


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	Belfast Health and Social Care Trust	
	Issue No: 011 Issue date: 05 March 2026	
	Regional Molecular Diagnostics Service Belfast City Hospital 51 Lisburn Road Belfast BT9 7AB United Kingdom	Contact : Louise McArt Tel : +44(0) 2895 040822 E-Mail: louise.mcart@belfasttrust.hscni.net Website: https://belfasttrust.hscni.net/service/laboratory-services/

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 Tower Block, Belfast City Hospital 51 Lisburn Road Belfast BT9 7AB	Local contact Head of Germline Dr Shirley Heggarty Shirley.Heggarty@belfasttrust.hscni.net 028 95045264	A
	Local contact Head of Somatic Dr Mark Catherwood Mark.Catherwood@belfasttrust.hscni.net 02895048138	



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS / TISSUES Whole blood Cultured cells CVS Cord blood Buccal cells Products of Conception Fresh / frozen tissue (including skin, muscle, spleen) Guthrie cards Saliva Urine Amniotic Fluid	<u>Molecular Genetics (Germline)</u> Detection of nucleic acid sequence variants and/or copy number changes for the purpose of clinical diagnosis DNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Documented in-house procedures using techniques and kits in combination with manufacturers instructions	A
		Manual and Automated DNA Extraction and Quantification	
		Manual Extraction Using: iGEN Biotech New iGENatal Kit/ Qiagen Gentra Puregene Blood Kit/ DNA Genotek prepIT.L2P Kit SOPs: LP 352 003 iGENatal LP 364 012 Puregene LP 364 014 prepIT.L2P	A
		Automated Extraction Using: Promega Maxwell CSC / Perkin Elmer Chemagic MSM1 SOPs: LP 366 051 Maxwell CSCLP 364 020 Chemagic	A
		DNA Quantification Using: IMPLEN Nanophotometer Pearl/ Invitrogen Qubit 4 Fluorometer SOPs: LI 366 020 Nanophotometer PD 305 307 Qubit	A



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics (Germline)</u> cont'd</p> <p>DNA amplification by PCR for fragment analysis or downstream use in sanger sequencing</p>	<p>DNA Amplification by PCR</p> <p>Using: In-house methods/ MegaMix Gold/ Eurogentec Primers/ Beckman Coulter Biomek i5 Automated Workstation/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Syngene G:BOX F3 Gel Documentation System</p> <p>SOPs: LI 362 104 PCR Conditions LP 366 001 Gel Electrophoresis LP 366 013 PCR LP 366 016 G:BOX F3 LP 366 032 Biomek i5</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics (Germline)</u> cont'd</p> <p>Detection of nucleic acid sequence variants (SNVs and Indels) in genes specified in definitive list and those identified through research and/or family (trio) NGS sequencing work [Definitive list in RMDS Test Accreditation List held by this laboratory]</p>	<p>Sanger Sequencing</p> <p>Using: In-house methods/ Applied Biosystems BigDye Terminator Cycle Sequencing Kit/ Beckman Coulter Agencourt AMPure XP PCR Purification System/ Beckman Coulter Agencourt CleanSEQ Dye-Terminator Removal/ Thermocyclers [Definitive list in Current Dept Equipment List/ Beckman Coulter Biomek i5 Automated Workstation/ Applied Biosystems 3500DX DNA Analyzer/ Applied Biosystems 3500 Genetic Analyzer/ SoftGenetics Mutation Surveyor Software/Alamut Visual Plus Software SOPs: LI 362 102 CleanSEQ LI 366 008 AMPure LP 366 008 Sanger Sequencing LP 366 028 Mutation Surveyor LP 366 032 Biomek i5LP 366 038 ABI 3500 LP 366 043 Variant Classification</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics (Germline)</u> cont'd</p> <p>Determination of copy number changes and methylation specific (MS) dosage changes [Definitive list in RMDS Test Accreditation List held by this laboratory]</p>	<p>Multiplex Ligation Probe Amplification (MLPA) (to include MS-MLPA)</p> <p>Using: MRC Holland SALSA MLPA Reagents and Probemixes/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500DX Genetic Analyzer/ Applied Biosystems 3500xL Genetic Analyzer SoftGenetics GeneMarker Software</p> <p>SOPs: LP 363 026 MS-MLPA LP 366 025 MLPA Set Up LP 366 026 MLPA Analysis LP 366 038 ABI 3500</p>	A
<p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p>Detection of nucleic acid point variants, small insertions and deletions [Definitive list in RMDS Test Accreditation List held by this laboratory]</p>	<p>Amplification Refractory Mutation System (ARMS)</p> <p>Using: Elucigene CF4 & CF-EU2/ Elucigene DPYD/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500DX DNA Analyzer/ Applied Biosystems 3500 Genetic Analyzer/ Applied Biosystems GeneMapper Software/ SoftGenetics GeneMarker Software</p> <p>SOPS: LI 362 081 CF Neonatal Reporting LP 362 083 CF Neonatal LP 363 032 CF Routine LP 363 073 DPYD genotyping LP 366 029 GeneMarker LP 366 034 GeneMapper LP 366 038 ABI 3500</p>	A



