

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8044</p> <p>Accredited to ISO 15189:2022</p>	<h3>Nottingham University Hospitals NHS Trust</h3> <p>Issue No: 011 Issue date: 28 November 2024</p>	
	<p>Molecular Genetics City Hospital Campus Hucknall Road Nottingham NG5 1PB United Kingdom</p>	<p>Contact: Dr Joanne Field Tel: +44 (0)1159691169 ext 75207 E-Mail: Joanne.Field@nuh.nhs.uk Website: https://www.nuh.nhs.uk/molecular-genetics</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 TISSUE AND FLUIDS</p> <p>Whole Blood, Amniocytes Chorionic villi Buccal/saliva samples Cultured cells Urine Formalin fixed paraffin embedded tumour sections] Soft Tissue</p> <p>Amniocytes Chorionic villi Cultured cells Soft Tissue</p> <p>Peripheral Blood Soft Tissue</p> <p>FFPE</p> <p>Saliva</p> <p>Peripheral Blood</p> <p>Peripheral Blood</p>	<p><u>Molecular Genetics examinations for the purpose of clinical diagnosis</u></p> <p>DNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and for long-term storage</p>	<p>Documented in-house methods incorporating manufacturers' instructions where relevant:</p> <p>Manual and automated DNA extraction and quantification</p> <p>Using:</p> <p>Phenol Chloroform</p> <p>BACC2/3 Nucleon Kit</p> <p>Cell lysis followed by Proteinase K digestion method</p> <p>Oragene</p> <p>Perkin Elmer Chemagic 360-D automated DNA extractor</p> <p>Promega Maxwell RSC DNA Extractor</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Uncultured amniocytes and chorionic villus samples</p>	<p><u>Molecular Genetics examinations for the purpose of clinical diagnosis</u> (cont'd)</p>	<p>Documented in-house methods incorporating manufacturers' instructions where relevant:</p> <p>RSC Cell DNA Purification Kit and Promega Maxwell RSC DNA Extractor</p> <p>Manual and automated DNA extraction and quantification</p> <p>Using:</p> <p>Quantification for QC purposes using NanoDrop 1000 Spectrophotometer and Qubit 3.0 Fluorometer)</p> <p>SOPs: GEN SOP-109-Chemagic DNA Extraction, GEN SOP-120 SOPs cover majority of samples GEN SOP 87 (paraffin –embedded tissue) GEN SOP 61 (amnio) GEN SOP-1 CVS extraction GEN SOP-14/29 (nucleon) GEN SOP-2 Clotted Blood GEN SOP-3 Soft tissue GEN SOP-81 Saliva (Oragene) GEN SOP-121 Maxwell amnio CVS</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Determination of copy number and methylation abnormalities</p>	<p>Documented in-house methods incorporating manufacturers' instructions where relevant:</p> <p>Multiplex Ligation Probe Amplification (MLPA) Using: MLPA using MRC Holland Kits and methylation specific PCR, and MJ-Engine, , thermocyclers Capillary electrophoresis using Applied Biosystems capillary sequencers Analysis using Genemapper and custom designed Excel spreadsheets for dosage analysis SOPs: GEN SOP-101/106 (MLPA SOP), PWAS SOP-15 (PWS/AS MS-MLPA SOP) HNPCC SOP-10 (MLH1 MS-MLPA SOP), GEN SOP-128 ABI3500XL operation</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources</p>	<p><u>Molecular Genetics examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of known sequence variants [definitive list of be held by this laboratory]</p>	<p>Documented in-house methods incorporating manufacturers' instructions where relevant:</p> <p>Gel Electrophoresis Using: Allele specific PCR and PCR followed by restriction enzyme digestion</p> <p>Using DNA using thermocyclers –using In house methods , agarose gel electrophoresis</p> <p>SOPs: HAEM POL-1, HAEM SOP-1 (HFE ARMS PCR), BRCA SOP-13 (BRCA1 exon 13 duplication PCR, GEN SOP-12 GEN SOP-67 (agarose gel electrophoresis)</p> <p>SOPs: SMA POL-1, SMA SOP-1, HAEM POL-1, HAEM SOP-1 GEN SOP-67 (agarose gel electrophoresis)</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources DNA from the above</p>	<p><u>Molecular Genetics examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of fragment length size, deletions, known mutations, repeat expansions and linkage markers (including microsatellite)</p>	<p>Documented in-house methods incorporating manufacturers' instructions where relevant:</p> <p>Fragment Analysis Elucigene CF-EU2 kit for PCR amplification</p> <p>Promega MSI analysis system v1.2 for PCR amplification</p> <p>Amplidex Asuragen FMR1 kit for PCR amplification</p> <p>In-house PCR and Triplet repeat PCR and thermocyclers Capillary electrophoresis/fluorescent electrophoresis using Applied Biosystems ABI3500xl capillary sequencer</p> <p>SOPs: CF POL-1, CF SOP-18 (CFEU2 SOP), CF SOP-19 (CFEU2 analysis SOP), GEN SOP-128 ABI3500xl operation</p> <p>Disease-specific policies: HD POL-1, DM POL-1, FRAX POL-1, DMD POL-1, HNPCC POL-3, SMA POL-1, UPD7 POL-1, UPD14 POL-1, PWAS POL-1, MAT CON POL-1</p> <p>Disease-specific SOPs: HD SOP-2,7,9; DM SOP-2,3,7,10; FRAX SOP-18,19,20; HNPCC SOP-7; DMD SOP-26; SMA SOP-4; CF SOP-13; UPD7 SOP-7, UPD14 SOP-17, PWAS SOP-16, MAT CON SOP-1</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources DNA from the above</p>	<p><u>Molecular Genetics examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Chromosomal aueploidy</u></p>	<p>Documented in-house methods incorporating manufacturers' instructions where relevant:</p> <p>DNA dosage analysis Using:</p> <p>Quantitative fluorescent PCR (QF-PCR) amplification and DNA using thermocyclers –using In house methods</p> <p>Capillary electrophoresis using Applied Biosystems 3500xl capillary sequencers</p> <p>SOPs: QF-PCR POL-1, QF-PCR SOP-3 (QF-PCR preparation and set-up), QF-PCR SOP-4 (QF-PCR Analysis), GEN SOP-128 ABI3500xl operation</p>
END		