


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2022</p>	<p style="text-align: center;">North Bristol NHS Trust</p> <p style="text-align: center;">Issue No: 009 Issue date: 25 July 2024</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;"> Bristol Genetics Laboratory Pathology Sciences Building Southmead Hospital Westbury on Trym BS10 5NB </td><td style="width: 50%;"> Contact: Laura Johnston Tel: +44 (0)117 414 6168 E-Mail: Laura.Johnston@nbt.nhs.uk Website: www.nbt.nhs.uk/severn-pathology/pathology-services/bristol-genetics-laboratory-bgl </td></tr> </table>	Bristol Genetics Laboratory Pathology Sciences Building Southmead Hospital Westbury on Trym BS10 5NB	Contact: Laura Johnston Tel: +44 (0)117 414 6168 E-Mail: Laura.Johnston@nbt.nhs.uk Website: www.nbt.nhs.uk/severn-pathology/pathology-services/bristol-genetics-laboratory-bgl
Bristol Genetics Laboratory Pathology Sciences Building Southmead Hospital Westbury on Trym BS10 5NB	Contact: Laura Johnston Tel: +44 (0)117 414 6168 E-Mail: Laura.Johnston@nbt.nhs.uk Website: www.nbt.nhs.uk/severn-pathology/pathology-services/bristol-genetics-laboratory-bgl		
Testing performed at the above address only			

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS Tissue, CVS, Saliva, Cultured cells Peripheral Blood, PET, Prenatal Peripheral Blood Peripheral Blood and Bone Marrow Peripheral Blood, Prenatal, Bone Marrow, FFPE and Blood Spot Solid tumour and tissue FFPE Plasma	<u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Documented in house procedures incorporating manufacturer's instructions (where relevant): Manual semi-automated and automated DNA /RNA extraction and quantification using: DNA Extraction : Manual extraction processes 17.6.28, 21.26, 17.6.32, 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 Automated extraction processes QIASymphony 17.6.41 Promega Maxwell RSC 48 instrument and Maxwell RSC DNA/RNA FFPE Kit (DNA and RNA) and in-house method SOP 17.6.42 ccfDNA extraction Manual extraction processes QIAmp Circulating Nucleic Acid Kit QIAvac 24 Plus vacuum manifold 17.6.39



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):
Plasma	DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage (cont'd)	Manual, semi-automated and automated DNA /RNA extraction and quantification using: DNA Quantification for QC purposes: Nanodrop ND2000 and ND8000 17.6.8 Qubit 4.0 and Qubit Flex 17.55.5
FFPE		RNA extraction: Manual process and automated using Qiacube 17.6.34
Peripheral Blood		Automated using Qiacube 20.12
Whole Blood, FFPE		Promega Maxwell RSC 48 instrument and Maxwell RSC simplyRNA Blood Kit (SOP 17.2.43) and Maxwell RSC DNA/RNA FFPE Kit (SOP 17.6.42)
Genomic DNA & RNA extracted in house from the sample types listed above and received as primary samples from external sources	Detection of nucleic acid sequence variant - SNVs and Indels [Definitive list in APP15/60]	RNA Quantification for QC purposes : Nanodrop ND2000 and ND8000, 17.6.8 Qubit 4.0 and Qubit Flex 17.55.5 Sanger Sequencing 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 17.23.8, MRD/S3/003 , 18.1, 17.23.5



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</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>Whole Blood</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><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</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>Genotyping DPYD</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>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Pyrosequencing Using: Qiagen Pyromark Q48Pyrosequencer PCR amplification using kits electrophoresis, Beckman Coulter NXp/FxP robots and Thermocyclers. BGL/TECH/PYRO/SOP/1</p> <p>Qualitative Real Time PCR Using: Life Technologies 7500 and 7500 FAST real time analysers and Quantstudio 5 analysers and: 17.23.12, 17.43.3, 20.27 BGL/TECH/REAL-TIME/SOP/1</p> <p>Genotyping using Loop-mediated isothermal Amplification (LAMP) Melt Analysis (LaCar) (Qualitative PCR) using Quantstudio 5 Manual or Automated Set Up using BioMek NxP liquid handler or FXP liquid handler BGL/TECH/REAL-TIME/SOP/2 Analysis using BGL/TECH/NGS/SOP/3</p> <p>cDNA generation: Manual method using Applied Biosystems cDNA Reverse Transcription Kit</p> <p>17.6.38</p> <p>Qualitative Reverse Transcriptase PCR (RTPCR) Using: G Storm Thermocycler and gel electrophoresis and Genesnap visualisation and: 20.13</p>



