

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>9322 Accredited to ISO 15189:2022</p>	<h3>Manchester University NHS Foundation Trust</h3> <p>Issue No: 011 Issue date: 02 October 2025</p>	
	<p>North West Genomic Laboratory Hub (Liverpool) Manchester Centre for Genomic Medicine Liverpool Women's NHS Foundation Trust Crown Street Liverpool L8 7SS</p>	<p>Contact: Dr Emma Howard PhD Tel: +44(0)151 702 4228 +44(0)161 701 4919 E-Mail: Emma.Howard@mft.nhs.uk Website: https://mft.nhs.uk/nwglh/</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Blood (includes fetal) Bone marrow Other tissues Fixed, cultured cells Other fluids</p> <p>Blood (includes fetal) Bone marrow</p> <p>Other tissues Fixed, cultured cells Other fluids</p> <p>Blood (including fetal) Bone marrow Lymph nodes Solid Tissues Solid Tumours Formalin fixed paraffin embedded tissue (FFPE) Fixed culture cells Other fluids</p>	<p><u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis:</u></p> <p><u>Cytogenetics</u></p> <p>Chromosome analysis for: Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders</p> <p>Macroscopic and microscopic detection and analysis of genetic rearrangements and/or genomic imbalance for haematological/oncology, developmental and reproductive medicine disorders including confirmation and inheritance testing following proband microarray findings</p>	<p>Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:</p> <p>Preparation of specified material for chromosome analysis using Robo-Sep S cell separator DOC5182 DOC5173</p> <p>G-banding macroscopic and microscopic examination, detection, analysis and reporting of G banding and karyotyping against considered normal G banding pattern Using Metasystems Image Analysis System and Dako automated coverslipper DOC5004 DOC5642 DOC5003 MP000018</p> <p>Fluorescent in situ hybridisation (FISH) using in-house procedures and manufacturer's instructions for Hybrite and Metasystems Image Analysis System DOC5094</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>SNP array data received from external source</p> <p>Blood, Blood spot, Fetal blood, buccal/saliva samples, urine, cultured cells, amniocytes, chorionic villi, solid tissues, tissue sections, products of conception, fetal tissue, embryo tissue, formalin fixed paraffin embedded tissue, Bone Marrow</p> <p>DNA</p>	<p><u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p>Chromosome profile analysis for detection of chromosomal imbalance as copy number gains or losses, and copy neutral changes. For diagnosis in Haematological/ Oncology disorders</p> <p><u>Molecular Genetics</u></p> <p>DNA extraction and quantification</p> <p>Mutation detection of sequence variants for the purpose of clinical diagnosis and quality assessment of PCR products:</p> <p>GJB6 (Connexin 30) Spinal Cerebellar Ataxia 1 (SCAR 1)</p>	<p>Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:</p> <p>Analysis and interpretation of Illumina GSA-Cyto+ SNP array data using Bionano VIA software DOC5967 DOC5988 DOC5989</p> <p>DNA extraction using Chemagic PRIME extractor and BioRobot EZ1 DOC5418 DOC5406 DOC5407 DOC5867</p> <p>DNA quantification for QC purposes using DropSense 16 and Advanced Nanodrop Spectrophotometer DOC5583 DOC5405</p> <p>Thermal Cyclers, Biomek Robot Nx, PCR & Agarose Gel electrophoresis DOC5387 DOC5148 DOC5409 DOC5439</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p><u>Molecular Genetics</u> (cont'd)</p>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	<p>Mutation detection, confirmation and carrier/ predictive testing for the purpose of clinical diagnosis in genes:</p> <p>Detection of clinical relevant nucleic acid sequence for confirmation/cascade testing of NGS results or family studies related to validated methods</p> <p>ABCD1 (Adrenoleukodystrophy) Notch3 (Cadasil) LDLR/ APOB ex27/ PCSK9 ex7 (Familial Hypercholesterolaemia) FXN (Friedreich Ataxia) GJB2 (Hearing Loss) PMP22/MPZ/GJB1/MFN2 (HMSN/HNPP) PLA2G6 (Infantile Neuroaxonal Dystrophy) SGCE (Myoclonic Dystonia) MTM1 (Myotubular Myopathy) PANK2 (Pantothenate kinase-associated neurodegeneration) MECP2 (Rett Syndrome) FGFR3 exon 9 and 12 (Achondroplasia and Hypochondroplasia) CFTR (Cystic fibrosis transmembrane conductance regulator)</p>	<p>PCR amplification and Sanger Sequencing of DNA using Thermal Cyclers, Nx Bravo automated Liquid handler, ABI 3730 DOC5387 DOC5388 DOC5397 DOC5415</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p><u>Molecular Genetics</u> (cont'd)</p>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	<p>Mutation detection for the purpose of clinical diagnosis, confirmation, carrier detection and predictive testing in disorders:</p> <p>Huntington Disease, Huntington Disease-like 2 Myotonic Dystrophy1, Myotonic Dystrophy2,</p> <p>Friedreich Ataxia,</p> <p>Oculopharyngeal Muscular Dystrophy, Spinal Bulbar Muscular Atrophy, Spinal Cerebellar Ataxia 1, 2, 3, 6, 7, 12 & 17, Dentatorubral-pallidoluysian atrophy, Maternal Cell Contamination</p>	<p>DNA PCR and fluorescent fragment size analysis (F-PCR), including PCR amplification of DNA using thermocyclers ABI 3500 and Genemapper software. DOC5387 DOC5388</p>
DNA	<p>Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in genes:</p> <p>Friedreich Ataxia, Myotonic Dystrophy1, Myotonic Dystrophy2</p>	DNA PCR, triplet-primed PCR (TP-PCR) and fluorescent fragment size analysis and QP-PCR
DNA	<p>Mutation detection, confirmation and carrier testing in disorders/ genes:</p> <p>Allele Specific PCR: Cystic Fibrosis</p>	<p>Allele-specific PCR amplification of DNA and Fluorescent fragment size analysis using Elucigene (Yourgene) diagnostic Kits, ABI 3500 DOC5387 DOC5388</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	<u>Molecular Genetics</u> (cont'd) Mutation detection for the purpose of clinical diagnosis, confirmation, carrier detection and predictive testing in C9orf72-related disorders	DNA PCR, repeat primed PCR and fluorescent fragment size analysis using thermocyclers, ABI3500XL, Genemapper software and Asuragen AmplideX PCR/CE C9orf72 kit in conjunction with: DOC5808 AmplideX PCR/CE C9orf72 Kit (Asuragen) protocol
DNA	Analysis of copy number changes for the purpose of clinical diagnosis and carrier/predictive testing in genes: Dystrophin, GJB1/PMP22/MPZ, LDLR CFTR SMN1/2	DNA PCR and dosage analysis by Multiplex ligation probe – dependant amplification (MLPA) using ABI3500 and Genemapper and Mutation Surveyor software. DOC5150
DNA	Dosage Analysis by quantitative fluorescent PCR: Rapid Aneuploidy Screening, Spinal Muscular Atrophy	DNA PCR and dosage analysis by quantitative fluorescent PCR (QF-PCR) amplification of DNA DOC5198 DOC5395

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