


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>20653</p> <p>Accredited to ISO 15189:2012</p>	<h3>The Royal Marsden NHS Foundation Trust</h3> <p>Issue No: 001 Issue date: 05 August 2021</p>	
	<p>Clinical Genomics The Royal Marsden Hospital 15 Cotswold Road Sutton SM2 5PT</p>	<p>Contact: Sue Alexander Tel: +44 (0)20 8661 3354 E-Mail: sue.alexander@rmh.nhs.uk Website: www.royalmarsden.nhs.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
<p>HUMAN TISSUE AND FLUIDS</p> <p>Blood</p> <p>bone marrow</p> <p>buffy coat</p> <p>lyophilised cells</p> <p>biological fluids</p> <p>Unfixed (fresh or frozen) tissue/cells</p> <p>Formalin fixed paraffin embedded tissues (FFPE)</p> <p>Saliva</p> <p>Plasma</p> <p>Plasma</p>	<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>Isolation of cfDNA</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: Manual Process using QIAmp Midi and Mini kits SMD25 SMD70 AutoMACS Pro Separator SMD146 Hemocue WBC analyser SMD158 Qiagen Qiasymphony SP SMD157 SMD01 Manual: using QIAmp mini kit SMD81 Automated: Promega Maxwell RSC SMD177 Manual using Qiagen Kit SMD73</p> <p>Manual: using Oragene Saliva kit SMD 139</p> <p>Manual using: QIAmp circulating NA kit MSD67 Roche Cobas sample preparation kit SMD90</p> <p>Manual using Roche AVENIO cfDNA SM167 Automated: Qiagen QIASymphony SP SMD100</p> <p>DNA Quantification for QC purposes: Qubit SMD61</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Blood</p> <p>Bone Marrow</p> <p>Biological Fluids Unfixed Tissue Formalin fixed paraffin embedded tissues (FFPE)</p> <p>Formalin fixed paraffin embedded tissues (FFPE)</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</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>RNA Extraction: Manual: using Qiagen RNeasy mini kit SMD03 Automated: Promega Maxwell RSC48 SMD179</p> <p>Manual using Ambions Recover ALL RNA purification kit SMD04</p> <p>RNA quantification for QC purposes: Qubit SMD61</p> <p>Dual DNA/RNA extraction</p> <p>Manual: using Allprep AND-RNA FFPE Qiagen extraction kit SMD86 Automated: Promega Maxwell RSC48 SMD186</p> <p>Nucleic Acid quantification for QC purposes: Qubit SMD61</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</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>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>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>Genomic DNA 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>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 or fusions in Soft Tissue Sarcoma [Definitive list in MDEW_0514]</p> <p>Detection of fragment length size, deletions, known mutations, repeat expansions, linkage markers, IG and TCR Gene re-arrangements. [Definitive list in MDEW_0514]</p> <p>Single nucleotide Polymorphism genotyping - Sample check [Definitive list in MDEW_0514]</p> <p>Qualitative Genotype analysis for SNV's Indels and Fusion transcripts [Definitive list in MDEW_0514]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Manual Method with Applied Biosystems Reverse Transcription Kit.: SMD11, SMD72</p> <p>Quantitative Real Time PCR Using: Manual Set up and ABI 7500 Fast sequence detection system real time system SMD05 SMD175 SMD17</p> <p>Fragment length analysis Using: QIAgility, Hamilton StarLet ABI Prism 3500 genetic analyser, 3730 genetic analyser, thermocycler, Genescan and Genemapper Analysis. Promega Powerplex 16 kit and CD3 purity check using Accumol SMD10 SMD175 SMD23 SMD12 SMD79 SMD173 SMD189 SMD09 SMD18</p> <p>SNP Genotyping Using: Thermal cycler 3730 DNA Analyzer SMD176 SMD22</p> <p>Qualitative Real Time PCR Using: QIAgility and Cobas z analyser 480 SMD41 SMD123 SMD169 SMD175</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Genomic DNA & RNA extracted in house from the sample types listed above and received as primary samples from external sources</p> <p>Genomic DNA & 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 - SNVs and Indels and Ig Variable regions [Definitive list in MDEW_0514]</p> <p>Detection of DNA sequence variants, Copy number Variants and Indels [Definitive list in MDEW_0514]</p> <p>Gene Screening of Large gene panels for genetic variants: [Definitive list is in MDEW_0514]</p> <p>SNV's, Indels and Structural Variants</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>Sanger Sequencing Using: Thermal cycler ABI 3130 X1 ABI 3500 Genetic analyser ABI 3730 DNA Analyser</p> <p>Analysis using Mutation Surveyor</p> <p>SMD07 SMD22 SMD23 SMD28 SMD124 SMD16</p> <p>ddPCR (digital drop PCR) Using: 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</p> <p>SMD85 SMD94 SMD115 SMD117 SMD161 SMD162</p> <p>Next Generation Sequencing:</p> <p>Library Preparation Kits</p> <p>QIAseq Targeted Custom Amplicon (Q33)</p> <p>Illumina Trusight (Pan cancer, TST170) KAPA/Nimblegen Baits Roche AVENIO Nonacus/Baits</p> <p>SMD168, SMD188 SMD180, SMD74, SMD165 SMD190</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 MDEW 0514]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Next Generation Sequencing: Using: Manual Process 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</p> <p>SMD61, SMD62, SMD182, SMD65, SMD60, SMD174, SMD133 SMD166</p> <p>NGS - Library preparation Automated: Hamilton STARlet Liquid Handler Hamilton NGS STAR Liquid Handler</p> <p>SMD183, SMD184, SMD153, SMD185</p> <p>Analysis: Analysis of BRCA1 and 2 SMD78, Somatic Mutation report SMD91, Pipeline SOP HPC SMD150, Somatic Mutations Report Webserver SMD170, Alamut SMD130, Variant Studio SMD131, Variant Interpretation and Classification SMD132, TST170 SMD180</p>
END		