


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>20653</p> <p>Accredited to ISO 15189:2022</p>	<h3>The Royal Marsden NHS Foundation Trust</h3> <p>Issue No: 013 Issue date: 02 December 2025</p>	
	<p><b>Clinical Genomics</b> The Royal Marsden Hospital 15 Cotswold Road Sutton SM2 5PT</p>	<p><b>Contact: Mikel Valganon Petrizan</b> Tel: +44 (0)20 8661 3354 E-Mail: <a href="mailto:Mikel.ValganonPetrizan@rmh.nhs.uk">Mikel.ValganonPetrizan@rmh.nhs.uk</a> Website: <a href="http://www.royalmarsden.nhs.uk">www.royalmarsden.nhs.uk</a></p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	<p><u>Genomic analysis for the purpose 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><b>DNA Extraction:</b> Manual Process using QIAmp Midi and Mini kits GEN-SOP-207</p> <p>AutoMACS Pro Separator GEN-SOP-149</p> <p>Automata workflow using Kingfisher extraction platform and Promega Maxwell HT Genomic DNA kit (A6050) GEN-SOP-930</p> <p>Kingfisher extraction platform and Promega Maxwell HT Genomic DNA kit (A6050) GEN-SOP-930</p> <p>Automata workflow using Kingfisher extraction platform and Promega Maxwell HT Genomic DNA kit (A6050) GEN-SOP-881</p> <p>Hemocue WBC analyser GEN-SOP-157</p>
Blood		
Bone marrow		
Blood Bone Marrow		
Blood Bone Marrow		
Saliva		
Buffy coat		



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HUMAN TISSUE and FLUIDS	<u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u>	Documented in house procedures incorporating manufacturer's instructions (where relevant):
	DNA/RNA Extraction, quantification, and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Manual semi-automated and automated DNA /RNA extraction and quantification using:
Lyophilised cells		Qiagen Qiasymphony GEN-SOP-156
Biological fluids		Qiagen Qiasymphony GEN-SOP-156
Unfixed (fresh or frozen) tissue/cells		Manual: QIAmp mini kit GEN-SOP-223
Formalin fixed paraffin embedded tissues (FFPE)		Automated: Promega Maxwell RSC GEN-SOP-185
Saliva		Automated: Saliva Extraction using the Maxwell. GEN-SOP 600
Plasma		<b>DNA Extraction:</b> Manual: QIAmp circulating NA kit GEN-SOP-215 Roche Cobas sample preparation kit GEN-SOP-122
Plasma	Isolation of cfDNA	Automated: Qiagen QIASymphony GEN-SOP-128 Marsden360 GEN-SOP 711 Manual Marsden360 GEN-SOP 712
		<b>DNA Quantification for QC purposes:</b> GEN-SOP-212
Blood		<b>RNA Extraction:</b> Manual: Qiagen RNeasy mini kit GEN-SOP-125



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<p>HUMAN TISSUE and FLUIDS (cont'd)</p> <p>Bone Marrow Biological fluids Unfixed tissue</p> <p>RNA Extracted from peripheral Blood, Bone Marrow Biological Fluids, Unfixed Tissue Formalin fixed paraffin embedded tissues (FFPE) (See above)</p> <p>Genomic RNA (cDNA) extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p><u>Genomic analysis for the purpose 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 (cont'd)</p> <p>Generation of cDNA by reverse transcriptase for subsequent in-house Analysis (see below)</p> <p>Quantitative analysis of known gene fusions events for the monitoring of malignancies for the purpose of clinical diagnosis of cancer and cancer MRD. Analysis of acute leukaemia, chronic myeloid leukaemia, and translocations [Definitive list in GEN-DOC-707]</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>Automated: Promega Maxwell RSC48 GEN-SOP-173</p> <p><b>RNA quantification for QC purposes:</b> Qubit GEN-SOP-212</p> <p><b>Nucleic Acid quantification for QC purposes:</b> Qubit GEN-SOP-212</p> <p><b>Manual Method</b> Applied Biosystems Reverse Transcription Kit.: GEN-SOP-131</p> <p><b>Quantitative Real Time PCR</b> Manual Set up and ABI 7500 Fast sequence detection system real time system GEN-SOP-8 GEN-SOP-9 GEN-SOP-170</p>



