

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8176 Accredited to ISO 15189:2022	Birmingham Women's and Children's NHS Foundation Trust	
	Issue No: 017	Issue date: 22 September 2026
	Birmingham Women's Hospital Mindelsohn Way Edgbaston Birmingham B15 2TG	Contact: Carly Mogg Tel: +44 (0)121 333 9999 Ext. 4925 E-Mail: carly.mogg@nhs.net Website: www.bwc.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
Birmingham Women's Hospital West Midlands Genomics Laboratory Mindelsohn Way Edgbaston Birmingham B15 2TG Local contact Carly Mogg 0121 335 8036	Molecular Genetics

Site activities performed away from the locations listed above:

Location details	Activity
Birmingham Research Park Limited Institute of Research and Development Birmingham Research Park Vincent Drive Edgbaston Birmingham B15 2SQ Local contact Carly Mogg 0121 335 8036	Reporting



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
	Sample processing, DNA/RNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long term storage	
Whole Blood Bone Marrow	Separation of lineage specific cell fractions	Lineage specific cell separation (1) Automated using Automacs Miltyeni Biotech autoMACS®Pro Separator PP 02.01.95
Whole Blood Bone Marrow Saliva (Oragene self-collection kit) Plasma	DNA extraction	Automated DNA Extraction (2) Qiagen QIASymphony SP platform with: QIASymphony DNA Midi Kit QIASymphony DSP virus kit SOPs: PP 03.01.21, PP 03.01.13, PP 03.01.48
Whole Blood Bone Marrow		(3) Qiagen QIAcube with Qiagen QIAamp DNA Blood Mini Kit SOP: PP 03.01.15
Dried Blood Spots		(4) Promega Maxwell RSC Promega Maxwell RSC Blood kit and Promega Casework Extraction kit SOP: PP 03.01.64



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MACS separated cell fractions Amniotic Fluid CVS	DNA Extraction	Automated DNA extraction (5) Qiagen EZ1or EZ2 EZ1&2 DNA Tissue Kit SOPs: PP 03.01.08, PP 03.01.14 PP 03.01.10
Fresh frozen solid tissue		(6) Qiagen EZ1 or EZ2 EZ1&2 Tissue Kit with manual homogenation SOP: PP 03.01.07
Fresh tissue Foetal Tissue POC		(7) Qiagen EZ1 or EZ2 EZ1&2 DNA Tissue Kit with tissue abruption using Precellys 24 Homogeniser SOP: PP 03.01.19
Peripheral Blood Bone Marrow Foetal Blood Mouth Wash Cultured Cells		Manual DNA Extraction (8) Qiagen Gentra Puregene Kit SOPs: PP 03.01.02, PP 03.01.06, PP 03.01.05
Peripheral Blood		(9) Biorad Instagene matrix SOP: PP 03.01.12
Saliva (Oragene self-collection kit)		(10) DNA extraction using Genotek Prep-IT kit SOP: PP 03.01.13



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in house using methods 1-12, 14 for the sample types listed above or received as primary sample type from an external source FFPE Whole Blood Bone Marrow	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant) DNA Quantification for QC purposes (11) Nanodrop 8000 (12) Qubit 2.0/4.0 fluorometer (13) Quantification of DNA samples using Quant-iT Picogreen assay and SpectraMax Gemini™ XPS Spectrofluorometer SOPs: PP 03.01.27, PP 03.01.36, PP 03.01.50 Automated dual DNA and RNA extraction and quantification (14) DNA and RNA extraction from FFPE scrolls and slides Promega Maxwell RSC instruments Promega Maxwell RSC RNA FFPE kit SOP: PP 03.01.68 Automated RNA extraction (15) Promega Maxwell RSC instruments Promega Maxwell RSC simplyRNA Blood kit SOPs: PP 03.01.65, PP.03.01.66



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HUMAN TISSUES AND BODY FLUIDS RNA extracted in house using method 14 and 15 for the sample type listed or received as primary sample type from an external source RNA extracted in house using methods 14, 15 and 16 for the sample types listed above or received as primary sample type from an external source Genomic DNA and RNA extracted in house using methods 1 to 17 from the sample types listed and received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Detection of nuclei acid sequence variants – SNVs, small indels and splice site mutations	Documented in house procedures incorporating manufacturer's instructions (where relevant) RNA Quantification for QC purposes (16) Qubit SOP: PP 03.01.36 Reverse Transcription (17) Manual High-Capacity cDNA Reverse Transcriptase kit (Applied Biosystems) SOP: PP 03.01.26 Sanger Sequencing Flexible scope limited to detection and/or confirmatory testing using in-house developed primers as defined in definitive list QA 01.02.60 Standard primer design methodology and PCR amplification (where relevant to internal samples and confirmatory processes) PCR blocks, ABI 3730 Capillary electrophoresis instruments Analysis and interpretation of variants by Mutation Surveyor software. SOPs: SEQ 01.01.26, PP 03.01.35 SOP: 01.01.10, SEQ 01.01.25



