


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>Cambridge University Hospitals NHS Foundation Trust</h3> <p>Issue No: 004 Issue date: 30 December 2020</p>	
	<p>East Genomic Laboratory Hub Box 143 Cambridge University Hospitals NHS Foundation Trust Cambridge Biomedical Campus Hills Road Cambridge CB2 0QQ</p>	<p>Contact: Natalie Holder Tel: +44 (0)1223 250722 E-Mail: natalie.holder@addenbrookes.nhs.uk Website: www.cuh.org.uk</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
HUMAN TISSUES AND BODY FLUIDS	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u></p> <p>DNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and longterm storage</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Manual and automated DNA extraction and quantification using:</b></p> <p><b>Automated Extraction:</b> Automated DNA extraction using Flex Star</p> <p>SOP 517 Automated DNA extraction using Qiagen EZ1</p> <p>SOP325, 439,174 and 176</p> <p><b>Manual extraction:</b> Phenol chloroform SOP SOP185, 003. 174, 176</p> <p>Qiagen QiaAmp DNA micro kit SOP 237</p> <p>Qiagen DNEASY SOP 410, 439</p>
Whole Blood		
Whole Blood,Buffy Coat CVS/Amniocentesis Tissues Guthrie Spots		
CVS/Amniocentesis Cultured Cells Tissues including skin and Buccal swabs		
Whole Blood		
Tissue Cultured Cells Fixed cells Bone marrow		



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Saliva and Buccal swabs</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p> <p>DNA Clean up</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>DNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and longterm storage (cont'd)</p> <p>Detection of nucleic acid sequence variants - SNVs and small indels</p> <p>[reference to definitive list of known targets (where appropriate) and purposes (eg 1-8 of your draft) as per GEN4</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Manual and automated DNA extraction and quantification using:</b></p> <p><b>Manual extraction:</b> Oragene</p> <p>SOP 267</p> <p>DNA Quantification for QC purposes:</p> <p>Nanodrop ND-1000 spectrophotometer and Qubit fluorometer</p> <p>SOPs 231 (Nanodrop (ND-1000) and 509 (Qubit)</p> <p>Qiagen QiaAmp DNA micro kit SOP414</p> <p><b>Sanger Sequencing</b> Using:</p> <p>Standard Primer Design methodology: SOP 518</p> <p>PCR/ Thermal cyclers, ABI3130, ABI 3730, Biomek robotics</p> <p>SOPs 069, 253, 254, 313, 079, 268</p> <p>Analysis using Mutation Surveyor by SoftGenetics</p> <p>SOP 255</p>



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Screening of large targeted single or multigene panels for genetic variants:</p> <p>reference to definitive list of panels, capture and genetic variant types as per GEN4] SNVs and Small indels</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Next Generation Sequencing</b></p> <p>Library Preparation and capture Illumina TruSight One Panels created managed using Gemini (GENome MINing)</p> <p>SOP 493</p> <p>PCR Thermal cyclers, ABI3130, Biomek robotics and Illumina Hiseqs 2500 and 4000</p> <p>SOPs 471, 549, 551</p> <p>Analysys using Dias Bioinformatics software</p> <p>SOP 545</p>
<p>PCR/Long Range PCR amplicons</p>	<p>SNVs and small indels for the purpose of diagnostic, confirmation, ad-hoc or familial testing</p> <p>And/or</p> <p>Detection and quantification of Low-level mosaic variants as inferred from Sanger sequencing data (or clinical phenotype)</p>	<p>In-house documented methods</p> <p>Using: Illumina MiSeq.</p> <p>SOPs:</p> <p>SOP445, 446,451, 546</p>



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Determination of fragment length size and detection of deletions, fusion deletions, known mutations, microsatellites, repeat expansions and linkage markers for the purpose of genotyping at specific known gene loci</p> <p>[Reference to definitive list as per GEN4]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Fluorescent Based Fragment Analysis</b></p> <p>Commercial Methods: Fluorescent Fragment Assays:</p> <p>Fluorescent ARMS using the Elucigene Cystic Fibrosis-EU2v1 kit.</p> <p>SOP 030</p> <p>QF-PCR kit (QF-PCR) - Devyser Compact</p> <p>SOPs 428 QF-PCR, 528 - MCC</p> <p>And:</p> <p>In house Fluorescent Fragment Assays using PCR and allele specific PCR and PCR of linked markers</p> <p>SOP348: DNA Testing for thrombosis risk factors, SOP257: Testing for HFE1 common mutations, SOP502: X-Chromosome inactivation PCR and analysis, SOP045: DNA testing for Prader-Willi syndrome and Angelman syndrome, SOP040: Testing for Huntington Disease (HD)</p> <p>Fluorescent Fragment Analysis using ABI 3130 and 3730 genetic analysers and GeneMarker software</p> <p>SOPs 079, 268 and 320</p>