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics (Germline)</u> cont'd</p> <p>Detection of nucleic acid sequence repeat expansions [Definitive list in RMDS Test Accreditation List held by this laboratory]</p>	<p>Repeat Fragment Detection</p> <p>Using: In-house methods/ MegaMix Gold/ Eurogentec Primers / Asuragen AmplideX PCR/CE FMR1 Kit/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500DX DNA Analyzer/ Applied Biosystems 3500xL Genetic Analyzer/ Applied Biosystems GeneMapper Software/ SOPs: LP 363 020 Friedreich Ataxia LP 363 021 Huntington Disease LP 363 022 Kennedy Syndrome LP 363 023 Fragile X Syndrome LP 363 025 Myotonic Dystrophy LP 363 039 Dominant Ataxias LP 366 034 GeneMapper LP 366 038 ABI 3500</p>	A
<p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p>Detection of nucleic acid short tandem repeats</p>	<p>Short Tandem Repeat Detection</p> <p>Using: Promega PowerPlex 16 System/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500DX DNA Analyzer/ Applied Biosystems 3500xL Genetic Analyzer/ Applied Biosystems GeneMapper Software</p> <p>SOPs: LP 363 036 Promega PowerPlex 16 LP 366 034 GeneMapper LP 366 038 ABI 3500</p>	A



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics (Germline)</u> cont'd</p> <p>Gene screening of large gene Panels and whole exome/virtual panels for genetic variants: SNVs CNVs Indels Trios [Definitive list in RMDS Test Accreditation List held by this laboratory]</p>	<p>Next Generation Sequencing (NGS)</p> <p>Library Preparation Using: Roche KAPA HyperPlus Kit/Roche Avenio Edge DNA HyperPlus Kit/Roche KAPA HyperCapture Reagents/Roche Avenio Edge Target Enrichment Reagents/ Hamilton Microlab STAR Liquid Handling System/Roche Avenio Edge System Invitrogen Qubit 4 Fluorometer/ Agilent 4200 TapeStation System/ Roche LightCycler480 Instrument II/ Thermocyclers [Definitive list in Current Dept Equipment List]</p> <p>SOPs: LF 362 109 Library Quantification LF 366 047 Library Preparation LI 362 109 Library Quantification LP 366 045 Library Preparation (Hamilton) LP 366 052 Library Preparation (Avenio)</p> <p>Next Generation Sequencing Set Up</p> <p>Using: NextSeq 500/550 High Output Kit/Illumina NextSeq 550DX</p> <p>SOPs: LF 366 047 Library Preparation LP 306 010 Targeted Cancer Panel LP 363 059 NGS Exome PD 305 305 NextSeq 550DX PD 305 306 NextSeq 500 and NextSeq 550 Libraries Guide</p>	<p>A</p> <p>A</p> <p>A</p>



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<p>EDTA Blood</p>	<p>Loop-mediated Isothermal Amplification for the detection of: Haemochromatosis</p>	<p>Loop-mediated Isothermal Amplification (LAMP)</p> <p>Using: LaCAR LAMP Human Haemochromatosis Kit/ Beckman Coulter Biomek 4000 Liquid Handler/ Roche LightCycler 480</p> <p>SOPs: LP 363 074 HFE Genotyping LP 366 032 Biomek PD 305 302 LightCycler 480</p>	A
<p>Genomic DNA</p>	<p>Human Factor II (Prothrombin) G20210A mutation Human Factor V Leiden G1691A mutation</p>	<p>Cobas Mutational Analysis</p> <p>Using Roche cobas Factor II and Factor V Test Roche COBAS Z 480 Analyser</p> <p>SOP: LP 363 080 Cobas Factor II and Factor V</p>	



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HUMAN BODY FLUIDS / TISSUES	<u>Molecular Genetics (Germline)</u> cont'd		
Genomic DNA	HAEMOPHILIA A - F8 Gene: Intron 1 Inversion	DNA Amplification by PCR & Detection by Gel Electrophoresis Using: Horizontal Gel Electrophoresis Tank Electrophoresis Power Supply Thermocyclers [Definitive list in Current Dept Equipment List] Syngene G:BOX F3 Gel Documentation System MegaMix Gold Eurogentec Primers SOP: LP 363 077 F8 Intron 1 Inversion	
Genomic DNA	HAEMOPHILIA A - F8 Gene: Intron 22 Inversion	DNA Amplification by PCR & Detection by Gel Electrophoresis Using: QINSTRUMENTS BioShake iQ Heatblock Horizontal Gel Electrophoresis Tank Electrophoresis Power Supply Thermocyclers [Definitive list in Current Dept Equipment List] Syngene G:BOX F3 Gel Documentation System MegaMix Gold Promega Bcl1 restriction enzyme Promega T4 DNA Ligase Eurogentec Primers SOP: LP 363 078 F8 Intron 22 Inversion	



