


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>North Bristol NHS Trust</h3> <p>Issue No: 004    Issue date: 16 November 2020</p>	
	<p>Bristol Genetics Laboratory Pathology Sciences Building Southmead Hospital Westbury on Trym BS10 5NB</p>	<p>Contact: Rachel Butler Tel: +44 (0)117 414 6168 E-Mail: rachel.butler@nbt.nhs.uk Website: www.nbt.nhs.uk/severn-pathology/pathology-services/bristol-genetics-laboratory-bgl</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
<p>HUMAN TISSUE AND FLUIDS</p> <p>Tissue, CVS, Saliva, Cultured cells Peripheral Blood, PET, Prenatal Peripheral Blood</p> <p>Peripheral Blood and Bone Marrow</p> <p>Peripheral Blood, Prenatal, Bone Marrow, FFPE and Blood Spot</p> <p>FFPE</p> <p>Peripheral Blood</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>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Manual semi-automated and automated DNA /RNA extraction and quantification using:</b></p> <p><b>DNA Extraction :</b> Manual extraction processes 17.6.28, 21.26, 17.6.32, 17.6.34 Qiagen Qiacube 17.6.33, 17.6.24, 17.6.36 Promega Tecan Freedom Evo 17.6.35 QIASymphony using QIASymphony DSP DNA Mini and Midi kit 17.6.37 EZ1 Biorobot 17.6.27</p> <p><b>DNA Quantification for QC purposes:</b> Nanodrop ND2000 and ND8000 17.6.8</p> <p><b>RNA extraction:</b> Manual process and automated using Qiacube 17.6.34, Automated using Qiacube 20.12</p> <p><b>RNA Quantification for QC purposes :</b> Nanodrop ND2000 and ND8000 17.6.8</p>



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<p><b>HUMAN TISSUE AND FLUIDS</b></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 extracted in house from the sample types listed above and received as primary samples from external sources (cont'd)</p> <p>Genomic DNA and RNA extracted in house from the sample types listed above and received as primary samples from external sources (cont'd)</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u></p> <p>Detection of nucleic acid sequence variant - SNVs and Indels [Definitive list in APP15/60]</p> <p>Detection of nucleic acid sequence variants, small indels and/or determination of methylation status [Definitive list in APP15/60]</p> <p>Qualitative Genotype analysis for SNVs, indels and fusion transcripts [Definitive list in APP15/60]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Sanger Sequencing</b> Using: Standard primer design methodology, PCR amplification, gel electrophoresis Beckman Coulter NXp/FxP robots and Thermocyclers. Sanger Sequencing performed using Applied Biosystems ABI 3730 DNA analyser and Mutation Surveyor software</p> <p>17.23.8, MRD/S3/003 , 18.1, 17.23.5</p> <p><b>Pyrosequencing</b> Using: Qiagen Pyromark Q96 Pyrosequencer PCR amplification using kits electrophoresis, Beckman Coulter NXp/FxP robots and Thermocyclers.</p> <p>17.23.16</p> <p><b>Qualitative Real Time PCR</b> Using: Life Technologies 7500 and 7500 FAST real time analysers and: 17.23.12, 17.43.3, 20.27</p>



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<p>HUMAN TISSUE AND FLUIDS</p> <p>RNA extracted from peripheral blood and bone marrow (see above)</p> <p>RNA extracted in house from the sample types listed above and received as primary samples from external sources (cont'd)</p> <p>Genomic DNA and RNA extracted in house from the sample types listed above and received as primary samples from external sources (cont'd)</p> <p>Genomic DNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources (cont'd)</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u></p> <p>Generation of cDNA by reverse transcriptase for subsequent in-house analysis (see below)</p> <p>For the qualitative detection of common fusion transcripts associated with malignancy [Definitive list in APP15/60]</p> <p>Quantitative analysis of known gene fusions events for the monitoring of malignancies [Definitive list in APP15/60]</p> <p>Gene screening of large gene panels for genetic variants [Definitive list in APP15/60]</p> <p>SNVs</p> <p>CNVs</p> <p>Indels</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>cDNA generation:</b> Manual method using Applied Biosystems cDNA Reverse Transcription Kit</p> <p>17.6.38</p> <p><b>Qualitative Reverse Transcriptase PCR (RTPCR)</b> Using: G Storm Thermocycler and gel electrophoresis and Genesnap visualisation and: 20.13</p> <p><b>Quantitative Real Time PCR</b> Using: Life Technologies 7500 and 7500 FAST real time analysers and: 17.23.12</p> <p>20.15: (RQ-PCR for BCR-ABL transcripts) MRD/S2/003, MRD/S4/003, MRD/S4/004, MRD/S5/001, MRD/S5/002</p> <p><b>Next Generation Sequencing:</b></p> <p><b>Library Preparation methods:</b> Haloplex Agilent Sureselect Illumina Trusight (Cancer and TST15) Haloplex Agilent Sureselect Agilent Sureselect Illumina Trusight (Cancer and TST15)</p>



