Schedule of Accreditation

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Birmingham Women's and Children's NHS Foundation Trust

Issue No: 008 **Issue date:** 03 March 2021

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Website: https://bwc.nhs.uk/west-midlands-regional-genetics-laboratory

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 TISSUE AND FLUIDS Whole Blood Amniotic Fluid CVS Wax-embedded tissue Slide sections Mouth washes Foetal blood Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc.) Bone Marrow	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> Extraction and Storage of RNA/ DNA:	Documented in- house methods for DNA and RNA extraction for the purposes of in house testing using one or a combination of commercial kits and manual extraction: Manual: PP 03.01.17 Extraction of cell free fetal nucleic acids from maternal blood using the QIAamp DSP virus kit PP 03.01.26 Preparation of cDNA from total RNA using High Capacity cDNA Reverse Transcriptase Qiacubes: PP 03.01.15 DNA extraction from blood/marrow using QIAamp Blood Mini Kit PP 03.01.44 RNA extraction from blood or bone marrow (Stage 1) PP 03.01.45 Extraction of total RNA from blood or bone marrow samples (Stage 2) Promega Maxwells: PP 03.01.43 Maxwell DNA Extraction from Formalin Fixed Paraffin Embedded Tissue QIA Symphony: PP 03.01.21 Automated Extraction of Nucleic acid using the QIAsymphony SP

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular Genetics activities for the purpose of clinical diagnosis (cont'd):	
Plasma	Extraction and Storage of RNA/ DNA:	Extraction of cell-free nucleic acids from plasma using the QIAamp Blood Mini Kit (250) for the purposes of in house Non-Invasive Prenatal Testing (NIPT) PP 04.01.86
Cell-Free DNA extracted in-house from plasma	Non Invasive Prenatal Testing (NIPT) for aneuploidy	Cell free DNA Library Preparation for Non-invasive Prenatal Testing (NIPT) using massively paralleled sequencing on the HiSeq 2500 instrument SEQ 01.01.53 Receipting, Processing and Reporting of Lucina NIPT referrals PN 01.01.33
Genomic DNA extracted in-house from Whole Blood Amniotic Fluid CVS Wax-embedded tissue Slide sections Mouth washes Foetal blood Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc.) Bone Marrow	DNA and RNA profiling for detection of abnormal sequences for common and rare genetic disease conditions:	
	Cystic Fibrosis	Luminex- detection of mutation using XTAG-39 CF assay kit SOP- FRAG 01.01.05 5Cystic Fibrosis - Luminex 200 (Technical)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular Genetics activities for the purpose of clinical diagnosis (cont'd):</u>	
Genomic DNA extracted in-house from the sample types listed above	DNA and RNA profiling for detection of abnormal sequences for common and rare genetic disease conditions	Fragment size analysis using ABI 3130 capillary sequencer: In house methods MG GS 3.8.11FRAG 01.01.06 Manual preparation of samples for fragment analysis on ABI 3130XL FRAG 01.01.13 MG GS 3.8.08 and ABI 3130 and/or Fragment analysis using GeneMapper and GeneMarker. FRAG 01.01.16 Quant fluor PCR (QF-PCR) trisomy screen – technical aspects and analysis

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd):	<u>Molecular Genetics activities for the purpose of clinical diagnosis (cont'd):</u>	
		PCR amplification of DNA/RNA using ABI 7500 or HT Sequence Detection System for sequencing, fragment analysis and quantitative analysis: PP 03.01.35 Polymerase Chain Reaction (PCR) Capillary electrophoresis using ABI 3730 genetic analyser: SEQ 01.01.10 The ABI 3730 Sequencing Process, and MG GS 5.3.01 SEQ 01.01.28 Manual Checking of Sequencing Results. In house methods MG GS 3.10.02, MG GS 3.8.01, Next Generation Sequencing In house methods MG GS 3.11.06 using MiSEQ Illumina Technology: SEQ 01.01.22 Illumina MiSeq Sequencing Setup In house methods using ABI 3500 for DNA sequence data analysis and Multiplex Ligation Probe Amplification (MLPA): SEQ 01.01.25
Whole Blood Amniotic Fluid CVS Wax-embedded tissue Slide sections Mouth washes Foetal blood Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc.) Bone Marrow	Visual detection of Heteroduplex	Clonality assessment of B and T cell (ALL) by visual analysis Visual detection of Heteroduplex analysis of PAGE Gel - QPCR 01.01.06 6UKALL Heteroduplex analysis of Biomed screening PCR

