


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 22188 Accredited to ISO 15189:2012</p>	<h3>Yourgene Genomic Services Limited</h3> <p>Issue No: 003 Issue date: 05 June 2023</p>	
	<p>Skelton House Lloyd Street, North Manchester Science Park Manchester M15 6SH United Kingdom</p>	<p>Contact: Claire Ryan Tel: +44 (0)161 669 8122 E-Mail: claire.ryan@yourgenehealth.com Email: info@yourgenehealth.com Website: https://yourgenehealth.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 testing</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 (ORF1ab, N and S 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>Documented in house methods including DHSC requirements for private providers of COVID-19 testing, to include:</p> <p>Sample Transfer and Registration of Inactivated COVID-19 Samples using Tecan SP150 (WI15-0001a)</p> <p>Automated sample handling using Molgen TTR (WI15-0001g)</p> <p>RNA Extraction from Respiratory Swab Samples using the Molgen PurePrep Pathogen Workflow (WI15-0001b)</p> <p>RNA Extraction of Viral Pathogens Using ThermoFisher MagMax Kit (WI15-0001j)</p> <p>Real Time PCR thermal cycler Thermofisher QuantStudio5 (384 well plate) (or (96 well plate) Real Time PCR using TaqPath SARS-CoV-2</p>



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<p>HUMAN BODY FLUIDS</p> <p>Nucleic Acid extracted in-house</p> <p>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 General Population testing</p> <p>Nucleic Acid extracted in house or received from accredited referring Providers listed on the DHSC Approved List for General Population testing</p>	<p>Virology examination procedures for the purposes of clinical diagnosis</p> <p>Detection of key SARS-CoV-2 variants of concern (VOC: Alpha, Beta, Gamma, Delta variants and B.1.429 (California))</p> <p>Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods</p> <p>Detection of key SARS-CoV-2 variants of concern (VOC: Alpha, Beta, Gamma, Delta variants and B.1.429 (California))</p> <p>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>Manual Library Preparation for SARS-CoV-2 Sequencing (WI15-0002c) BioRad S1000 Thermo Cycler. Lunatic RNA Quantification Platform 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)</p> <p>Illumina NextSeq 550Dx and LunarScript NEBNext Artic Library Prep kit (WI15-0002f, WI15-0002g, WI15-0002j, SL15-0006 Reporting of SARS-CoV-2 Sequencing Results)</p>



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<p>HUMAN BODY FLUIDS</p> <p>Maternal Blood in Streck tubes</p>	<p>Molecular Genomic Analysis for the purposes of clinical diagnosis</p> <ul style="list-style-type: none"> • Screening of autosomal aneuploidies for Chromosomes 21, 18, and 13 (Down's, Edwards' and Patau's syndromes). • Screening for sex chromosome aneuploidies of X and Y (Turner, Klinefelter's and Jacobs's syndromes, Trisomy X). • Screening for rare autosomal aneuploidies. 	<p>Documented in house methods</p> <p>DNA extraction and Next Generation Sequencing (NGS) for Non-invasive prenatal testing (NIPT)</p> <p>Receipt, Labelling, Processing and Storage of Clinical Samples for NIPT (SL1-0013)</p> <p>IONA NX Workflow at YourGene Health (SL14-0001)</p> <p>Instructions for Use for the IONA Nx cfDNA Library Prep Dx Kit as part of the IONA® Nx NIPT Workflow (IFU013)</p> <p>IONA Nx Report Generation and Generation of Revised Reports i(WI14-0002)</p>
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