Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UKAS MEDICAL **8694** **Accredited to ISO 15189:2022**	**Oxford University Hospitals NHS Foundation Trust** **Issue No:** 015 **Issue date:** 11 November 2026	
	Oxford Genetics Laboratories **Churchill Hospital** **Old Road** **Headington** **Oxford** **OX3 7LE**	**Contact: Carl Fratter** **Tel: +44(0)1865 226025** **E-Mail: Carl.Fratter@ouh.nhs.uk** **Website: www.ouh.nhs.uk/geneticslab**

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Oxford Regional Genetics Laboratories Churchill Hospital Old Road Headington Oxford OX3 7LE	**Local contact** **Carl Fratter** (contact details above)	Molecular Genetics CytoGenetics Molecular Haematology	CH

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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Preparation, 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 and automated nucleic acid extraction, cDNA preparation and quantification using:** **Automated or semi-automated extraction:**	
Blood		Tecan Evo-HSM Robot with ReliaPrep™ Large Volume HT gDNA Isolation kit DNA SOP 159, 440	CH
Blood Bone Marrow Fresh Tissue Cultured Cells Saliva/Buccal (Oragene collections) Urine		Promega Maxwell RSC platform with Maxwell RSC Blood DNA Kit DNA SOP 159, 607	CH
FFPE fixed tissue		Promega Maxwell RSC platform with Maxwell RSC FFPE DNA Kit DNA SOP 159, SOP 931	CH
Blood Spots		Promega Maxwell RSC platform with Maxwell RSC FFPE RNA kit and incubation buffer for DNA extraction. DNA SOP 159, SOP 608	CH
FFPE		Promega Maxwell CSC platform with Maxwell RSC FFPE DNA Plus Kit for DNA extraction SOP-931	CH

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HUMAN TISSUES AND BODY FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Preparation, 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 and automated nucleic acid extraction, cDNA preparation and quantification using:** **Automated or semi-automated extraction:**	
Blood Bone marrow Cell isolates Slide scrapes CSF GTC lysate		Promega Maxwell CSC platform with Maxwell AS1321 Blood DNA Kit for DNA extraction SOP 929	CH
Blood Bone Marrow		Promega Maxwell CSC platform with Maxwell CSC RNA Blood Kit for RNA extraction and cDNA preparation using: Thermal cyclers SOP 930	CH
		Manual DNA extraction	
Bloods Pleural Effusions Urine		Manual DNA extraction using InstaGENE Matrix CYTO SOP 376, DNA SOP 159	CH
		DNA Quantification	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source		DNA Quantification for QC purposes: Qubit fluorometer, Nanodrop (ND-2000) and Glomax SOPs: CYTO SOP 456, DNA SOP 038, 040, 083, 669, and 672	CH

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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) **Fragment Analysis**	CH
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Detection of specific SNVs and indels (including confirmatory testing) [Definitive list as per GEN DOC 926]	Non-fluorescent PCR amplification followed by restriction enzyme digest using: Thermal cycler and gel electrophoresis equipment SOPs DNA SOP 002, 090	CH
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Presence/absence of DNA regions (including confirmatory testing) [Definitive list: GEN DOC 926]	Non-fluorescent PCR amplification followed by agarose gel electrophoresis using: Thermal cyclers and gel electrophoresis equipment SOPs DNA SOP 002, 062	CH
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Detection of expansions including triplet repeats, microsatellite marker analysis, detection of specific SNVs and indels (including confirmatory testing) [Definitive list: DOC 926]	PCR amplification using fluorescently tagged primers, followed by restriction enzyme digest where required, and fragment analysis using commercially available kits or assays designed in house using: Thermal cyclers and ABI 3730 Analysis using Gene Mapper software SOP 002, 034, 079, 081, 090, 376, 768, 940, DNA SOP 126, 184, 2006-0014	CH