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd):	<u>Molecular Genetics activities for the purpose of clinical diagnosis (cont'd):</u>	
Genomic DNA extracted in-house from the sample types listed above	Post-transplant Chimaerism analysis- dual population monitoring of DNA	Microsatellite analysis: TP 01.01.63 Post-transplant (BMT) chimaerism microsatellite analysis on the ABI fragment analysers, and HOA 01.01.14 Post-Transplant Chimaerism Analysis using ChimerMarker Software
Genomic DNA extracted in-house from the sample types listed above	Macroscopic examination of sequence and analysis and reporting against normal pattern	SEQ 01.01.25 Use of Mutation Surveyor for on-screen sequence checking. SEQ 01.01.28 Manual Checking of Sequencing Results SEQ 01.01.29 Interpretation of Sequence Variants Macroscopic band detection and analysis and reporting: FRAG 01.01.13 Fragment analysis using GeneMapper and GeneMarker FRAG 01.01.14 Creating and editing panel files for MLPA analysis on GeneMarker HOA 01.01.14 Post-Transplant Chimaerism Analysis using ChimerMarker Software HOA 01.01.15 FLT3-itd and NPM1 Analysis

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd):	<u>Molecular Genetics activities for the purpose of clinical diagnosis (cont'd):</u>	
Genomic DNA extracted in-house from the sample types listed above (cont'd):	Macroscopic examination of sequence and analysis and reporting against normal pattern (cont'd):	TP 01.01.60 RT-PCR for PML-RARA & CBFB-MYH11 in AML TP 01.01.61 Nested RT-PCR for BCR/ABL1 follow-up samples TP 01.01.63 Post-transplant (BMT) chimaerism microsatellite analysis on the ABI fragment analysers TP 01.01.64 PCR based clonality testing to identify clonal B cell and T cell populations. TP 01.01.67 Single step RT-PCR for BCR-ABL1 GL 01.01.20 Guidelines for Reporting Molecular Results Visual and data comparison to known controls and reporting: QPCR 01.01.11 Real-Time Quantitative RQ-PCR for Acute and Rare Variant fusions (Taqman 7500) QPCR 01.01.17 RQ-PCR checking, scoring & reporting guidelines QPCR 01.01.27 Real-Time Quantitative PCR (RQ-PCR) for BCR-ABL1 e13a2 and e14a2 fusions Data analysis and reporting: SOP-MG GS 7.8QPCR 01.01.01 Detection of JAK2 V617F using Droplet Digital PCR and the BioRad QX200

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd): Whole Blood Amniotic Fluid CVS Foetal blood Products of Conception Bone Marrow Tissues/Skin Biopsy	<u>Cytogenetics activities for the purpose of clinical diagnosis</u> Chromosome analysis for; - Prenatal Diagnosis Reproductive Medicine Disorders Developmental Disorders Haemto/Oncology Disorders Chromosome Breakage Disorders	Chromosome Culture by In-house procedures using commercial medias Preparation of material for chromosome analysis Harvesting – Manual and Robotic Harvester: TP 01.01.15 Use and maintenance of Multiprep Cell Sprint - robotic harvester Manual Harvest-SOP- PP 02.01.40 Harvesting: Manual harvesting - Postnatal Microarray profiling using Oligonucleotide arrays Cytosure HT Array Set-up: HT Labelling, purification and hybridisation: ARRAY 01.02.04 Cytosure HT Array scanning and Feature Extraction of files ARRAY 01.02.05 Cytosure HT Array cytosure upload, QC check and technical processing ARRAY 01.02.06 Microarray analysis using OGT Cytosure DD 01.01.15 Fluorescent in situ Hybridisation (FISH) using In-house procedures and commercial kits (Cytocell, Abbott-Vysis, Dako, Kreatech and Metasystems); and Thermobrite hybridisation station Macroscopic and microscopic detection and analysis of genetic re-arrangements and/or genomic imbalance

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd):	<u>Cytogenetics activities for the purpose of clinical diagnosis (cont'd):</u>	
Whole Blood Amniotic Fluid CVS Foetal blood Products of Conception Bone Marrow Tissues/Skin Biopsy	Chromosome analysis for (cont'd);- Prenatal Diagnosis Reproductive Medicine Disorders Developmental Disorders Haemto/Oncology Disorders Chromosome Breakage Disorders	PP 03.01.26 Preparation of cDNA from total RNA using High Capacity cDNA Reverse Transcriptase FISH 01.01.18 Analysing a FISH case FISH 01.01.19 Analysis and it's Documentation FISH 01.01.20 Analysis of Duplications and Deletions FISH 01.01.21 Analysing Paraffin Sections FISH 01.01.22 Guidelines for BMT analysis & Checking of sex mismatched BMT samples FISH 01.01.41 Analysis Oncology numbers of metaphases & interphases to be scored in FISH cases
	Detection and analysis of G banding and Karyotyping against considered normal pattern / profile	Macroscopic and microscopic examination:Banding-SOP KARYO 01.01.04;Cyto 2.3; Macroscopic and microscopic examination , detection, analysis and reporting of G banding and Karyotyping against considered normal pattern/profile G-Banding Protocol – Manual Processing and Use of Varistain Banding Machine
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