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<p>HUMAN TISSUE 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. Unless otherwise stated testing is undertaken on DNA</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Detection of fragment length size, deletions, known mutations, repeat expansions, MSI, - Linkage markers, IG and TCR Gene re-arrangements. [Definitive list in GEN-DOC-707]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Fragment length analysis</b> QIAgility ABI 3500 genetic analyser ABI 3730xl genetic analyser Thermal cycler Genescan Genemapper Analysis Promega Powerplex 16 kit CD3 purity check using Accumol GEN-SOP-12 GEN-SOP-14 GEN-SOP-204 GEN-SOP-193 GEN-SOP-175 GEN-SOP-126 GEN-SOP 170 GEN-SOP 200 GEN-SOP 138 GEN-SOP 123 GEN-SOP 598</p>
<p>Genomic DNA (extracted in house) from the sample types listed above or received from external sources</p>	<p>Multiplex Ligation-dependent Probe Amplification for the detection of DNA methylation analysis</p>	<p><b>MLPA</b> ABI 3500 genetic analyser ABI 3730xl genetic analyser Thermal cycler GEN-SOP 674 GEN-SOP 678</p>
<p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p>Qualitative Genotype analysis for SNV's Indels and Fusion transcripts [Definitive list in GEN-DOC-707]</p>	<p><b>Qualitative Real Time PCR</b> Cobas z analyser 480 GEN-SOP-210 GEN-SOP-139 GEN-SOP-165 GEN-SOP-170</p>
<p>Genomic DNA &amp; RNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p>Detection of DNA sequence variants - SNVs and Indels and Ig Variable regions [Definitive list in GEN-DOC-707]</p>	<p><b>Sanger Sequencing</b> Thermal cycler ABI 3500 Genetic analyser ABI 3730 Genetic Analyser GEN-SOP-200 GEN-SOP-159</p>



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<p>HUMAN TISSUE and FLUIDS (cont'd)</p> <p>Genomic DNA &amp; RNA extracted in house from the sample types listed above and received as primary samples from external sources</p> <p>Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Detection of DNA sequence variants, Copy number Variants and Indels [Definitive list in GEN-DOC-707]</p> <p>Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC-707]</p> <p>SNV's Indels, Structural variants and Copy Number Variants.</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>ddPCR (digital drop PCR)</b> QX200 Automated Droplet Generator PX1™ PCR plate sealer DG32™ Automated Droplet Generator Cartridges C1000 Touch Thermal Cycler with 96-Deep Well Reaction Module QX200 Droplet Reader PC and QuantaSoft GEN-SOP-225 GEN-SOP-135 GEN-SOP-161 GEN-SOP-11</p> <p><b>Next Generation Sequencing: Library Preparation Kits</b></p> <p>Illumina Trusight (Pan cancer) KAPA/Nimblegen Baits Nonacus/Baits GEN-SOP-219 GEN-SOP-176</p>



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<p>HUMAN TISSUE and FLUIDS (cont'd)</p> <p>Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC-707]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Next Generation Sequencing: Manual Process</b> Eppendorf Concentrator Plus ABI 7500 Fast Real-Time PCR System Thermal cycler Qubit Tapestation 2200 Tapestation 4200 Fluoroskan microplate fluorometer Illumina NextSeq 500 NGS platform Illumina NextSeq 550Dx NGS platform Illumina NovaSeq 6000 NGS platform GEN-SOP-212 GEN-SOP-213 GEN-SOP-214 GEN-SOP-169 GEN-SOP-144 GEN-SOP-164</p>
<p>Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources</p>	<p>Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC 707]</p>	<p><b>NGS - Library preparation Automated:</b> Hamilton STARlet Liquid Handler Hamilton NGS STAR Liquid Handler GEN-SOP-174 Marsden360 GEN-SOP710</p>
<p>Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources (cont'd)</p>	<p>Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC 707] (cont'd)</p>	<p><b>NGS - Library preparation Analysis:</b> Somatic Mutation report Pipeline SOP HPC GEN-SOP-152</p> <p>Somatic Mutations Report Webserver GEN-SOP-167</p> <p>Alamut GEN-SOP-142</p>