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed and received as primary samples from an external source Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed above or received as primary sample type from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Detection of fragment length size, deletions, known SNVs and small indels, gene rearrangements, repeat expansions, linkage makers, short tandem repeats, microsatellites and methylation status Determination of copy number changes	Documented in house procedures incorporating manufacturer's instructions (where relevant) Fragment Length Analysis using Capillary Electrophoresis Flexible scope limited to detection testing using in-house developed kits as defined in definitive list QA 01.02.60 PCR, methylation specific PCR, Triplet Repeat PCR using in-house methods Equipment PCR blocks and resolution using an ABI 3500XL capillary sequencer Analysis GeneMapper and GeneMarker SOPs: FRAG 01.01.07 FRAG 01.01.13 Quantitative Fluorescence PCR (QF-PCR) Flexible scope limited to detection of copy number change in chromosome using in-house developed kits as defined in definitive list QA 01.02.60 In-house methods for trisomy screen Equipment Thermocyclers Resolution by capillary electrophoresis using ABI 3500XL Analysis Genemarker and Genemapper SOP: FRAG 01.01.16, PN 01.01.18



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HUMAN TISSUES AND BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
cDNA extracted in-house using methods 14 to 17 from the sample types listed above or received as primary sample type from an external source	Qualitative Genotype analysis for SNVs, indels and fusion transcripts	Qualitative Reverse Transcriptase PCR (RTPCR) Flexible scope limited to detection testing using in-house kits as defined in definitive list QA 01.02.60 Qualitative Reverse Transcriptase PCR (RTPCR) (Including nested) Equipment Thermal cyclers Agarose gel electrophoresis SOPs: TP 01.01.67, TP 01.01.61, TP 01.01.60
RNA extracted in house using methods 14 to 17 from sample types listed above and received as primary samples from an external source	For the quantitative detection of common fusion transcripts	Quantitative Real Time PCR (RQ-PCR) Flexible scope limited to quantitative detection of common fusion transcripts using in house developed methods as defined in definitive list QA 01.02.60 In house methodology Equipment ABI 7500 Real time PCR system Software ABI Taqman Software SOPs: QPCR 01.01.11, HOA 01.01.57, QPCR 01.01.27, HOA 01.01.61



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HUMAN TISSUES AND BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed and received as primary samples from an external source	Determination of methylation status and copy number – deletions and duplications	Multiplex Ligation-dependent Probe Amplification (MLPA) and methylation specific (MS) MLPA Flexible scope limited to multiple ligation and methylation specific MPLA using commercial MRC Holland Kits as defined in definitive list QA 01.02.60 Equipment Thermal cyclers ABI3500xl Kit Commercial MRC Holland kits Analysis GeneMarker and Genemapper SOPs: FRAG 01.01.04 FRAG 01.01.10
Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed	Post-transplant Chimaerism analysis - % donor engraftment Loci: D4S2366 D2S1338 D13S742 Penta D D10S2325 D12S391 D18S51 D13S634 D18S535 D6S957 D21S11 D18S386 D13S305 D21S1437 FGA Penta	Microsatellite analysis using in house PCR methodology Equipment ABI 3500 XL Analysis ChimerMarker Software SOPs: TP 01.01.63, HOA 01.01.14



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed above	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Detection of known SNVs and indels at high sensitivity	Documented in house procedures incorporating manufacturer's instructions (where relevant) Droplet Digital PCR Flexible scope limited to in-house developed kits as defined in definitive list QA 01.02.60 Equipment BioRAD QX200 Droplet Reader BioRAD AutoDroplet Generator BioRAD PCR Plate Reader Bio-Rad PrimePCR ddPCR Mutation Detection Assay BRAF p.V600E In-house assay for JAK2p.V617F Analysis integrated software SOPs: QPCR 01.01.01, QPCR 01.01.31 Next Generation Sequencing VeriSeq Solution v 2.0 for Non-invasive Prenatal Testing (NIPT) Automated cfDNA extraction Library Preparation Hamilton Star Liquid Handler Massively paralleled sequencing NextSeq 550 Analysis VeriSeq NIPT LRM module Receipting, Processing and Reporting of Lucina NIPT referrals PN 01.01.43 SOP: SEQ 01.01.69
Cell-Free DNA extracted in-house from plasma using methods 2, 12 and/or 13 or received as primary sample type from an external source	CNV/(Rapid screening for aneuploidy (T13,18,21)	



