


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<p>The Newcastle upon Tyne Hospitals NHS Foundation Trust</p> <p>Issue No:006 Issue date: 19 November 2024</p>	
	<p>Northern Genetics Service The Newcastle upon Tyne Hospitals NHS Foundation Trust, Institute of Genetic Medicine, Central Parkway, Newcastle upon Tyne, Tyne & Wear NE1 3BZ</p>	<p>Contact: Amritjit Singh Tel: +44 (0)191 282 0848 E-Mail: Amritjit.Singh@nhs.net Website: https://www.newcastlelaboratories.com</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Cytogenetics and Molecular Genetics Newcastle Genetics Laboratory Institute of Genetic Medicine Central Parkway Newcastle upon Tyne Tyne & Wear NE1 3BZ</p> <p>Local contact Amritjit Singh</p>	Genetic Analysis	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Muscle Immunoanalysis Unit Lower Ground Floor Dental Hospital Richardson Road Newcastle upon Tyne NE2 4AZ</p> <p>Local Contact Dr Richard Charlton</p>	Muscle Immunoanalysis	B
<p>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</p> <p>Local Contact Mr Gavin Cuthbert</p>	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
<p>HUMAN TISSUES & FLUIDS</p> <p>Whole Blood</p> <p>Whole blood, Bone Marrow, Foetal Blood</p> <p>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)</p> <p>Whole Blood, Bone Marrow, Foetal Blood</p>	<p>Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>DNA Extraction</p> <p>Manual, semi-automated and automated DNA/RNA extraction and quantification using:</p> <p>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.</p> <p>Qiagen QIA Symphony with midi or mini kit</p> <p>SOP: GENE915</p> <p>Qiagen EZ1 XL Advanced with: EZ1 200 µ or 350µl blood kits</p> <p>SOP: GENE 739</p> <p>EZ1 Tissue Kit</p> <p>SOP GENE743, GENE747, GENE738, GENE746, GENE744, GENE745</p> <p>Maxwell RSC with</p> <p>Maxwell RSC Whole Blood DNA blood kit</p> <p>SOPs:GENE 740</p>	<p>A</p>



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<p>HUMAN TISSUES & FLUIDS</p> <p>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</p> <p>Whole Blood, Bone Marrow,</p> <p>FFPE, Slide Sections, fresh solid tissue</p>	<p>Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Maxwell RSC FFPE Plus DNA kit</p> <p>SOPs: GENE612, GENE611, GENE609, GENE608, GENE742</p> <p>DNA Quantification for QC purposes: Glomax Multi detection System using Nanodrop 1000 and 2000 and Quantiflour ds DNA kit</p> <p>SOPs GENE881 and GENE846</p> <p>RNA EXTRACTION</p> <p>Maxwell RSC with RNA extraction using RSC simply RNA Blood kit with reverse transcription to cDNA using superscript III with in-house methods</p> <p>SOPs: GENE858, GENE859, GENE1527</p> <p>RNA extraction using RSC Maxwell FFPE kit with reverse transcription to cDNA using superscript III using in-house methods</p> <p>SOPs GENE860</p>	



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<p>HUMAN TISSUES & FLUIDS</p> <p>Genomic DNA and RNA extracted in-house from the sample types listed and received as primary samples from external sources</p>	<p>Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer</p> <p>Detection of nucleic acid sequence variants – SNVs, small indels and breakpoints</p> <p>Confirmatory and cascade testing</p> <p>Detection of known or unknown sequence changes - analytic capacity as per SOPS</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Sanger Sequencing</p> <p>Using</p> <p>Standard primer design methodology and PCR amplification (where relevant to internal samples)</p> <p>And:</p> <p>PCR blocks, Biomek NXp liquid handling robot (pre- and post-analytical), ABI3500xl Capillary electrophoresis instruments</p> <p>And: Ampure XP BigDye Terminator Cleanseq</p> <p>Analysis using Mutation Surveyor software and interpretation of variants by ClassIC software.</p> <p>Procedures: (equipment): GENE 735, GENE627, GENE162, (procedures and analysis): GENE956, GENE164, GENE195, GENE422 (specific disorders): GENE1501 , GENE1516, GENE1502, GENE173, GENE1515, GENE1512, GENE1507, GENE1511, GENE925, GENE165, GENE957, GENE922, GENE1519, GENE909, GENE1520</p>	<p align="center">A</p>



