


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8806 Accredited to ISO 15189:2022	NHS Tayside	
	Issue No: 009 Issue date: 10 July 2025	
	East of Scotland Regional Genetics Level 6 Ninewells Hospital Dundee DD1 9SY	Contact: Dr David Baty Tel: +44 (0)1382 496271 E-Mail: david.baty@nhs.scot Website: http://www.esrg.scot.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity
Address Level 6 Ninewells Hospital Dundee DD1 9SY	Local contact Dr David Baty 01382 496271	Molecular Genetic Cytogenetic Molecular Pathology Molecular Haematology testing



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS</p> <p>Peripheral Blood, Bone Marrow</p> <p>Saliva</p> <p>FFPE LMD tissue</p> <p>Amniotic Fluid</p> <p>Peripheral Blood</p> <p>Peripheral Blood FFPE Fresh Tissue</p> <p>Urine FFPE</p> <p>FFPE</p>	<p><u>Genomic analysis for the purposes of clinical diagnosis of rare disease and cancer</u></p> <p>DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long term storage</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Manual, semi-automated and automated DNA /RNA extraction and quantification using:</p> <p>DNA Extraction:</p> <p>Manual extraction processes:</p> <p>Flexigene (MGM085)</p> <p>Oragene (MGM106)</p> <p>Qiagen Microkit (MGM264)</p> <p>Igenatal (MGM287)</p> <p>Automated DNA Extraction Processes:</p> <p>Qiagen QiaSymphony (MGE053, MGM230)</p> <p>EZ1 & EZ1 Advanced XL (MGE023, MGE063, MGM084, MGM247 MGM097 MGM235)</p> <p>Maxwell RSC (MGE126, MGM311, MGM316 & MGM320)</p> <p>(MGM316 & MGM320 FFPE) Biorobots</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Peripheral Blood Bone Marrow</p>	<p><u>Genomic analysis for the purposes of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long term storage</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Manual, semi-automated and automated DNA /RNA extraction and quantification using:</p> <p>DNA Quantification for QC purposes: Qubit Fluorometer (MGM299)</p> <p>Automated RNA Extraction processes EZ1 and RNA Cell Mini Kit (MGM242)</p> <p>RNA Quantification for QC purposes:</p> <p>Qubit</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from the sample type listed above and received as primary samples from external sources</p>	<p>Detection of nucleic acid sequence variant - SNVs and Indels [definitive list to be held by this laboratory]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Sanger Sequencing Using:</p> <p>PCR Amplification using: documented in-house procedures on Veriti thermocyclers. (MGM001, MGM144, MGM207, MGM229, MGM237, MGM243, MGE036, MGM313)</p> <p>Sequencing of products using: Standard primer design methodology (Primer Design (SOP GEN084), PCR amplification, gel electrophoresis, capillary electrophoresis, Beckman Biomeck robot, HamiltonStar Robot, Veriti Thermocyclers, Applied Biosystems ABI 3730 DNA analyser and examination and analysis of sequence data using Mutation Surveyor software package).</p> <p>(MGM313 Sequencing –PCR guide, MGE035, MGE067, MGM220, MGM238, MGM012, MGM103, MGE045, MGE128, MGM096, MGM277 MGM229, MGM319)</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples and DNA from external sources</p> <p>Peripheral Blood</p>	<p>Detection of nucleic acid sequence variants and small indels [definitive list held by this laboratory].</p> <p>Quantitative analysis of known gene fusions events for the monitoring of malignancies [definitive list of fusions and transcripts to be held by this laboratory]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Pyrosequencing</p> <p>Using: Qiagen PyroMarkQ24 platform using in-house procedures and Qiagen therascreen kits as per:</p> <p>SOPs MGM174, MGM175, MGM178, MGM228, MGM241, MGM257, MGM258, MGM270, MGM272, MGM286, GEN064.</p> <p>Quantitative Real Time PCR</p> <p>Using: Fully automated nucleic acid extraction, reverse transcription and QPCR by Cepheid GeneXpert BCR-ABL Ultra System</p> <p>(MGM302)</p>