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<p>HUMAN TISSUE AND FLUIDS (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> (cont'd)</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>IDT</p> <p>Gene Screening Gene rearrangements at the immunoglobulin and T cell receptor loci for minimal residual disease (MRD)</p> <p>SNP genotyping for identity checks for NGS for WGS</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Quantitative Real Time PCR Using: Life Technologies 7500 and 7500 FAST real time analysers and Quantstudio 5 analysers and: 20.15: (RQ-PCR for BCR-ABL transcripts) MRD/S2/003, MRD/S4/003, MRD/S5/001</p> <p>Next Generation Sequencing:</p> <p>Library Preparation methods: Nextera Flex with Twist Biosciences Illumina TSO500 Illumina Trusight TST15</p> <p>Nextera Flex with Twist Biosciences probe set</p> <p>Nextera Flex with Twist Biosciences probe set Illumina Trusight TST15 Illumina TSO500</p> <p>Illumina TSO500</p> <p>Library Preparation Amplicon based MRD 17.55.24</p> <p>Library Preparation Amplicon based</p>



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<p>HUMAN TISSUE AND FLUIDS (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> (cont'd)</p> <p>Gene screening of large gene panels for genetic variants [Definitive list in APP15/60]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Next Generation Sequencing: Using: Agilent 2200 and 4200 Tapestation, Qubit 2.0, 4.0 and Qubit Flex Fluorometer, thermal cycler and Beckman Biomek i7 Hybrid liquid handling robot and Illumina MiSeq and/or NextSeq or NovaSeq 6000 17.55.4, 17.55.5, 17.55.6, 17.55.21, 17.55.22, Covaris LE220R (only TSO500 on DNA extracted from FFPE) BGL/TECH/NGS/SOP/1 BGL/TECH/NGS/SOP/2 BGL/TECH/NGS/SOP/4 BGL/TECH/NGS/SOP/6 BGL/TECH/NGS/SOP/7 BGL/TECH/NGS/SOP/8 Analysis using: Clinical Exome and targeted panel pipeline 25.2 Somatic VariantsBGL/Analysis/SOP/1 BGL/SOLIDTUMOUR/SOP/1 MRD NGS pipeline 25.9 DNA nexus somatic pipelines (SOP 25.10) SNP genotyping pipeline BGL/TECH/NGS/SOP/3</p>
<p>Genomic DNA extracted in house from peripheral blood, bone marrow trephine or fresh tissue</p>	<p>SNP array for Oncology</p>	<p>Qubit 4.0 and Qubit Flex Fluorometer, NextSeq550 array scanner and Infinium CytoSNP-850K v1.2 BeadChip Assay 17.55.5 BGL/TECH/ARRAY/SNP MICROARRAY/SOP/1 Analysis using: BGL/ANALYSIS/SOP/2</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>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>Genomic DNA extracted in house from peripheral blood, bone marrow and FFPE tissues</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, 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>Detection of single nucleotide variants and small indels [Definitive list in APP15/60]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant):</p> <p>Fragment length analysis</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 17.23.25, 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/1, BGL/TECH/FRAG/SOP/2, BGL/RD3/SOP/1</p> <p>Multiplex Ligation Probe Amplification (MLPA)</p> <p>Using: G Storm thermocyclers, ABI 3730, Beckman CEQ8000 and GeneMarker and Coffalyser data analysis software 17.23.18, 12.55</p> <p>Southern Blotting</p> <p>Using: Model 400 and Carbolite Hybridisation incubators, Stratolinker and XO Graph, and Chemiluminescence detection 17.8.1</p> <p>Droplet digital PCR</p> <p>Using : BioRAD QX200 Droplet Reader BioRAD AutoDroplet Generator BioRAD PCR Plate Reader and: BGL/TECH/ddPCR/SOP/1</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Whole blood Amniotic fluid CVS Foetal Blood Products of conception Bone Marrow Whole Blood Tissues/Skin Biopsies Buccal cells</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</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>Culturing and processing of human tissue/cells to provide interphase cells: Automated process using StemCell Robosep fully automated cell separator using: SOP 3.30 And 2.5, 2.7, 2.8 (Prenatal) 3.4 (Constitutional – blood) 3.7, (Oncology) 3.30, 4.0, 4.6, 4.20 (Solid tissue)</p> <p>Cell Harvesting: Manual harvesting using 3.16, 3.28</p> <p>Automated process using Genial Genetics Coverslip Harvester and: 2.12</p> <p>Chromosome analysis Microscopic analysis of G banded chromosomes Carl Zeiss light microscope and Metasystems Image analysis suite and: 13.3, 10 and 10.2 7.1, 7.3, 7.5, 3.22, 4.13 Manual analysis using: 10, 10.2, 7.4, 7.5, 7.7</p>



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END		