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<p>HUMAN TISSUES & FLUIDS</p> <p>Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources</p>	<p>Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer</p> <p>Detection of fragment length size, deletions, known SNVs and small indels, repeat expansions, linkage makers, short tandem repeats, microsatellites and methylation status</p> <p>Angelman/Prader Willi syndrome by bisulphite conversion</p> <p>Cystic Fibrosis (including neonatal screening)</p> <p>FLT3/NPM1 in AML</p> <p>Identity / zygosity testing</p> <p>Microsatellite instability by PCR and analysis of microsatellite markers</p> <p>Monitoring stem-cell transplants</p> <p>X-inactivation</p> <p>Tri/tetra nucleotide repeat fragment detection and interpretation (including PCR and TP-PCR)</p> <p>MGMT methylation status determined by bisulphite conversion</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Fragment Length Analysis Resolution Using</p> <p>Capillary Electrophoresis</p> <p>PCR, methylation specific PCR, Triplet Repeat PCR using in-house methods and commercial kits as listed:</p> <p>Zymo Research EZ DNA Methylation kit Elucigene CFEU50 kit Powerplex 16HS</p> <p>Equipment:</p> <p>PCR blocks, BiomekNXp liquid handling robot and ABI3500xl Capillary electrophoresis instruments and Gel Electrophoresis</p> <p>Analysis using GeneMarker or GeneMapper software</p> <p>Imaging of gels (where appropriate) by Geneflash (Syngene Bioluminescence Imaging)</p> <p>Fragment Length Analysis SOPs: GENE735, GENE627, GENE1557, GENE586, GENE396, GENE932, GENE160, GENE380, GENE621, GENE937, GENE952, GENE1489, GENE1503, GENE954, GENE919, GENE1493, GENE193, GENE914, GENE913, GENE931, GENE930, GENE1514, GENE1490, GENE1508, GENE1509, GENE1513, GENE934, GENE1509, GENE954</p>	<p>A</p>



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<p>HUMAN TISSUES & FLUIDS</p> <p>RNA reverse transcribed to cDNA in-house or received from external sources</p>	<p>Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer</p> <p>Validation of splicing variants and fusion events</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>PCR blocks, BiomekNXp liquid handling robot, ABI3500xl Capillary electrophoresis instruments and agarose gel electrophoresis (for QC purposes)</p> <p>Imaging of gels by Geneflash (Syngene Biolmaging)</p> <p>Procedures (equipment): GENE735, GENE627, GENE1557, GENE586 (procedures and analysis): GENE396, GENE932, GENE160, GENE380, GENE621, GENE909 (specific disorders): GENE396, GENE952, GENE1489, GENE1503, GENE954, GENE919, GENE1493, GENE193, GENE914, GENE913, GENE931, GENE930, GENE1514, GENE1490, GENE1508, GENE1509, GENE1513, GENE934,</p>	



