Schedule of Accreditation

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No:003 **Issue date**: 24 May 2021

Northern Genetics Service
The Newcastle upon Tyne Hospitals NHS Foundation Trust,
Institute of Genetic Medicine,
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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 Cytogenetics and Molecular Genetics Newcastle Genetics Laboratory Institute of Genetic Medicine Central Parkway Newcastle upon Tyne Tyne & Wear NE1 3BZ	**Local contact** Amritjit **Singh**	Genetic Analysis	A

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Muscle Immunoanalysis Unit Lower Ground Floor Dental Hospital Richardson Road Newcastle upon Tyne NE2 4AZ	**Local Contact** Dr Richard Charlton	Muscle Immunoanalysis	B
North of England Haemato-oncology Malignancy Diagnostic Service (NEHODS) Blood Sciences Flow Laboratory Level 3, Leazes Wing Royal Victoria Infirmary Newcastle upon Tyne NE1 4LP	**Local Contact** Mr Gavin Cuthbert	Specimen Processing for haemato-oncological samples	C

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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 TISSUES & FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant) **DNA Extraction** Manual, semi-automated and automated DNA/RNA extraction and quantification using: Documented in-house methods - For DNA extraction using one or a combination of the techniques below by in-house procedures using commercial kits and manual extraction.	A
Whole Blood		Qiagen QIA Symphony with midi or mini kit SOP: 15761 Qiagen EZ1 XL Advanced with:	
Whole blood, Bone Marrow, Foetal Blood		EZ1 200 µ or 350µl blood kits SOPs 28563	
Blood spots, Amniotic Fluid, CVS, FFPE, slide sections and fixed cells, Products of conception, fresh solid tissue, Separated cells from whole blood and bone marrow (separation by UKAS accredited external laboratory)		EZ1 Tissue Kit SOP 13713, 13712, 13711, 13715, 13709, 13714, 13708	
Whole Blood, Bone Marrow, Foetal Blood		Maxwell 16 with Maxwell 16 LEV DNA blood kit SOP 28563, 28569	

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HUMAN TISSUES & FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)	
Separated cells from whole blood and bone marrow, Amniotic fluid, CVS, FFPE tissue, Slide sections, Fixed Cells, Buccal scrapes, Products of conception, fresh solid tissue, Separated cells from blood and bone marrow		Maxwell 16 FFPE Plus Lev DNA kit SOP 28627, 28569, 28631, 28554, 27998,28626, 28569	
		Manual extraction	
Mouthwashes		Oragene kit SOP 8975	
		DNA Quantification for QC purposes: Nanodrop and Quantiflour SOPs 3834 and 14564	
		RNA EXTRACTION	
Whole Blood, Bone Marrow,		**Maxwell 16 with** RNA extraction using simply RNA Blood kit with reverse transcription to cDNA using superscript III with in-house methods	
		SOPs, 28538, 28539	
FFPE, Slide Sections, fresh solid tissue		RNA extraction using Maxwell FFPE kit with reverse transcription to cDNA using superscript III using in-house methods SOPs 28674, 28673	

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HUMAN TISSUES & FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)	
Genomic DNA and RNA extracted in-house from the sample types listed and received as primary samples from external sources	Detection of nuclei acid sequence variants – SNVs, small indels and breakpoints [Definitive list in Sanger Sequencing Targets in NGL EQMS 30827]	**Sanger Sequencing** Using Standard primer design methodology and PCR amplification (where relevant to internal samples) And: PCR blocks, Biomek NXp liquid handling robot, ABI3500xl Capillary electrophoresis instruments Analysis using Mutation Surveyor software and interpretation of variants by Alamut software. Procedures: (equipment): 5247, 5180, 14667, 5730 (procedures and analysis): 5580, 3835, 11945, 5502, 4387 (specific disorders): 5175, 5639, 4258, 14756, 5621, 5235, 5142, 11952, 3996, 8241, 10194, 7950, 5173, 5581, 8239, 5455, 5451, 8772, 5231, 5640, 4259, 11678, 4260, 9197, 5167	A
Genomic DNA extracted in-house	Targeted mutation analysis for the HFE-related haemochromatosis H63D and C282Y gene variants using a Luna probe assay	Procedures: (procedures and analysis): 5459, 8230 And: Idaho Technology LightScanner, Biomek NXp liquid handling robot	

