Schedule of Accreditation

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Accredited to ISO 15189:2022

Belfast Health and Social Care Trust

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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	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	Regional Molecular Diagnostics Service Germline Somatic	A
Address Health Sciences Building, Queen's University Belfast 97 Lisburn Road Belfast BT9 7AE	**Local contact** Head of Somatic Dr Mark Catherwood Mark.Catherwood@belfasttrust.hscni.net 028 95048138	Regional Molecular Diagnostics Service Somatic	B

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	Molecular Genetics (Germline)		
	Detection of nucleic acid sequence variants and/or copy number changes for the purpose of clinical diagnosis	Documented in-house procedures using techniques and kits in combination with manufacturers instructions	
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	DNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Manual and Automated DNA Extraction and Quantification	A
		Manual Extraction	A
		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	
		Automated Extraction	A
		Using: Promega Maxwell CSC / Perkin Elmer Chemagic MSM1	
		SOPs: LP 366 051 Maxwell CSCLP 364 020 Chemagic	
		DNA Quantification	A
		Using: IMPLEN Nanophotometer Pearl/ Invitrogen Qubit 4 Fluorometer	
		SOPs: LI 366 020 Nanophotometer PD 305 307 Qubit	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	DNA amplification by PCR for fragment analysis or downstream use in sanger sequencing	DNA Amplification by PCR 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 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	A
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	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]	Sanger Sequencing 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	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Determination of copy number changes and methylation specific (MS) dosage changes [Definitive list in RMDS Test Accreditation List held by this laboratory]	Multiplex Ligation Probe Amplification (MLPA) (to include MS-MLPA) Using: MRC Holland SALSA MLPA Reagents and Probemixes/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500 Genetic Analyzer/ SoftGenetics GeneMarker Software SOPs: LP 363 026 MS-MLPA LP 366 025 MLPA Set Up LP 366 026 MLPA Analysis LP 366 038 ABI 3500	A
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Detection of nucleic acid point variants, small insertions and deletions [Definitive list in RMDS Test Accreditation List held by this laboratory]	Amplification Refractory Mutation System (ARMS) 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 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	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Detection of nucleic acid sequence repeat expansions [Definitive list in RMDS Test Accreditation List held by this laboratory]	Repeat Fragment Detection 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	A
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Detection of nucleic acid short tandem repeats	Short Tandem Repeat Detection Using: Promega PowerPlex 16 System/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Applied Biosystems 3500DX DNA Analyzer/ Applied Biosystems 3500 Genetic Analyzer/ Applied Biosystems GeneMapper Software SOPs: LP 363 036 Promega PowerPlex 16 LP 366 034 GeneMapper LP 366 038 ABI 3500	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	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]	Next Generation Sequencing (NGS) 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] SOPs: LF 362 109 Library Quantification LF 366 047Library Preparation LI 362 109 Library Quantification LP 366 045 Library Preparation (Hamilton) LP 366 052 Library Preparation (Avenio) Next Generation Sequencing Set Up Using: NextSeq 500/550 High Output Kit/Illumina NextSeq 550DX 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	A A A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	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]	Next Generation Sequencing Analysis Using: Germline Variant Calling and Annotation Pipeline (benchmarked against NHSE Pipeline Tool using Coriell Reference DNA)/ Congenica (for tertiary analysis) SOPs: LP 363 059 NGS Exome LP 306 010 Targeted Cancer Panel LP 307 004 GitHub LP 307 005 Microsoft Azure LP 307 007 Germline Pipeline LP 307 008 Congenica Analysis	A
EDTA Blood	Loop-mediated Isothermal Amplification for the detection of: Haemochromatosis	Loop-mediated Isothermal Amplification (LAMP) Using: LaCAR LAMP Human Haemochromatosis Kit/ Beckman Coulter Biomek 4000 Liquid Handler/ Roche LightCycler 480 SOPs: LP 363 074 HFE Genotyping LP 366 032 Biomek PD 305 302 LightCycler 480	A
Genomic DNA	Human Factor II (Prothrombin) G20210A mutation Human Factor V Leiden G1691A mutation	Cobas Mutational Analysis Using Roche cobas Factor II and Factor V Test SOP: LP 363 080 Cobas Factor II and Factor V	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Chromosome analysis for the purpose of clinical diagnosis	Documented in-house procedures using techniques and kits in combination with manufacturers' instructions:	
Whole blood Amniotic fluid CSF Cord blood Bone marrow Tissues	Detection of chromosomal rearrangements or aberrations arising from: Prenatally detected disorders Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders	Karyotyping and G-Banding Cell Culturing and Harvesting Using: Manual methods SOPs: 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	A A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