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<p>HUMAN TISSUES & FLUIDS</p> <p>Genomic DNA extracted in-house from the sample types listed</p> <p>RNA extracted in house from FFPE or received as primary samples from external sources</p>	<p>Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer</p> <p>Determination of copy number changes</p> <p>Confirmatory testing of fusion events by RT-PCR-analytic capacity as per GENE36</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Quantitative Fluorescence PCR (QF-PCR)</p> <p>Using:</p> <p>In-house methods And:</p> <p>Thermocyclers. Resolution by capillary electrophoresis using ABI 3500XL</p> <p>Analysis using SoftGenetics.</p> <p>Procedures: [Prenatal] : GENE979, GENE314, GENE312</p> <p>Qualitative Reverse Transcriptase PCR (RT-PCR)</p> <p>RT-PCR using in-house methods with resolution by agarose gel analysis and fragment sizing (where appropriate) using ABI 3500xl Genetics analyser</p> <p>Procedures: GENE155, GENE156, GENE462, GENE154</p>	<p>A</p>



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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)	A
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-analytic capacity as per GENE51	Multiplex Ligation-dependent Probe Amplification (MLPA) Using In-house or commercial kits, thermocyclers, Biomek NXp automated liquid handler, ABI3500xl (Pre-analytical) Procedures: (equipment and kits): GENE735, GENE627, GENE586 (procedures and analysis): GENE929, GENE660 (specific disorders): GEBE953, GENE945, GENE949	
Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources	Classification of Microsatellite Instability (MSI) status (stable/unstable) and genotyping of BRAF & NRAS/KRAS	Next Generation Sequencing using MSI-Plus assay (patent protected) and sequencing by MiSeq (FFPE CRC tumour samples). Procedures: GENE259, GENE1689	
RNA extracted from whole blood	BCR-ABL monitoring in chronic myeloid leukaemia	Amplification of RNA by real time PCR on a Roche LC480 light cycler using a commercial kit (Ipsogen) and data analysis using Roche software according to procedure GENE720	A



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<p>HUMAN TISSUES & FLUIDS</p> <p>Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources</p>	<p>Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer</p> <p>Detection of insertions, deletions, substitutions, and other polymorphisms in NRAS KRAS BRAF EGFR JAK2 V617F TPMT NUDT15 ALK-activating variants in neuroblastoma, HFE variants c.845G>A p.(Cys282Tyr) & c.187C>G p.(His63Asp) FLT3-TKD MYD88 DPYD Mutation Detection for the following targets: <i>DPYD</i> c.1905+1G>A <i>DPYD</i>*2A rs3918290 <i>DPYD</i> c.2846A>T p.(Asp949Val) rs67376798 <i>DPYD</i> c.1679T>G p.(Ile560Ser) <i>DYPD</i>*13 rs55886062 <i>DPYD</i> c.1236G>A p.(Glu412Glu) HapB3 rs56038477 <i>DPYD</i> c.1129-5923C>G HapB3 rs75017182</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Analysis using MassARRAY 4 MALDI-TOF (Matrix-Assisted Laser Desorption Ionization Time Of Flight) and iPLEX single base extension (SBE) chemistry. Extension primer design using by Assay Design Suite (ADS) software and interpretation using Typer 4 software.</p> <p>Procedures:</p> <p>GENE 1486 GENE1569</p> <p>GENE 1486 GENE 1424</p>	



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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 -analytic capacity as per GENE119	Analysis of NGS myeloid panel derived data using in house filtering tool. Variant interpretation supported by the ClassIC 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 -analytic capacity as per GENE174	Analysis of NGS panel derived data using in house filtering tool. Variant interpretation supported by the ClassIC 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: GENE334, GENE342, GENE343, GENE349, GENE359 [Prenatal] GENE349, GENE351, GENE352	