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<p>HUMAN TISSUES AND FLUIDS</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples and DNA from external sources (cont'd)</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples from external sources.</p>	<p>Gene screening of large targeted gene panels for nucleic acid SNVs and small indels –[definitive list of panels and genetic variant types to be held by this laboratory]</p> <p>SNV/indels</p> <p>Detection of fragment length size, deletions, known mutations, repeat expansions, short tandem repeats (definitive list to be held by this laboratory]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing:</p> <p>For targeted panels:</p> <p>Library Preparation Methods: QIASeq Targeted DNA Panel (MGM315)</p> <p>Qubit 2.0 Fluorometer, thermal cycler and, Illumina MiSeq platform SOPs MGM299, MGE036, MGE130</p> <p>Analysis using: Targeted panel pipeline Qiagen Biomedical Genomics Workbench and Qiagen Clinical Insight Interpret (QCI).</p> <p>SOPs MGM307, MGM317, MGM322.</p> <p>Fragment Length Analysis</p> <p>Using: CFTR Analysis by capillary electrophoresis (as detailed below) using Elucigene CFEU2v1 Amplification Refractory Mutation System PCR Kit. SOP MGM308</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples from external sources.</p>	<p>Detection of fragment length size, deletions, known mutations, repeat expansions, short tandem repeats (definitive list to be held by this laboratory]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Fragment Length Analysis</p> <p>Using: BIOMED2 IdentiClone Assays using capillary electrophoresis (as detailed above). SOPs MGM244, MGM271.</p> <p>Amplification refractory mutation detection system (ARMS) using in-house agarose gel electrophoresis or capillary electrophoresis (as detailed above). SOPs MGM101, MGM252, MGM308. Manual resolution: Gel electrophoresis to separate DNA fragments using documented in-house procedures. SOPs MGE055, MGM314, MGM151</p> <p>Automated resolution: Capillary electrophoresis for fragment separation using the ABI3730 genetic analyser.</p> <p>Analysis using GeneMarker software SOP GEN057.</p> <p>SOPs MGE031, MGE045, MGM025, MGM029, MGM042, MGM044, MGM054, MGM137, MGM257, MGM303.</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples and DNA from external sources</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples and DNA from external sources</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples and DNA from external sources</p>	<p>Determination of copy number changes and methylation status [definitive list of targets assessed to be held by this laboratory].</p> <p>Rapid diagnosis of common trisomys, [definitive list of targets assessed to be held by this laboratory].</p> <p>Determination of copy number changes and identity matching [definitive list of targets assessed to be held by this laboratory].</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Multiplex Ligation Probe Amplification (MLPA)</p> <p>Using: MRC Holland kits, Veriti thermocyclers, ABI3730 and GeneMarker data analysis software to detect dosage abnormalities by capillary electrophoresis</p> <p>SOPS MGM112, GEN065, GEN070</p> <p>QF-PCR</p> <p>Using: QF-PCR using the Devyser Compact and XY Kits and Elucigene kits by capillary electrophoresis on ABI3730 (as detailed above).</p> <p>SOPS MGM282, MGM183</p> <p>Powerplex HS16 Kit for the detection of molar pregnancy by capillary electrophoresis on ABI3730 (as detailed above).</p> <p>SOP MGM280</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Cells harvested from: Whole blood Amniotic fluid CVS Bone marrow Lymph node Fresh tissue samples</p>		<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Slide preparation and G Banding:</p> <p>SOPs NGLSM024, NGLSM021</p> <p>Chromosome analysis Microscopic analysis of G banded chromosomes</p> <p>Olympus light microscope and Bioview Image analysis system and:</p> <p>Manual G banded bright field analysis analysis and karyotyping against considered normal pattern/profile using:</p> <p>SOP MGE078, GEN010, GEN013</p> <p>Image analysis using: SOPs MGE081, NGLSM118</p>
<p>DNA</p>	<p>Clinical Exome TruSight Expanded One panel using Illumina DNA Prep with Enrichment (previously known as Nextera Flex for enrichment)</p>	<p>Using validated methods on Illumina NextSeq platform: VAL585, MGM323, MGM310 & MGE141</p>
<p>Blood (STRECK)</p>	<p>Non-invasive prenatal testing (NIPT) The VeriSeq NIPT Solution v2 – CE-IVD prenatal screening test used to detect fetal aneuploidies of chromosomes 21, 18 and 13 from maternal blood samples.</p>	<p>Using verified (VER065) CE-IVD method MGM325 on Hamilton Star robot MGE142 and Illumina NextSeq550DX platform MGE141</p>
<p>DNA</p>	<p>Targeted panel NGS using Illumina DNA Prep with Enrichment (previously known as Nextera Flex for Enrichment) using custom Twist panels</p>	<p>Using validated method on existing Illumina MiSeq platform: VAL615, MGM330 on existing MiSeq platform and MGM331.</p>



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END		