

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>9322</b> Accredited to ISO 15189:2022</p>	<h3>Manchester University NHS Foundation Trust</h3> <p><b>Issue No:</b> 008    <b>Issue date:</b> 21 November 2024</p>	
	<p><b>North West Genomic Laboratory Hub (Liverpool)</b>  <b>Manchester Centre for Genomic Medicine</b>  <b>Liverpool Women's NHS Foundation Trust</b>  <b>Crown Street</b>  <b>Liverpool</b>  <b>L8 7SS</b></p>	<p><b>Contact: Dr Emma Howard PhD</b>  <b>Tel: +44(0)151 702 4228</b>  <b>+44(0)161 701 4919</b>  <b>E-Mail: Emma.Howard@mft.nhs.uk</b>  <b>Website: <a href="https://mft.nhs.uk/nwglh/">https://mft.nhs.uk/nwglh/</a></b></p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY TISSUE AND FLUIDS</b></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>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><u>Molecular Genetics</u></p> <p>DNA extraction for detection of abnormal sequences for common and rare genetic disease conditions</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>DNA extraction using Chemagic PRIME extractor and BioRobot EZ1 DOC5418 DOC5406 DOC5407 DOC5867</p> <p>DNA quantification for QC purposes: DropSense 16, Advanced Nanodrop Spectrophotometer DOC5583 DOC5405</p> <p>Thermal Cyclers, Biomek Robot Nx, PCR &amp; 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)</p>	<p>PCR amplification and Sanger Sequencing of DNA using Thermal Cyclers, Biomek Robot Nx Bravo automated Liquid handler, ABI 3730 DOC5387 DOC5148 DOC5388 DOC5397</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, 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&amp; 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 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)	<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>Analysis of copy number changes for the purpose of clinical diagnosis and carrier/predictive testing in genes:</p> <p>ABCD1, Dystrophin, GJB1/PMP22/MPZ, MECP2, LDLR, SGCE, PANK2/PLA2G6</p>	DNA PCR and dosage analysis by Multiplex ligation probe – dependant amplification (MLPA) DOC5150
DNA	<p>Dosage Analysis by quantitative fluorescent PCR:</p> <p>Rapid Aneuploidy Screening, Spinal Muscular Atrophy</p>	DNA PCR and dosage analysis by quantitative fluorescent PCR (QF-PCR) amplification of DNA DOC5198 DOC5395
DNA	<p>Mutation detection of sequence variants for the purpose of clinical diagnosis and carrier testing in genes:</p> <p>LHON, HFE</p>	DNA PCR and Pyrosequencing using Thermal Cyclers, PyroMark PSQ-96 ID DOC 5387 DOC 5435
END		