Schedule of Accreditation

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Accredited to ISO 15189:2022

Birmingham Women's and Children's NHS Foundation Trust

Issue No: 013 **Issue date:** 04 June 2025

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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 Regional Genetics Laboratory Mindelsohn Way Edgbaston Birmingham B15 2TG	**Local contact** Jennie Bell	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** Jennie Bell	Reporting

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Sample processing, 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)
Whole Blood Bone Marrow		**Lineage specific cell separation** Automated using Automacs Miltenyi Biotech autoMACS®Pro Separator SOP: PP 02.01.95
Whole Blood Bone Marrow Saliva (Oragene self collection kit) Plasma		**Manual and automated DNA extraction and quantification using:** 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		Qiagen QIAcube with Qiagen QIAamp DNA Blood Mini Kit SOP: PP 03.01.15

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HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
FFPE Dried Blood Spots		Promega Maxwell 16 with Promega Maxwell 16 FFPE Plus LEV DNA Purification Kit and LEV Blood Kit PP 03.01.43 PP 03.01.46
MACS separated cell fractions Amniotic Fluid CVS		Qiagen EZ1 using EZ1Tissue Kit PP 03.01.08: PP 03.01.14: PP 03.01.10:
Fresh frozen solid tissue*		Qiagen EZ1 using EZ1Tissue Kit with manual homogenation PP 03.01.07
Fresh tissue Foetal Tissue POC		Qiagen EZ1 using EZ1Tissue Kit with tissue abruption using Precellys 24 Homogeniser PP 03.01.19
		Manual DNA Extraction:
Peripheral Blood Bone Marrow Foetal Blood Mouth Wash Cultured Cells		Qiagen Gentra Puregene Kit PP 03.01.02 PP 03.01.06 PP 03.01.05
Peripheral Blood		Biorad Instagene matrix PP 03.01.12
Peripheral Blood Bone Marrow, Foetal Blood CVS,Fixed Cells		Phenol Chloroform extraction PP 03.01.03, PP 03.01.04 PP 03.01.11

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HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
Peripheral Blood Bone Marrow Foetal Blood		Phenol Chloroform extraction – High Risk protocol PP 03.01.24
Saliva (Oragene self collection kit)		DNA extraction using Genotek Prep-IT kit PP.03.01.13
Genomic DNA extracted inhouse from the sample types listed above or received as primary sample type from an external source		**DNA Quantification for QC purposes** Nanodrop 8000 Qubit 2.0/4.0 fluorometerPicogreen quantification process for DNA samples using Fluroskan SOPs: PP 03.01.27 PP 03.01.36 PP 03.01.50
FFPE	Sample processing, DNA/RNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long term storage	**Automated dual DNA and RNA extraction and quantification using:** Dual DNA and RNA extraction using Promega Maxwell 16 LEV RNA FFPE Purigication Kit and Promega Maxwell IVD MP 01.01.55

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HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Sample processing, 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) **Automated RNA extraction using:**
Whole Blood Bone Marrow		Extraction of total RNA using the Promega Maxwell IVD and Promega Maxwell 16 LEV simply RNA Blood Kit PP 03.01.47
RNA extracted inhouse from the sample types listed above or received as primary sample type from an external source		**Reverse Transcritpion** Manual -High Capacity cDNA Reverse Transcriptase kit (Applied Biosystems) PP 03.01.26:
RNA extracted inhouse from FFPE		**RNA Quantification for QC purposes** Qubit PP 03.01.36
Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources	Detection of SNVs and Small indels [definitive list QA 01.02.60]	**Fluorescence based ARMS PCR** Multiplexing Luminex commercial CF XTAG kit: Equipment: Luminex 200 Analysis using: Luminex integrated software SOP: FRAG 01.01.05

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS Genomic DNA and RNA extracted in-house from the sample types listed and received as primary samples from external sources	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Detection of nuclei acid sequence variants – SNVs, small indels and splice site mutations [definitive list QA 01.02.60]	Documented in house procedures incorporating manufacturer's instructions (where relevant) **Sanger Sequencing** **Using** Standard primer design methodology and PCR amplification (where relevant to internal samples and confirmatory processes) SOP: SEQ 01.01.26 PP 03.01.35 And: PCR blocks, ABI 3730 Capillary electrophoresis instruments Analysis and interpretation of variants by Mutation Surveyor software. SOP: 01.01.10 SEQ 01.01.25 **Fragment Length Analysis** **Fragment Length Analysis using Capillary Electrophoresis**
Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources	Detection of fragment length size, deletions, known SNVs and small indels, gene rearrangements, repeat expansions, linkage makers, short tandem repeats, microsatellites and methylation status [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 using GeneMapper and GeneMarker SOPs: FRAG 01.01.07 FRAG 01.01.13