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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)	
		Fragment Analysis	
Blood Bone Marrow Tissue	Lymphoma B Clonality (IgH rearrangements)	Commercial (Invivoscribe) fragment analysis using ABI instrumentation SOP 943	CH
	Lymphoma T Clonality (TCR re-arrangements)	SOP 972	CH
Blood Bone Marrow	Chimerism STR pattern analysis (Chimerism) to detect mixed samples (e.g. Maternal contamination / Chimerism	Promega Powerplex Fusion commercial kit, and fragment analysis using ABI 3730 instrumentation SOP 942, SOP 953	CH
		Real-Time PCR	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Quantification of mtDNA copy number [Definitive list as per GEN DOC 926]	Real-time PCR using commercially available kits or in-house designed assays Using: ABI 7500 Analysis using 7500 software SOPs DNA SOP 052, 013	CH
Blood Bone Marrow	Acute Leukaemia MRD monitoring (PML::RARA, CBFB::MYH11, RUNX1::RUNX1T1, NPM1	Commercial QPCR (Qiagen) kit for MRD using QIAGEN Rotorgene, SOP 971	CH
Blood Bone Marrow	BCR::ABL1 analysis (ALL, CML) Diagnosis and monitoring of MRD (p210, p190 only)	Published multiplex PCR method using thermocycler. Commercial quantitative PCR kit (Qiagen) using the Qiagen Rotorgene for MRD. SOP 936, 937	CH

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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) **Digital Droplet PCR**	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Targeted detection and quantification of known germline and somatic variants; SNVs, CNVs [Definitive list: DOC 926]	Reaction setup using in-house or commercial primer/probe mixes using: Techne PCR Machines, Biorad AutoDG for droplet generation and Biorad QX200 Droplet Reader. Analysis using QX Manager Software. SOP 665, 666, 667, 941, 944	CH
		Sanger sequencing	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Detection of nucleic acid sequence variants - SNVs and small indels [Definitive list:GEN DOC 926]	Using: Standard Primer Design methodology: Robot: Biomek NX-MC (96) ABI 3730 and analysis using Mutation surveyor software and Alamut SOPs DNA SOP 023, 049, 140, 731, GEN SOP 156	CH

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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**	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Screening of large targeted single or multigene panels for nucleic acid sequence variants; SNVs, indels [Definitive list: GEN DOC 926]	Next generation sequencing with target enrichment using; Twist Human Core Exome Kit using: Veriti PCR Machines, GloMax®-Multi+' Plate Reader, Agilent 4200 Tape Station, and Novaseq X Plus Sequencing products run on Illumina NovaSeq (located within the West Midlands Regional Genetics Laboratory). Analysis of DNA sequence data generated internally or externally using an in-house validated bioinformatics pipeline. Variant interpretation using Alamut DNA SOP 2019 606, SOP 227, 602, 603, 621, 622, 712	CH
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Screening of large targeted single or multigene panels for nucleic acid sequence variants; SNVs, indels [Definitive list: DOC 926]	Next generation sequencing with target enrichment using Twist FH targeted panel using: Veriti PCR Machines, GloMax®-Multi+' Plate Reader, Agilent 4200 Tape Station and run on Illumina MiSeq, and Novaseq X Plus Analysis of DNA sequence data using an in-house validated bioinformatics pipeline. DNA SOP 2019 606, SOP 227, 603, 621, 622, 628, 712	CH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
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**	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Screening of large targeted single or multigene panels for nucleic acid sequence variants; SNVs, indels and CNVs [Definitive list:GEN DOC 926]	Next Generation Sequencing using Illumina NexteraXTUsing: Dyad PCR Machines Glomax Multi+ Plate Reader, Illumina MiSeq, Agilent 2200 Tape Station Analysis of DNA sequence data using an in-house validated bioinformatics pipeline SOP 227, DNA SOP 421, , 2019 592 and 2019 593.	CH
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Screening of large targeted single or multigene panels for nucleic acid sequence variants; SNVs, indels and CNVs [Definitive list:GEN DOC 926]	Next Generation Sequencing using SOPHiA Genetics custom panel kitUsing: Veriti (Applied Biosystems) PCR Machines'GloMax®-Multi+' Plate Reader, Illumina MiSeq, Agilent 4200 Tape Station, and Novaseq X Plus Analysis using the Sophia Genetics bioinformatics DDM pipeline. Variant interpretation using Alamut SOP 460, 528, DNA SOP 0227, 316, 2015 327.	CH