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA and RNA extracted in house using methods 1 to 17 from the sample types listed and samples received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Gene screening of large gene panels for genetic variants	Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing Flexible scope limited to gene panels for genetic variant testing using in-house developed kits as defined in definitive list QA 01.02.60 Library preparation Agilent 2200 Tapestation Qubit 2.0 Fluorometer Thermal cycler 2.0 Fluorometer Sequencing Illumina MiSeq Bioinformatics NIPD RHDO Bioinformatics Pipeline and NIPD Bespoke Bioinformatics Pipeline Quality trimming of reads, Alignment, QC steps, Variant Calling and genotyping of known variants for each region of interest Alignment of reads Bowtie2 BBmap (for troubleshooting) Variant caller Platypus Software and Platforms Python, Bedtools, FASTQC, Picard tools, Samtools, Trimmomatic SOPs: BI 01.01.08, BI 01.01.07, SEQ 01.01.22



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA and RNA extracted in house using methods 1 to 17 from the sample types listed and samples received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer SNVs/indels	Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing Flexible scope limited to SNV/Indels testing using in-house developed kits as defined in definitive list QA.01.02.60 Library preparation KAPA Hyper plus/ NimbleGen (Roche) Sequencing Illumina MiSeq Bioinformatics In house NIPD RHDO Bioinformatics Pipeline and NIPD Bespoke Bioinformatics Pipeline Quality trimming of reads, Alignment, QC steps, Variant Calling and genotyping of known variants for each region of interest Alignment of reads Bowtie2 BBmap (for troubleshooting) Variant caller Platypus Software and Platforms Python, Bedtools, FASTQC Picard tools, Samtools, Trimmomatic SOPs: PN 01.02.10, PN 01.02.04, BI 01.01.08, BI 01.01.07, SEQ 01.01.22



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA and RNA extracted and reverse transcribed in house using methods 1 to 17 from the sample types listed and samples received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer SNVs/indels	Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing Flexible scope limited to SNV/Indels testing using in-house developed kits as defined in definitive list QA 01.02.60 Library preparation Multiplex PCR (QIAGEN) Sequencing Illumina MiSeq Bioinformatics In house NIPD RHDO Bioinformatics Pipeline and NIPD Bespoke Bioinformatics Pipeline Quality trimming of reads, Alignment, QC steps, Variant Calling and genotyping of known variants for each region of interest Alignment of reads Bowtie2 BBmap (for troubleshooting) Variant caller Platypus Software and Platforms Python, Bedtools, FASTQC Picard tools, Samtools, Trimmomatic SOPs :PN 01.02.02, PN 01.02.03, BI 01.01.08, BI 01.01.07, SEQ 01.01.22



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed and received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Next Generation Whole Exome Sequencing with genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Single Nucleotide Variants (SNVs), Insertions/deletions (indels), Copy Number Variants (CNVs)	Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing Flexible scope limited to SNV/Indels/CNVs detection using in-house developed method as defined in definitive list QA 01.02.60 Whole Exome Sequencing Nonacus Cell3 Target ExomeCG Enrichment system Sequencing Illumina NovaSeq 6000 Analysis Congenica Decision Support Software SOPs: SEQ 01.01.68, SEQ 01.01.71, RD 01.01.87, PN 01.01.42, RD 01.01.88



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed and received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Next Generation Sequencing of large gene panels with genomic analysis for the purpose of clinical diagnosis and management in acquired cancer Single Nucleotide Variants (SNVs), Insertions/deletions (indels)	Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing Illumina TruSight Oncology 500 HT enrichment Sequencing Illumina NovaSeq 6000 Bioinformatics In-house Bioinformatics pipeline employing Illumina DRAGEN Bio-IT platform and Agilent Alissa Interpret software Documented in-house methods: Demultiplexing, Trimming, Alignment, Variant calling, QC steps and checks and identification of potentially clinical actionable variation from panel data from cancer samples Genome alignment Dragen aligner Variant Callers Dragen variant caller Software and Platforms Illumina DRAGEN Bio-IT Platform Bcftools DeepTools BCL convert SOPs: SEQ 01.01.73, SEQ 01.01.71, BI 01.01.27, SC 01.02.14