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Determination of fragment size length, Detection of deletions, fusion deletions, known mutations, repeat expansions and inversions for the purpose of genotyping at specific known gene loci</p> <p>[Reference to definitive list as per GEN4]</p> <p>Detection of repeat expansions too large to be amplified by PCR</p> <p>[Reference to definitive list as per GEN4]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Gel electrophoresis based Fragment Analysis</b></p> <p>In house methods for:</p> <p>Long range PCR, MS-PCR, inverse shifting PCR followed by gel electrophoresis.</p> <p>SOP041: DNA testing for Incontinentia Pigmenti (IP), SOP045: DNA testing for Prader-Willi syndrome and Angelman syndrome, SOP387: Haemophilia A (F8) Inversion screening and SOP246: Testing for GRA</p> <p>Gel Electrophoresis and visualisation SOPs: 0.16, 076, 386:</p> <p>And</p> <p><b>In house methods for:</b></p> <p>Southern blot hybridization analysis using labelled probes.</p> <p>SOPs 037: DNA testing for FMR1 expansion (Fragile X &amp; FXTAS 043 (DNA testing for Myotonic Dystrophy)</p> <p>Southern blot protocol 358 (Digoxigenin Southern Blot)</p>



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)</p> <p>Cytogenetic examinations for diagnosing postnatal disorders prenatal diagnosis, neoplastic genetics including haemato-oncology, loss of pregnancy by detection of sub microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number and copy neutral loss/absence of heterozygosity</p> <p>Detection of whole exon deletions/duplications and specific methylation abnormalities</p> <p>[Reference to definitive list as per GEN4 to be inserted here]</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Microarray</b></p> <p>Using: Affymetrix Genechip 3000 and Agilent G2565BA scanners:</p> <p>SOPs 438 and 452</p> <p>Analysis by Affymetrix chromosome analysis suite and Agilent Cytogenomics data analysis softwares and:</p> <p>SOPs298 and 453</p> <p>Affymetrix 750K Cytoscan and Agilent 8x60K ISCA.</p> <p>SOPs 438, 452, 489 and 453</p> <p><b>Multiplex Ligation Probe Analysis (MLPA) and methylation specific MS-MLPA</b></p> <p>using: in house or commercial MRC Holland kits</p> <p>Thermal cyclers and ABI 3130 /3730 Genetic Analyser</p> <p>Analysis using GeneMarker</p> <p>SOPs 384, 405, 079,428, 251, 564</p>



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Whole blood Amniotic fluid Chorionic villus samples Products of Conception Tissues Stem cells</p> <p>Fixed cell slides from human tissues and body fluids:</p> <p>Amniotic fluid CVS Stemcells Wholeblood</p>	<p><u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)</u></p> <p>G-Banding/Karyotyping</p> <p>Detection of constitutional chromosomal rearrangements or aberrations arising from:</p> <p>Prenatally detected disorders Development disorders Inherited Haematology/Oncology Disorders</p> <p>(Preparative Pre-examination steps listed first)</p> <p>Detection and analysis of genomic rearrangements and imbalances. Confirmation of genomic rearrangements detected using alternative technologies and family follow up studies in the diagnosis of constitutional disorders using locus specific probes:</p> <p>Deletion Copy Number/Amplification</p>	<p>Documented in house procedures incorporating manufacturer's instructions (where relevant)</p> <p><b>Manual culturing and processing of humans tissue to provide interphase cells:</b> using commercial media and:</p> <p>SOPs: 175, 178, 176, 174</p> <p>Cell Harvesting : Manual harvesting using in house methods : SOPs 141 (whole blood and prenatal and tissue cultures 142)</p> <p>Slide Preparation, coverslipping and storage : SOP 180</p> <p><b>Microscopic Analysis and reporting of G banded chromosomes:</b> Using: Brightfield microscopes:</p> <p>SOPs: 137 (G-banding procedure) and 135 (Analysis)</p> <p><b>Fluorescent in-situ hybridisation (FISH)</b></p> <p>Using:</p> <p>Cytocell and Vysis commercial kits, Vysis HYBrite hotplate and applied imaging (Leica)</p> <p>Analysis using: Cytovision analysis software and and fluorescent microscope system</p> <p>SOPs SOP 158 (Fluorescent in-situ hybridisation), 187 (Fluorescent microscope), and 160 (FISH analysis and checking)</p>
END		