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 and received as primary samples from external sources	Detection of fragment length size, deletions, known SNVs and small indels, repeat expansions, linkage makers, short tandem repeats, microsatellites and methylation status [definitive list held: NGL EQMS 30828]	**Fragment Length Analysis** Resolution Using Capillary Electrophoresis PCR, methylation specific PCR, Triplet Repeat PCR using in-house methods and commercial kits as listed: Zymo Research EZ DNA Methylation kit Elucigene CFEU50 kit Powerplex 16HS Equipment: PCR blocks, BiomekNXp liquid handling robot and ABI3500xl Capillary electrophoresis instruments and Gel Electorphoresis Analysis using GeneMarker or GeneMapper software Imaging of gels (where approprirate) by Geneflash (Syngene BioImaging)	A
RNA reverse transcribed to cDNA in-house or received from external sources	Validation of splicing variants and fusion events	PCR blocks, BiomekNXp liquid handling robot, ABI3500xl Capillary electrophoresis instruments and agarose gel electrophoresis (for QC purposes) Imaging of gels by Geneflash (Syngene BioImaging) Procedures (equipment): 5247, 5180, 5673, 3787, 8230, 5732 (procedures and analysis): 5349, 3995, 10261, 1899, 14076, 4184, 5231 (specific disorders): 5348, 5194, 5130, 5132, 5459, 5693, 7676, 5583, 5692, 5830, 5233, 5234, 5181, 5196, 5172, 5322, 5193, 5461, 5322	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Genomic DNA and RNA extracted in-house	Targeted mutation analysis (SNVs and small indels) for HFE-related haemochromatosis	PCR using in-house procedures And: BiomekNXp liquid handling robot and Idaho Technology LightScanner, Light Scanner Analysis using CALL-IT™ software Procedures: (procedures and analysis): 5459, 8230	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES & FLUIDS	Genomics analysis for the purpose of clinical diagnosis or 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	**Quantitative Fluorescence PCR (QF-PCR)** **Using:** In-house methods And: Thermocyclers. Resolution by capillary electrophoresis using ABI 3130 Analysis using SoftGenetics. Procedures: [Prenatal] : 2750, 2757, 7240, 3469 [Foetal] 5226	A
RNA extracted in house from FFPE or received as primary samples from external sources	Qualitative detection of common fusion genes [definitive list in NGL EQMS 30829]	**Qualitative Reverse Transcriptase PCR (RT-PCR)** RT-PCR using in-house methods with resolution by agarose gel analysis and fragment sizing (where appropriate) using ABI 3500xl Genetics analyser Procedures: 9653, 3545, 3544, 19736	
Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources	Determination of copy number – deletions and duplications [definitive list in: NGL EQMS 30830]	**Multiplex Ligation-dependent Probe Amplification (MLPA)** Using In-house or commercial kits, thermocyclers, Biomek NXp automated liquid handler, ABI3500xl Procedures: (equipment and kits): 5247, 5180, 8230, 5732 (procedures and analysis): 4955,4956 (specific disorders): 5452, 5346, 5495	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Sequencing data files received from an external source within the NE&Y GLH.	Detection of SNVs and small indels and fusions associated with myeloid neoplasms [definitive targets listed in NGS Myeloid SOP EQMS Doc 29136].	Analysis of NGS myeloid panel derived data using in house filtering tool. Variant interpretation supported by the Alamut Software tool, gene knowledge bases and variant databases.	A
Sequencing data files received from an external source within the NE&Y GLH.	Detection of SNVs, small indels and CNVs associated with Familial Hypercholesterolemia and inherited cancers [definitive list in FH EQMS 21843, Bowel EQMS 8772, Breast + ovarian CA EQMS 5621]	Analysis of NGS panel derived data using in house filtering tool. Variant interpretation supported by the Alamut Software tool, gene knowledge bases and variant databases. Confirmatory and cascade testing by Sanger Sequencing as above.	
Genomic DNA extracted in house from peripheral blood	Cytogenetic examinations for diagnosing postnatal disorders, prenatal diagnosis, neoplastic genetics including haemato-oncology and solid tumours, and loss of pregnancy. By detection of microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number	**SNP Array:** CytoSNP 850K Bead Arrays using Illumina methods and a NextSeq 550. Analysis and interpretation of genetic imbalances using BlueFuse Multi and web based UCSC genome browser Procedures: 17692, 17686, 17753, 17736, 17744 [Prenatal] 3469, 17736, 17739, 17740, [Foetal] 14493	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES & FLUIDS	Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)	