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HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
Genomic DNA extracted in-house from the sample types listed	Determination of copy number changes [definitive list QA 01.02.60]	Quantitative Fluorescence PCR (QF-PCR) Using: In-house methods for trisomy screen And: Thermocyclers. Resolution by capillary electorphesis using ABI 3500XL. Analysis using Genemarker and Genemapper SOP: FRAG 01.01.16 PN 01.01.18
Genomic DNA and RNA extracted in house from the sample types listed above and received as primary samples from external sources (cont'd)	Qualitative Genotype analysis for SNVs, indels and fusion transcripts [definitive list QA 01.02.60]	Qualitative Reverse Transcriptase PCR (RTPCR) (Including nested) Using: Agarose gel electrophoresis SOPs:TP 01.01.67 TP 01.01.61 TP 01.01.60
RNA extracted in house from the sample types listed above and received as primary samples from external sources (cont'd)	For the quantitative detection of common fusion transcripts [definitive list QA 01.02.60]	Quantitative Real Time PCR (RQ-PCR) Using: In house methodology ABI 7500 Real time PCR system 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	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources	Determination of methylation status and copy number – deletions and duplications [definitive list QA 01.02.60]	Multiplex Ligation-dependent Probe Amplification (MLPA) and methylation specific (MS) MLPA. Using Commercial MRC Hollandkits, thermocyclers and ABI3500xl Analysis using GeneMarker and Genemapper SOPs:FRAG 01.01.04 FRAG 01.01.10
Genomic DNA extracted in-house from the sample types listed above	Post-transplant Chimaerism analysis - % donor engraftment	Microsatellite analysis using in house PCR methodology and ABI 3500 XL. Analysis using; ChimerMarker Software SOPs: TP 01.01.63, HOA 01.01.14
Genomic DNA extracted in-house from the sample types listed above	Detection of known SNVs and indels at high sensitivity [definitive list QA 01.02.60]	**Droplet Digital PCR** Using: BioRAD commercial Kits and in-house methodology BioRAD QX200 Droplet Reader BioRAD AutoDroplet Generator BioRAD PCR Plate Reader Analysis using integrated software SOPs: QPCR 01.01.01, QPCR 01.01.31

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HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant) **Next Generation Sequencing**
Cell-Free DNA extracted in-house from plasma	CNV/(Rapid screening for aneuploidy (T13,18,21)	VeriSeq Solution v 2.0 For Non-invasive Prenatal Testing (NIPT) using With Automated cfDNA extraction and Library Preparation using Hamilton Star Liquid Handler and with massively paralleled sequencing on a NextSeq 550 with VeriSeq NIPT LRM module for anlaysis. Receipting, Processing and Reporting of Lucina NIPT referrals PN 01.01.43 And SEQ 01.01.69 NIPT Veriseq Technical protocol
Genomic DNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources (cont'd)	Gene screening of large gene panels for genetic variants – [definitive list QA 01.02.60] SNVs/indels SNVs/indels	**Next Generation Sequencing:** Sequencing by MiSeq KAPA Hyper plus/ NimbleGen (Roche) SOP:PN 01.02.10 PN 01.02.04 Multiplex PCR (QIAgen) SOP:PN 01.02.02 PN 01.02.03

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS Genomic DNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant) **Next Generation Sequencing (cont):** <u>Analysis using:</u> Agilent 2200 Tapestation, Qubit 2.0 Fluorometer, thermal cycler and 2.0 Fluorometer, Illumina MiSEQ Analysis using: BI 01.01.08: NIPD RHDO Bioinformatics Pipeline BI 01.01.07: NIPD Bespoke Bioinformatics Pipeline SEQ 01.01.22
DNA obtained from whole blood	DYPD testing	**PCR with Maldi-TOF** Agena MassArray PG 01.01.03

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HUMAN TISSUES AND BODY FLUIDS Whole Blood Amniotic Fluid CVS Foetal blood Products of Conception Bone Marrow Tissues/Skin Biopsy	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer G-banding/Karyotyping: 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) **Culturing and processing of human tissue/cells using in-house and commercial media to provide interphase cells:** Cell Separation using autoMACS (see processesing section) **Cell Harvesting** Automated process using Multiprep Cell Sprint Robotic Harvester SOP TP 01.01.15 Manual Process SOP: PP 02.01.40 Chromosome analysis, Microscopic and Macroscopic analysis of G banded chromosomes using Manual Processing and Varistain Banding Instrument and microscopes Analysis using Metasystems Icaris SOPs: 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	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)
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 villius samples	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	**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 PP 02.01.40 And commercial and in house developed probes. Hybridisation using Hybrite/Thermobrite Analysis Fluorescence microscope and metasystems ISIS SOPs FISH 01.01.04,FISH 01.01.95, FISH 01.01.97, GI 01.01.06
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