to Release 5 Day Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods 2 and 8 Day testing for international arrivals Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods	Real Time PCR thermal cycler Thermofisher QuantStudio5 (384 well plate) (WI15-0001f) or (96 well plate) (WI15-0001d) Real Time PCR using TaqPath SARS-CoV-2 (WI15-0001e)
Nucleic Acid extracted in-house	Detection of key SARS-CoV-2 variants of concern (VOC: Alpha, Beta, Gamma, Delta variants and B.1.429 (California))	BioRad S1000 Thermo Cycler. Lunatic RNA Quantification Platform
Nucleic Acid or Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) swabs and nasal swabs in inactivating viral transport media received from referring Providers accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and who are listed on the DHSC Approved List for Day 2 and day 8 tests for international arrivals	2 Day testing for international arrivals Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods	Real Time PCR thermal cycler Thermofisher QuantStudio5 (96 well plate) AB Ion torrent S5 system and & Ion Chef. AB Torrent Suite software Using Next Generation Sequencing and in-house procedures (WI15-0002a, WI15-0002b, WI15-0002c, WI15-0002d, WI15-0002e)

END