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<p><b>HUMAN TISSUE AND FLUIDS</b></p> <p>Genomic DNA and RNA extracted in house from the sample types listed and samples received as primary samples 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. 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</p> <p>Genomic DNA extracted in house from the sample types listed</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u></p> <p>Gene screening of large gene panels for genetic variants [Definitive list in APP15/60]</p> <p>Detection of fragment length size, deletions, known mutations, repeat expansions, linkage markers. [Definitive list in APP15/60]</p> <p>Determination of copy number changes [Definitive list in APP15/60]</p> <p>Detection of large gene rearrangements [Definitive list in APP15/60]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Next Generation Sequencing:</b> Using: Diagen Biorupter, Agilent 2200 TapeStation, Qubit 2.0 Fluorometer, thermal cycler and Illumina MiSeq and/or NextSeq 17.55.3, 17.55.4, 17.55.5, 17.55.6, 17.55.14, 17.55.17, 17.55.21, 17.55.22, Analysis using: Clinical Exome and targeted panel pipeline 25.2 Somatic pipeline 25.5 Somatic Variants_BGL/SOP/Analysis/1</p> <p><b>Fragment length analysis</b></p> <p>Nucleic acid amplification Using: G Storm thermocyclers (GS0004M) and Coulter CEQ8000 / ABI 3730 and 3500 Genetic Analysers using GeneMarker and Genemapper analysis software 17.23.4, 17.23.14, ,17.23.2,20.17, BGL/TECH/FRAG/SOP/3 17.4.1, 17.4.6, 17.7.9, 17.46.1,BGL/TECH/FRAG/SOP/2, BGL/RD3/SOP/1</p> <p><b>Multiplex Ligation Probe Amplification (MLPA)</b></p> <p>Using: G Storm thermocyclers, Beckman CEQ8000 and GeneMarker and Coffalyser data analysis software 17.23.18, 17.23.4, 12.55</p> <p><b>Southern Blotting</b></p> <p>Using: Model 400 and Carbolite Hybridisation incubators, Stratolinker and XO Graph, and Chemiluminescence detection 17.8.1</p>



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<p><b>HUMAN TISSUE AND FLUIDS</b></p> <p>Genomic DNA extracted in house from peripheral blood, bone marrow and FFPE tissues</p> <p>Whole blood Amniotic fluid CVS Foetal Blood Products of conception Bone Marrow Whole Blood Tissues/Skin Biopsies Buccal cells</p>	<p>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</p> <p>Detection of single nucleotide variants and small indels [Definitive list in APP15/60]</p> <p>G-banding/Karyotyping:</p> <p>Detection of chromosomal rearrangements or aberrations arising from: (e.g.)</p> <p>Prenatally detected Disorders Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders</p> <p>(preparative pre-examination steps listed first)</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Droplet digital PCR</b> Using : BioRAD QX200 Droplet Reader BioRAD AutoDroplet Generator BioRAD PCR Plate Reader and:</p> <p><b>Culturing and processing of human tissue/cells to provide interphase cells:</b> Automated process using StemCell Robosep fully automated cell separator using: SOP 3.30 And 2.5, 2.7, 2.9 (Prenatal) 3.4 (Constitutional – blood) 3.7, 3.11 (Oncology) 3.12, 3.30, 4.0, 4.6, 4.20 (Solid tissue)</p> <p>Cell Harvesting: Automated process to provide material suitable for analysis using Freedom EVO 100 Tecan Liquid Handling Robot and: 3.15 Manual harvesting using 3.16, 3.28</p> <p>Automated process using Genial Genetics Coverslip Harvester and: 2.12</p> <p><b>Chromosome analysis</b> <b>Microscopic analysis of G banded chromosomes</b> Carl Zeiss light microscope and Metasystems Image analysis suite and: 13.3, 10 and 10.2 7.1, 7.3, 7.5, 7.10, 3.22, 4.12, 4.13 Manual analysis using: 10, 10.2, 7.4, 7.5, 7.7</p>



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<p>HUMAN TISSUE AND FLUIDS</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p> <p>Formalin fixed paraffin embedded tissue (FFPE) Peripheral Blood Bone Marrow Fixed culture cells (more specific – cultured, uncultured PB, Marrow, AFs etc) Amniotic fluid CVS- Chorionic villus samples</p>	<p>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</p> <p>Cytogenetic examinations for diagnosing postnatal disorders prenatal diagnosis, neoplastic genetics including haemato-oncology and solid tumours loss of pregnancy</p> <p>by detection of sub microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number</p> <p>Detection of chromosomal aberrations in the diagnosis of haematological malignancy, bone marrow failure syndromes, non-haematological malignancies and constitutional disorders, solid tumours and companion testing Break-apart probes Fusion products Deletion Insertion Copy Number / Amplification</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p><b>Array Comparative Genomic Hybridisation (aCGH)</b> processing Competitive hybridisation of patient and control DNA using hybridisation oven, MiVac and Agilent array scanner and Scigene Little Dipper slide washer. Analysis and interpretation of genetic imbalances using Cytosure Interpret software 21.24 21.11</p> <p><b>Fluorescence in situ hybridisation (FISH)</b> Fluorescent in situ hybridisation (FISH) using commercial and in house developed probes by Hybrite using: SOP0504, SOP0502, SOP0524 and analysis using Fluorescent microscope and Carl Zeiss Metasystems Image analysis suite. and: SOP13.3</p>
END		