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<p>HUMAN TISSUE and FLUIDS (cont'd)</p> <p>DNA extracted from Formalin-Fixed Paraffin-Embedded (FFPE) tissue Bone marrow Blood.</p> <p>RNA extracted from Formalin-Fixed Paraffin-Embedded (FFPE) tissue Unfixed (fresh or frozen) tissue/cells Bone marrow Blood Cell lines</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)</u></p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Variant Studio Variant Interpretation and Classification GEN-SOP-143</p> <p>Marsden360 BIP Results GEN-SOP 713</p> <p>Marsden360 QIAGEN Clinical Insights Interpret GEN-SOP 715</p> <p>Illumina's DRAGEN (Dynamic Read Analysis for Genomics) Pipeline Somatic Mutations Report using Webserver GEN-SOP 167</p> <p>RNA fusion calling Pipeline. In-house pipeline – Arriba and StarFusion combination RNA Pan-Cancer Analysis GEN-SOP 718</p>



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<p>HUMAN TISSUE and FLUIDS (cont'd)</p> <p>Whole blood collected in Streck cell-free DNA Blood collection tubes</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Cell free DNA (cfDNA) NGS for tumour profiling in advanced cancers (stage III and IV).</p> <p>74 genes targeted panel – examined for single nucleotide variants (SNV) and insertions/deletions (indels)</p> <p>18 genes for copy number variants (CNV)</p> <p>6 genes for fusions</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Next Generation Sequencing:</b></p> <p>DNA extraction: QiasymphonySP Instrument GEN-SOP 711</p> <p>Automated Library preparation: Hamilton Microlab STARlet Hamilton Microlab STAR GEN-SOP 710</p> <p>PCR for library preparation: Veriti Thermocycler GEN-SOP 710</p> <p>Library quantification: Agilent 4200 TapeStation GEN-SOP 710</p> <p>Sequencing platform: NextSeq 550 Sequencing System GEN-SOP 710</p> <p>Software: Qiagen Clinical Insights (QCI) Interpret Software GEN-SOP 715</p>



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<p>HUMAN TISSUES and BODY FLUIDS</p> <p>Whole blood Bone marrow Tissues/skin biopsy</p>	<p><u>Cytogenetic examinations for the purpose of clinical diagnosis</u></p> <p>Chromosome analyses for: Haemato-oncology disorders Solid tumours</p>	<p>In-house documented procedures based on equipment manuals as relevant.</p> <p>Chromosome culture using commercial media and harvesting GEN-SOP-38 GEN-SOP-41 GEN-SOP-55 GEN-SOP-60 GEN-SOP-61 GEN-SOP-63 GEN-SOP-68 GEN-SOP 73</p> <p>Microscopic analysis and reporting of G Banding and karyotype against considered normal pattern/profile. GEN-SOP-36 GEN-SOP-56 GEN-SOP-60 GEN-SOP 16</p>
<p>Bone Marrow Blood</p>	<p>Prognostic information in regard to Myeloma</p>	<p>Isolation of highly purified cell populations (in particular CD138 Positive cells) AutoMacsPro Miltenyi Biotech AutoMACS CD138+ cell separation GEN-SOP-97</p> <p>Fluorescent in-situ hybridisation (FISH) using in-house procedures and Kreatech, Cytocell, Vysis and Zytovision commercial kits</p> <p>GEN-SOP-52 GEN-SOP-53 GEN-SOP-56 GEN-SOP-60 GEN-SOP-85 GEN-SOP-78 GEN-SOP 79</p>



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HUMAN TISSUES and BODY FLUIDS  Paraffin embedded tissue	<u>Cytogenetic examinations for the purpose of clinical diagnosis</u>  Solid tumours	In-house documented procedures based on equipment manuals as relevant.  Fluorescent in-situ hybridisation (FISH) using in-house procedures and Kreatech, Cytocell and Vysis commercial kits GEN-SOP-52 GEN-SOP-53 GEN-SOP-54 GEN-SOP-56 GEN-SOP-60
END		