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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed and received as primary samples from an external source	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Next Generation Sequencing of large gene panels with genomic analysis for the purpose of clinical diagnosis and management in haematological neoplasia Single Nucleotide Variants (SNVs), Insertions/deletions (indels), Copy Number Variants (CNVs), Structural Variants (SVs)	Documented in house procedures incorporating manufacturer's instructions (where relevant) Next Generation Sequencing Nonacus Cell3 Target enrichment kit Automation Hamilton Microlab Star Sequencing Illumina NovaSeq 6000 Bioinformatics In-house Bioinformatics pipeline employing Illumina DRAGEN Bio-IT platform and Agilent Alissa Interpret software Documented in-house methods: Demultiplexing, Trimming, Alignment, Variant calling, QC steps and checks and identification of potentially clinical actionable variation from panel data from cancer samples Genome alignment Dragen aligner Variant Callers Dragen variant caller Pindel (additional ITD detection) Software and Platforms Illumina DRAGEN Bio-IT Platform, Bcftools, Deeptools, BCL convert, VerifyBamID, Bedtools, Samtools SOPs:SEQ 01.01.85, SEQ 01.01.71, BI 01.01.29, HOA 01.01.69, HOA 01.01.71



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HUMAN TISSUES AND BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
Prepared NGS libraries received from an external source	Next Generation Sequencing of libraries prepared by external sources	Sequencing Illumina NovaSeq 6000 SOP: SEQ 01.01.71
Genomic DNA and RNA extracted in-house using the methods 1 to 17 from FFPE and received as primary samples from external sources.	Next Generation Sequencing with genomic analysis for the purpose of clinical diagnosis and management in acquired cancer Single Nucleotide Variants (SNVs), Insertions/deletions (indels), Copy Number Variants (CNVs), Inter and Intra Genetic Fusions	ThermoFisher Genexus Integrated Sequencer for library preparation, sequencing and analysis Oncomine Precision Assay Oncomine Comprehensive Assay SOPs: SEQ 01.01.76, SC 01.02.10, SC 01.02.16, HOA 01.01.66, HOA 01.01.40, SEQ 01.01.76, SC 01.02.23 Microarray
Genomic DNA extracted in-house using methods 1 to 15 from the sample types listed and received as primary samples from external sources	Chromosomal Microarray analysis for germline and acquired copy number variants (CNV) and copy neutral loss of heterozygosity (CN-LOH) in postnatal disorders, prenatal diagnosis and pregnancy loss, and haemato-oncology	SNP Array Illumina Infinium HTS Assay Illumina iScan system Automation Tecan Freedom Evo Analysis Bionano NxClinical software. SOPs: ARRAY 01.01.45, DD 01.01.24, DD 01.01.25, PN 01.01.38, HOA 01.01.55, HOA 01.01.26



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HUMAN TISSUES AND BODY FLUIDS Whole Blood Amniotic Fluid CVS Foetal blood Products of Conception Bone Marrow Tissues/Skin Biopsy	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer Detection of chromosomal rearrangements or aberrations arising from: (e.g.) Prenatal Diagnosis Reproductive Medicine Disorders Developmental Disorders Haemto/Oncology Disorders Chromosome Breakage Disorders (preparative pre-examination steps listed first)	Documented in house procedures incorporating manufacturer's instructions (where relevant) G-banding/Karyotyping Culturing and processing of human tissue/cells using in-house and commercial media to provide interphase cells Cell Separation using autoMACS (see processing section) Cell Harvesting Automated process using Multiprep Cell Sprint Robotic Harvester Manual Process Chromosome analysis Microscopic and Macroscopic analysis of G banded chromosomes using Manual Processing and Varistain Banding Instrument and microscopes Analysis Metasystems Icaros SOPs: SOP TP 01.01.15, SOP: PP 02.01.40, PP 02.01.92, PP 02.01.93, PP 02.01.94, KARYO 01.01.06, GL 01.01.19, HOA 01.01.05



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HUMAN TISSUES AND BODY FLUIDS Formalin fixed paraffin embedded tissue (FFPE) Peripheral Blood Bone Marrow Fixed culture cells (more specific – cultured, uncultured PB, Marrow, AFs etc) Amniotic fluid CVS- Chronic villus samples	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer 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	Documented in house procedures incorporating manufacturer's instructions (where relevant) Fluorescence in situ hybridisation (FISH) Culturing and processing of human tissue/cells using in-house and commercial media to provide interphase/metaphase cells: Preparation and harvesting as for G-banding Manual Process Commercial and in house developed probes. Hybridisation using Hybrite/Thermobrite Analysis Fluorescence microscope and metasystems ISIS SOPs: PP 02.01.40, FISH 01.01.04, FISH 01.01.95, FISH 01.01.97, GI 01.01.06
END		