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<p>HUMAN TISSUES & FLUIDS</p> <p>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</p>	<p>Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer</p> <p><u>G-banding/Karyotyping</u></p> <p>Detection of chromosomal rearrangements or aberrations arising from (e.g)</p> <p>Prenatal Diagnosis Neoplastic Genetics including Haemato-Oncology and Solid Tumours. Postnatal Disorders Loss of pregnancy</p> <p>Preparative pre-examination steps listed first</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Culturing and processing of human tissue/cells to provide interphase cells:</p> <p>Manual/automated process using:</p> <p>Cell harvesting: SOP GENE522 Processing – SOPs GENE308, GENE307, GENE310, GENE574 Feeding GENE516 Subbing GENE579</p> <p>Slide Preparation: GENE577, GENE578</p> <p>Automated Cell capture GENE571</p> <p>SOPs</p> <p>[Postnatal] GENE577, GENE571, GENE301, GENE521</p> <p>[Haemato-Oncology] GENE470</p> <p>[Prenatal] GENE496, GENE289, GENE528, GENE290, GENE16, GENE521</p> <p>[Foetal] GENE308, GENE575, GENE516, GENE579, GENE522, GENE519</p> <p>Chromosome analysis:</p> <p>Microscopic analysis of G banded chromosomes using light microscopy and Cytovision image analysis system [Postnatal] GENE521 [Haemato-Oncology] GENE438, GENE449 [Prenatal] GENE306 [Foetal] GENE521, GENE317</p>	<p>A</p> <p>A</p>



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HUMAN TISSUES & FLUIDS	<p>Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer</p> <p>Detection of chromosomal aberrations in the diagnosis of</p> <p>Haematological malignancy, bone marrow failure syndromes Non-haematological malignancies</p> <p>Break-apart probes Fusion products Deletion Insertion Copy Number/Amplification</p> <p>Analytic capacity as per SOP GENE35</p> <p><u>Muscle Immunoanalysis</u></p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p>Fluorescence in situ hybridisation:</p> <p>(FISH) using manual in-house methods and commercial kits (including, Abbott Vysis, Cytocell, Kreatech, Metasystems, TCAG), Thermobrite/ Hybrite denaturation stations and fluorescent microscopy</p> <p>Procedures:</p> <p>[Haemato-Oncology] GENE440, GENE446, GENE448, GENE441.</p>	A
Frozen skeletal muscle tissue only	<p>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</p> <p><u>Immunohistochemistry</u></p> <p>Immunohistochemistry analysis and interpretation of data to progress a diagnosis</p>		B
Frozen skeletal muscle tissue	<p>Antibodies listed below:</p> <p>α-Dystroglycan α-Sarcoglycan</p>	<p>Manual immunohistochemistry staining using procedures: -</p> <p>Cryostat SOP No 1-48 MIU107 Immunohistochemistry SOP No 3-3 GENE38 Microscopy and imaging SOP 4-59 MIU156 Interpreting and reporting results SOP No 4-6 MIU157</p>	B



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<p>HUMAN TISSUES & FLUIDS</p> <p>Frozen skeletal muscle tissue</p>	<p>Genetic examination for the purposes of clinical diagnosis (cont'd)</p> <p>Immunohistochemistry analysis and interpretation of data to progress a diagnosis (cont'd)</p> <p>Antibodies listed below:</p> <ul style="list-style-type: none"> β-Dystroglycan β-Sarcoglycan β-Spectrin Caveolin 3 Collagen VI Desmin Fast myosin γ-Sarcoglycan Laminin α2 chain Laminin α5 chain MHC Class 1 Myosin heavy chain (neonatal) Myotilin nNOS p62 Slow myosin STIM1 Utrophin Valosin-containing protein 		<p align="center">B</p>



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Homogenised skeletal muscle biopsies	<p><u>Immunoblotting analysis and interpretation of data to progress a diagnosis</u></p> <p>Antibodies listed below:</p> <p>α-Sarcoglycan β-Dystroglycan Calpain 3 Dysferlin Dystrophin (C-term) Dystrophin (Rod) Laminin α2 chain Telethonin</p>	<p>Procedures:</p> <p>Cryostat SOP No 1-48 MIU107 Sample homogenisation and protein assay SOP No 3-9 DocMIU125 Western blotting SOP No 3-6MIU124 Fluorochem (Western blot imaging) SOP 1-47 Doc MIU106 Interpreting and reporting results SOP No 4-6 MIU157</p>	B
END			