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p>	<p>Cytogenetics (Germline and Somatic)</p> <p>Diagnosis of aneuploidy in products of conception, intrauterine deaths, neonatal deaths, stillbirths and by rapid prenatal diagnosis</p>	<p>Quantitative Fluorescence-Polymerase Chain Reaction (QF-PCR)</p>	A
		<p>Products of Conception, Intrauterine Deaths, Neonatal Deaths and Stillbirths</p> <p>Using: Yourgene® QST* R-PL / Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500DX Genetic Analyzer/ Applied Biosystems 3500xL Genetic Analyzer/ SoftGenetics GeneMarker Software</p> <p>SOPs: LP 352 001 QF-PCR Tissue Set Up LP 352 002 QF-PCR Tissue Analysis LP 366 038 ABI 3500xL</p>	A
		<p>Rapid Prenatal Diagnosis</p> <p>Using: Yourgene® QST*R Base kit/ Yourgene® QST*R Plus Trisomy 13Kit/ Yourgene® QST*R Plus Trisomy 18 Kit/ Yourgene® QST*R Plus Trisomy 21 Kit/ Yourgene® QST*R Plus XY Kit/ Applied Biosystems 3500DX Genetic Analyzer/ Applied Biosystems 3500xL Genetic Analyzer/ SoftGenetics GeneMarker Software/ Applied Biosystems GeneMapper Software</p> <p>SOPs: LP 352 003 QF-PCR AF Set Up LP 352 004 QF-PCR AF Analysis LP 366 038 ABI 3500xL</p>	A



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HUMAN BODY FLUIDS / TISSUES	Cytogenetics (Germline and Somatic)		
	Chromosome analysis for the purpose of clinical diagnosis	Documented in-house procedures using techniques and kits in combination with manufacturers' instructions:	
Whole blood	Detection of chromosomal rearrangements or aberrations arising from:	Karyotyping and G-Banding	A
Amniotic fluid	Prenatally detected disorders	Cell Culturing and Harvesting	A
CSF	Developmental disorders	Using:	
Cord blood	Reproductive medicine disorders	Manual methods	
Bone marrow	Haematological/Oncology disorders	SOPs:	
Tissues		Prenatal	
		LP 345 001 AF Culture	
		LP 345 002 AF/Tissue	
		LP 345 003 Solid Tissue Culture	
		Developmental Delay	
		LP 345 016 Blood Culture	
		LP 345 034 Blood Harvest	
		Haematological/Oncology	
		LP 345 029 BM & Blood Culture	
		LP 345 030 BM & Blood Harvest	



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HUMAN BODY FLUIDS / TISSUES	Cytogenetics (Germline and Somatic)	<p>Chromosome Preparation and G-Banding</p> <p>Using: ADSBiotec Hanabi-PVI Metaphase Spreader/ Thermo Scientific ClearVue Coverslipper</p> <p>SOPs: LP 345 033 Slide Making QA LP 346 011 G-Banding LP 351 005 Hanabi</p> <p>Microscopic Analysis of G-Banded Chromosomes</p> <p>Using: Leica Microsystems DM5500B Microscope/Olympus BX53 Microscope/Olympus BX63 Microscope/ASI Slide Loader and Metaphase Finder</p> <p>SOPs: Analysis LP 347 033 DM5500B Use LP 348 008 Cancer Chromosome Analysis LP 348 034 Constitutional Chromosome Analysis</p>	<p>A</p> <p>A</p>



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<p>HUMAN BODY FLUIDS / TISSUES</p> <p>Whole blood Amniotic fluid CVS CSF Cord blood Bone marrow Tissues Buccal cells Products of conception</p>	<p align="center">Cytogenetics (Germline and Somatic)</p> <p>Detection of chromosomal aberrations in the diagnosis of constitutional disorders and haematological malignancy using a range of probe types including: Break-apart probes Fusion probes Deletion probes Insertion probes Copy Number Amplification probes [Definitive list in RMDS FISH Probe List held by this laboratory]</p>	<p>Fluorescence In Situ Hybridisation (FISH)</p> <p>Using: A range of probe suppliers including: Abbott Vysis/Cytocell/Empire Genomics/ [Definitive list in FISH Probe List] Stemcell EasySep Human CD138 Positive Selection Kit/ Stemcell EasySep Human CD19 Positive Selection Kit/ StemCell RoboSep-S Cell Separator/ Abbott StatSpin ThermoBrite S500/ Leica Microsystems DM5500B Microscope/ Olympus BX53 Microscope/Olympus BX63 Microscope/ASI Slide Loader and Metaphase Finder</p> <p>SOPS: LI 347 007 ThermoBrite LI 347 034 Cytovision Spot Counting Analysis LP 345 037 CD138+ Selection LP 345 038 CD19+ Selection LP 347 001 Buccal Swabs Interphase FISH LP 347 002 FISH Set Up LP 347 003 Blood/BM FISH LP 347 005 Post Hybridisation FISH Washes LP 347 033 DM5500B Use LP 348 011 Cytovision Scanning Classifiers LP 348 038 FISH Analysis</p>	<p align="center">A</p>



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END			