Whole blood Bone marrow Amniotic fluid Chorionic villi Foetus and placenta Products of conception Tissue biopsy (tumour, skin, placenta, liver, lymph nodes etc) Solid tumours Paraffinised histology samples Slide sections Mouth washes/swabs	<u>G-banding/Karyotyping</u> Detection of chromosomal rearrangements or aberrations arising from (e.g) Prenatal Diagnosis Neoplastic Genetics including Haemato-Oncology and Solid Tumours. Postnatal Disorders Loss of pregnancy Preparative pre-examination steps listed first	**Culturing and processing of human tissue/cells to provide interphase cells:** Manual/automated process using… Cell harvesting: SOP 2989 Processing – SOPs 3322/25813/26225/25717 Feeding 2717 Subbing 2986 Slide Preparation: 10889/27815 Automated Cell capture 10888 SOPs [Postnatal] 15725, 3436, 16960, 3438, 3439, 10889,10888, 4907, 3448, 3449, 10433, 3441, 3580 [Haemato-Oncology] 12552, 3062, 5687, 5689. [Prenatal] 5166, 2661, 2666, 2667, 2669, 2657, 2681, 2780, 2781, 2782, 3314, 3345, 3358, 3468, 4414, 4909, 4968, 16546, 3441 [Foetal] 3321, 3322, 3323, 2697, 2708, 2711, 2717, 2986, 2989, 2993, 3324, 3325, 3328 **Chromosome analysis:** Microscopic analysis of G banded chromosomes using light microscopy and Cytovision image analysis system [Postnatal] 3441 [Haemato-Oncology] 5356, 5358, 11992 [Prenatal] 4950, 3469, 4907 [Foetal] 3328, 3441, 4907, 4323	A A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES & FLUIDS	Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer	Documented in house procedures incorporating manufacturer's instructions (where relevant)	
	Detection of chromosomal aberrations in the diagnosis of Haematological malignancy, bone marrow failure syndromes Non-haematological malignancies Break-apart probes Fusion products Deletion Insertion Copy Number/Amplification [Definitive list of probes in scope as per NGL EQMS 30832]	**Fluorescence in situ hybridisation:** (FISH) using manual in-house methods and commercial kits (including, Abbott Vysis, Cytocell, Kreatech, Metasystems, TCAG), Thermobrite/ Hybrite denaturation stations and fluorescent microscopy Procedures: [Postnatal] 3580,16960 [Haemato-Oncology] 3138, 3081, 5368, 12084. [Prenatal] 3358, 3580 [Foetal] 3358	A
	<u>Muscle Immunoanalysis</u>		
Frozen skeletal muscle tissue only	Examination of tissues to identify or exclude protein and morphological abnormalities for the purposes of diagnosing Limb Girdle muscular dystrophies and overlapping or allelic conditions		B
	<u>Immunohistochemistry</u> Immunohistochemistry analysis and interpretation of data to progress a diagnosis		
Frozen skeletal muscle tissue	Antibodies listed below: αB-Crystallin α-Dystroglycan α-Sarcoglycan ACTN3	Manual immunohistochemistry staining using procedures: - Cryostat SOP No 1-48 Doc ID14836 Immunohistochemistry SOP No 3-3 Doc ID3385 Microscopy and imaging SOP 4-59 Doc ID22001 Interpreting and reporting results SOP No 4-6 Doc ID2641 Antibodies – assessment and optimisation SOP No 4-18 Doc ID3397 MIU Protein Function Doc ID15918	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES & FLUIDS Frozen skeletal muscle tissue	Genetic examination for the purposes of clinical diagnosis (cont'd) Immunohistochemistry analysis and interpretation of data to progress a diagnosis (cont'd) Antibodies listed below: β-Dystroglycan β-Sarcoglycan β-Spectrin Calpain 3 Calsequestrin Caveolin 3 Collagen VI Desmin Fast myosin γ-Sarcoglycan Lamin A/C Laminin α2 chain Laminin α5 chain Laminin β1 chain Laminin γ1 chain MHC Class 1 Myosin heavy chain (developmental) Myosin heavy chain (neonatal) Myotilin NCAM nNOS p62 Plectin PTRF/Cavin-1 Slow myosin STIM1 Telethonin TOR1AIP1 Ubiquitin Utrophin Valosin-containing protein		B

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Homogenised skeletal muscle biopsies	Immunoblotting analysis and interpretation of data to progress a diagnosis Antibodies listed below: αB-Crystallin α-Dystroglycan α-Sarcoglycan β-Dystroglycan β-Sarcoglycan β-Spectrin Calpain 3 Caveolin 3 Collagen VI Desmin Dysferlin Dystrophin (C-term) Dystrophin (N-term) Dystrophin (Rod) δ-Sarcoglycan Emerin γ-Sarcoglycan Lamin A/C Laminin α2 chain nNOS Plectin PTRF/Cavin-1 Telethonin Utrophin	Procedures: Cryostat SOP No 1-48 Doc ID14836 Sample homogenisation and protein assay SOP No 3-9 Doc ID13664 Western blotting SOP No 3-6 Doc ID1986 Fluorochem (Western blot imaging) SOP 1-47 Doc ID10420 Interpreting and reporting results SOP No 4-6 Doc ID2641 Antibodies – assessment and optimisation SOP No 4-18 Doc ID3397 MIU Protein Function Doc ID15918	B
END			