# Schedule of Accreditation

**issued by**

# United Kingdom Accreditation Service

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

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| **9028**<br><br>**Accredited to ISO 15189:2012** | **The Newcastle upon Tyne Hospitals NHS Foundation Trust**<br><br>**Issue No:**004 **Issue date**: 06 July 2023 | |
| | **Northern Genetics Service**<br>**The Newcastle upon Tyne Hospitals NHS Foundation Trust,**<br>**Institute of Genetic Medicine,**<br>**Central Parkway,**<br>**Newcastle upon Tyne,**<br>**Tyne & Wear**<br>**NE1 3BZ** | **Contact: Amritjit Singh**<br>**Tel: +44 (0)191 282 0848**<br>**E-Mail: Amritjit.Singh@nuth.nhs.uk**<br>**Website: https://www.newcastlelaboratories.com** |
| **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**<br>Cytogenetics and Molecular Genetics<br>Newcastle Genetics Laboratory<br>Institute of Genetic Medicine<br>Central Parkway<br>Newcastle upon Tyne<br>Tyne & Wear<br>NE1 3BZ | **Local contact**<br>Amritjit **Singh** | Genetic Analysis | A |

**Site activities performed away from the locations listed above:**

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

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## The Newcastle upon Tyne Hospitals NHS Foundation Trust

**Issue No:** 004 **Issue date:** 06 July 2023

**Testing performed by the Organisation at the locations specified**

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)<br><br>**DNA Extraction**<br><br>Manual, semi-automated and automated DNA/RNA extraction and quantification using:<br><br>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<br><br>SOP: GENE915 | |
| Whole blood, Bone Marrow, Foetal Blood | | Qiagen EZ1 XL Advanced with:<br><br>EZ1 200 µ or 350µl blood kits<br><br>SOP: GENE 739 | |
| 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<br><br>SOP GENE743, GENE747, GENE738, GENE746, GENE744, GENE745 | |
| Whole Blood, Bone Marrow, Foetal Blood | | Maxwell RSC with<br><br>Maxwell RSC Whole Blood DNA blood kit<br><br>SOPs:GENE 740 | |

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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 RSC FFPE Plus DNA kit<br><br>SOPs: GENE612, GENE611, GENE609, GENE608, GENE742 | |
| | | **DNA Quantification for QC purposes:**<br>Glomax Multi detection System using<br>Nanodrop 1000 and 2000 and Quantiflour ds DNA kit<br><br>SOPs GENE881 and GENE846 | |
| Whole Blood, Bone Marrow, | | **RNA EXTRACTION**<br><br>**Maxwell RSC with**<br>RNA extraction using RSC simply RNA Blood kit with reverse transcription to cDNA using superscript III<br>with in-house methods<br><br>SOPs: GENE858, GENE859, GENE1527 | |
| FFPE, Slide Sections, fresh solid tissue | | RNA extraction using RSC Maxwell FFPE kit with reverse transcription to cDNA using superscript III using in-house methods<br><br>SOPs GENE860 | |

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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 nucleic acid sequence variants – SNVs, small indels and breakpoints<br><br>Confirmatory and cascade testing<br><br>Detection of known or unknown sequence changes - analytic capacity as per SOPS | **Sanger Sequencing**<br><br>Using<br><br>Standard primer design methodology and PCR amplification (where relevant to internal samples)<br><br>And:<br><br>PCR blocks, Biomek NXp liquid handling robot (pre- and post-analytical), ABI3500xl Capillary electrophoresis instruments<br><br>And:<br>Ampure XP<br>BigDye Terminator<br>Cleanseq<br><br>Analysis using Mutation Surveyor software and interpretation of variants by Alamut software.<br><br>Procedures:<br>(equipment): GENE 735, GENE627, GENE162,<br>(procedures and analysis): GENE956, GENE164, GENE195, GENE422<br>(specific disorders): GENE1501 , GENE1516, GENE1502, GENE173, GENE1515, GENE1512, GENE1507, GENE1511, GENE925, GENE165, GENE957, GENE922, GENE1519, GENE909, GENE1520 | A |

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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) | |
| | | **Fragment Length Analysis** Resolution Using | A |
| 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<br><br>Angelman/Prader Willi syndrome by bisulphite conversion<br><br>Cystic Fibrosis (including neonatal screening)<br><br>FLT3/NPM1 in AML<br><br>Identity / zygosity testing<br><br>Microsatellite instability by PCR and analysis of microsatellite markers<br><br>Monitoring stem-cell transplants<br><br>X-inactivation<br><br>Tri/tetra nucleotide repeat fragment detection and interpretation (including PCR and TP-PCR)<br><br>MGMT methylation status determined by bisulphite conversion | Capillary Electrophoresis<br><br>PCR, methylation specific PCR, Triplet Repeat PCR using in-house methods and commercial kits as listed:<br><br>Zymo Research EZ DNA Methylation kit<br>Elucigene CFEU50 kit<br>Powerplex 16HS<br><br>Equipment:<br><br>PCR blocks, BiomekNXp liquid handling robot and ABI3500xl Capillary electrophoresis instruments and Gel Electorphoresis<br><br>Analysis using GeneMarker or GeneMapper software<br><br>Imaging of gels (where approprirate) by Geneflash (Syngene BioImaging)<br><br>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 | |