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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**	
FFPE DNA	Screening of large targeted single or multigene panels for nucleic acid sequence variants; SNVs and indels [Definitive list: DOC 926]	Next Generation Sequencing using the S5 Ion Torrent Sequencer (Thermofisher) for the Ampliqseq commercial somatic Cancer 50 gene diagnostic panel (Thermofisher) and custom designed Acquired Ampliseq panel. Analysis of DNA sequence data using an in-house validated bioinformatics pipeline. SOP 946, 947, 948	CH
		SNP Array processing	
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Screening of the whole genome for copy number changes and absence of heterozygosity of particular genomic regions associated with syndromic uniparental disomy or somatic loss of heterozygosity. [Definitive list: DOC 926]	SNP Array processing undertaken at WMRGL using an Illumina based array platform. SNP Array analysis using data provided by WMRGL and analysed through NxClinical software (BioNano). SOP 066, 067, 271, 700, 735, 770, 771, CYTO SOP 701	CH

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HUMAN TISSUES AND BODY FLUIDS Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from external source	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer Detection of whole or partial gene deletions, duplications probe specific SNVs and indels and methylation status [Definitive list: DOC 926]	Documented in house procedures incorporating manufacturer's instructions (where relevant) **Multiplex Ligation Probe Analysis (MLPA) and methylation specific MS-MLPA** Using: Multiplex Ligation-dependant Probe Amplification (MLPA) (using MRC Holland kit) or custom design MLPA (using a kit template supplied by MRC-Holland) Methylation specific MLPA kit (MS-MLPA) Using Thermal cyclers and ABI 3730 with analysis using Coffalyser software DNA SOP 2015 374, 050, 128, 204	CH

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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)	
Products of conception Biopsies (includes skin) Tissues CSF Pleural Fluid, Ascites Whole Blood Bone Marrow	Detection of chromosomal rearrangements or aberrations arising from: *(e.g)* Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders (Preparative Pre-examination steps listed first) [Definitive list:DOC 926]	<u>G-Banding/Karyotyping</u> Manual culturing using commercial media, processing (cell harvesting and slide preparation and banding) of human tissue to provide metaphase cells Using: Safety cabinets, incubators, centrifuges, hotplate, Karyotype analysis of metaphase chromosomes light microscopy using: Microscopes, Cytovision Image Capture System CYTO SOP 67, 111, 185, 271, SOP 414	CH
Products of conception Biopsies (includes skin) Tissues CSF Pleural Fluid, Ascites Whole Blood Bone Marrow Urine Buccal swabs	(Preparative Pre-examination steps for FISH) [Definitive list: DOC 926]	**Direct preparation** (without culture) to provide fixed interphase cellsAnd Processing of FFPE sections for material suitable for FISH Using: Hotplate, fume hood, water bath, and Hybrite/Thermobrite SOPs 67, 132, 271, 340, 352	CH

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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)	CH
Fixed cultured cells as prepared as detailed in G-banding/Karyotyping section Fixed uncultured cells FFPE sections	Targeted analysis of the genome for copy number alterations, balanced chromosome rearrangements, mosaicism and formation of gene fusions. Using locus specific probes for: Translocations and/or inversion Deletions Fusions Copy Number [Definitive list:GEN DOC 926]	**Fluorescence in situ hybridisation (FISH)** using: Hybrite/Thermobrite, UV light box, microfuge fume hood and waterbath. FISH analysis by use of fluorescently tagged probes and fluorescence microscopy to detect copy number and spatial location of specific regions of the genome using: Cytovision Image Capture System CYTO SOP 067, 132, 271, 340, 352, 364, SOP 412, 414	CH
Blood DNA	Screening of large targeted single or multigene panels for nucleic acid sequence variants; SNVs and indels [Definitive list: DOC 926]	Next Generation Sequencing using custom designed commercial NGS panel (somatic myeloid disorder diagnostic gene panel) using: Illlumina NextSeq 550, SeqCap EZ HyperCap (Roche) and Agilent 4200 Tape Station Illumina Novaseq X Plus Analysis of DNA sequence data using an in-house validated bioinformatics pipeline. SOP 932, 935	CH

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