		Chromosome Preparation and G-Banding Using: ADSBiotec Hanabi-PVI Metaphase Spreader/ Thermo Scientific ClearVue Coverslipper SOPs: LP 345 033 Slide Making QA LP 346 011 G-Banding LP 351 005 Hanabi	A
		Microscopic Analysis of G-Banded Chromsomes Using: Leica Microsystems DM5500B Microscope/ Leica Biosystems GSL-120 Slide Loader/ Leica Biosystems CytoVision Image Analysis Capture System SOPs: LI 348 003 GSL120 Cancer Analysis LI 348 004 GSL120 Constitutional Analysis LP 347 033 DM5500B Use LP 348 005 GSL120 Set Up LP 348 008 Cancer Chromosome Analysis LP 348 011 Cytovision Scanning Classifiers LP 348 034 Constitutional Chromosome Analysis	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Whole blood Amniotic fluid CVS CSF Cord blood Bone marrow Tissues Buccal cells Products of conception	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]	Fluorescence In Situ Hybridisation (FISH) 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/ Leica Biosystems GSL-120 Slide Loader/ Leica Biosystems CytoVision Image Analysis Capture System/ 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 348 005 GSL120 Set Up LP 348 011 Cytovision Scanning Classifiers LP 348 038 FISH Analysis	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Genomic analysis for detection of copy number changes or loss of heterozygosity arising from: Prenatally detected disorders Developmental disorders Reproductive medicine disorders	Single Nucleotide Polymorphism (SNP) Microarray Using: Illumina Infinium CytoSNP-850K BeadChip Kit/ Illumina NextSeq 550 Instrument/ VWR Hybridisation Oven/ Tecan Te-Flow Unit/ Thermocyclers [Definitive list in Current Dept Equipment List]/ Illumina BlueFuse Multi Software SOPs: LP 350 006 Microarray Set Up LP 350 012 Microarray Analysis PD 305 318 Recommendations for Microarray in Pregnancy	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS / TISSUES	Solid Tumours (Somatic)		
	Detection of specific gene alterations and antigen expression, in a range of cancer types to facilitate targeted treatment decisions	Documented in-house procedures using techniques and kits in combination with manufacturers instructions:	
	DNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Manual and Automated DNA Extraction and Quantification	B
Plasma	Extraction of cfDNA	Manual Extraction Using: Roche Cobas cfDNA Sample Preparation Kit SOPs: LP 390 033 Cobas cfDNA Extraction	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin Fixed Paraffin Embedded Tissue	Extraction of DNA	Automated Extraction Using: Promega Maxwell 16 FFPE Plus LEV DNA Purification Kit/ Promega Maxwell 16 Instrument/ Sakura Tissue-Tek Prisma E2D Automated Slide Stainer and Coverslipper Film E2 SOPs: PMC-SOP-11 Macrodissection & Maxwell Extraction PMC-SOP-12 Maxwell PMC-SOP-42 Tissue-Tek	B
		DNA Quantification Using: Invitrogen Qubit dsDNA HS Assay Kit/ Invitrogen Qubit dsDNA BR Assay Kit/ Invitrogen Qubit 2 Fluorometer SOPs: PMC-SOP-14 Qubit Quantification PMC-SOP-17 Qubit	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin Fixed Paraffin Embedded Tissue	Immunohistochemistry for the detection of: Breast cancer – PD-L1 Gastric cancer – HER2 Lung cancer - PD-L1	Immunohistochemistry (IHC) Using: Roche VENTANA PD-L1 (SP142) Assay/ Roche VENTANA anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody/ Roche VENTANA PD-L1 (SP263) Assay/ Roche Ventana Benchmark Ultra/ Sakura Tissue-Tek Prisma E2D Automated Slide Stainer and Coverslipper Film E2/ Olympus BX53 Light Microscope SOPs: LP 390 237 IHC Set Up LP 390 236 IHC Analysis PMC-SOP-120 Ventana Benchmark Ultra PMC-SOP-42 Tissue-Tek PMC-SOP-55 Olympus BX53	B
Formalin Fixed Paraffin Embedded Tissue	Fluorescent Insitu Hybridisation for the detection of: Breast cancer – ERBB2	Fluorescent Insitu Hybridisation (FISH) Using: Leica HER2 FISH system/ Leica BOND RX/ Zeiss AxioImager Z2 SOPs: LP 390 183 ERBB2 FISH Set Up LP 390 142 ERBB2 FISH Analysis LI 390 107 ERBB2 Tumour Annotation PMC-SOP-34 BOND RX PMC-SOP-52 AxioImager Z2	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Cobas Mutational Analysis for the detection of: Lung cancer – EGFR (DNA/cfDNA) Melanoma cancer – BRAF & NRAS	Cobas Mutational Analysis Using: Cobas BRAF/NRAS Mutation Test/ Cobas EGFR Mutation Test/ Cobas z 480 Analyser SOPs: LP 390 035 BRAF/NRAS Cobas LP 390 038 EGFR Cobas PMC-EXT-303 Cobas z 480 Analyser	B
Formalin Fixed Paraffin Embedded Tissue	Tumour Annotation	Tumour Annotation Using: Olympus BX53 Light Microscope SOPs: PMC-SOP-15 Tumour Content and Cellularity PMC-SOP-55 Olympus BX53	B
Genomic DNA	Pancancer Panel	Next Generation Sequencing Using:	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
		Library Preparation Equipment: Invitrogen Qubit 4 Fluorometer Agilent 4200 Tapestation System Thermocyclers [Definitive list in iPassport Equipment Module] Reagents: Roche KAPA HyperPlus Kit Roche KAPA HyperCap Roche KAPA Hyperchoice Target Enrichement Probes SOP: PMC-SOP-74 Library Preparation Next Generation Sequencing Set Up Equipment: Illumina NovaSeq 6000 SOP: PMC-SOP-24 NovaSeq-6000 PMC-SOP-56 Sequencing on the NovaSeq 6000 Next Generation Sequencing Analysis Equipment: PanCancer Workflow Package for Analysis of Targeted Sequencing Data SOP: PMC-SOP-107 Analysis and Reporting PMC-SOP-79 Manual Analysis Using Integrative Genomics Viewer PMC-SOP-108 PanCancer Pipeline PMC-SOP-154 NGS Data Management	
END			