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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) | |
| 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)<br><br>Imaging of gels by Geneflash (Syngene BioImaging)<br><br>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, | |

| 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)**<br><br>**Using:**<br><br>In-house methods<br>And:<br><br>Thermocyclers. Resolution by capillary electrophoresis using ABI 3500XL<br><br>Analysis using SoftGenetics.<br><br>Procedures:<br>[Prenatal] : GENE979, GENE314, GENE312 | A |
| RNA extracted in house from FFPE or received as primary samples from external sources | Confirmatory testing of fusion events by RT-PCR-analytic capacity as per GENE36 | **Qualitative Reverse Transcriptase PCR (RT-PCR)**<br><br>RT-PCR using in-house methods with resolution by agarose gel analysis and fragment sizing (where appropriate) using ABI 3500xl Genetics analyser<br><br>Procedures:<br>GENE155, GENE156, GENE462, GENE154 | |

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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) | |
| 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)**<br><br>Using<br><br>In-house or commercial kits, thermocyclers, Biomek NXp automated liquid handler, ABI3500xl (Pre-analytical)<br><br>Procedures:<br>(equipment and kits): GENE735, GENE627, GENE586<br>(procedures and analysis): GENE929,GENE660<br>(specific disorders): GEBE953, GENE945, GENE949 | 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 -analytic capacity as per GENE119 | Analysis of NGS myeloid panel derived data using in house filtering tool.<br><br>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 -analytic capacity as per GENE174 | Analysis of NGS panel derived data using in house filtering tool.<br><br>Variant interpretation supported by the Alamut Software tool, gene knowledge bases and variant databases.<br><br>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.<br><br>By detection of microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number | **SNP Array:**<br>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<br><br>Procedures:<br>GENE334, GENE342, GENE343, GENE349, GENE359<br>[Prenatal] GENE349, GENE351, GENE352 | |

| 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<br>Bone marrow<br>Amniotic fluid<br>Chorionic villi<br>Foetus and placenta<br>Products of conception<br>Tissue biopsy (tumour, skin, placenta, liver, lymph nodes etc)<br>Solid tumours<br>Paraffinised histology samples<br>Slide sections<br>Mouth washes/swabs | <u>G-banding/Karyotyping</u><br><br>Detection of chromosomal rearrangements or aberrations arising from (e.g)<br><br>Prenatal Diagnosis<br>Neoplastic Genetics including Haemato-Oncology and Solid Tumours.<br>Postnatal Disorders<br>Loss of pregnancy<br><br>Preparative pre-examination steps listed first | **Culturing and processing of human tissue/cells to provide interphase cells:**<br><br>Manual/automated process using:<br><br>Cell harvesting: SOP GENE522<br>Processing – SOPs GENE308, GENE307, GENE310, GENE574<br>Feeding GENE516<br>Subbing GENE579<br><br>Slide Preparation: GENE577, GENE578<br><br>Automated Cell capture GENE571<br><br>SOPs<br><br>[Postnatal] GENE577,GENE571, GENE301, GENE521<br><br>[Haemato-Oncology] GENE470<br><br>[Prenatal] GENE496, GENE289, GENE528, GENE290, GENE16, GENE521<br><br>[Foetal] GENE308, GENE575, GENE516, GENE579, GENE522, GENE519 | A |
| | | **Chromosome analysis:**<br><br>Microscopic analysis of G banded chromosomes using light microscopy and Cytovision image analysis system<br>[Postnatal] GENE521<br>[Haemato-Oncology] GENE438, GENE449<br>[Prenatal] GENE306<br>[Foetal] GENE521, GENE317 | A |

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|---|---|---|---|
| HUMAN TISSUES & FLUIDS | Genomics analysis for the purpose of clinical diagnosis or rare disease and cancer<br><br>Detection of chromosomal aberrations in the diagnosis of<br><br>Haematological malignancy, bone marrow failure syndromes<br>Non-haematological malignancies<br><br>Break-apart probes<br>Fusion products<br>Deletion<br>Insertion<br>Copy Number/Amplification<br><br>Analytic capacity as per SOP GENE35<br><br><u>Muscle Immunoanalysis</u> | Documented in house procedures incorporating manufacturer's instructions (where relevant)<br><br>**Fluorescence in situ hybridisation:**<br><br>(FISH) using manual in-house methods and commercial kits (including, Abbott Vysis, Cytocell, Kreatech, Metasystems, TCAG), Thermobrite/ Hybrite denaturation stations and fluorescent microscopy<br><br>Procedures:<br><br>[Haemato-Oncology] GENE440, GENE446, GENE448, GENE441. | A |
| 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<br><br><u>Immunohistochemistry</u><br><br>Immunohistochemistry analysis and interpretation of data to progress a diagnosis | | B |
| Frozen skeletal muscle tissue | Antibodies listed below:<br><br>αB-Crystallin<br>α-Dystroglycan<br>α-Sarcoglycan<br>ACTN3 | Manual immunohistochemistry staining using procedures: -<br><br>Cryostat SOP No 1-48 MIU107<br>Immunohistochemistry SOP No 3-3 GENE38<br>Microscopy and imaging SOP 4-59 MIU156<br>Interpreting and reporting results SOP No 4-6 MIU157 | B |

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

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| Homogenised skeletal muscle biopsies | <u>Immunoblotting analysis and interpretation of data to progress a diagnosis</u><br><br>Antibodies listed below:<br><br>α-Sarcoglycan<br>β-Dystroglycan<br>Calpain 3<br>Dysferlin<br>Dystrophin (C-term)<br>Dystrophin (Rod)<br>Laminin α2 chain<br>Telethonin | Procedures:<br>Cryostat SOP No 1-48 MIU107<br>Sample homogenisation and protein assay SOP No 3-9 DocMIU125<br>Western blotting SOP No 3-6MIU124<br>Fluorochem (Western blot imaging) SOP 1-47 Doc MIU106<br>Interpreting and reporting results SOP No 4-6 MIU157 | B |
| END | | | |