# Schedule of Accreditation

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# United Kingdom Accreditation Service

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

**8127**

**Accredited to ISO 15189:2012**

## St George's University Hospitals NHS Foundation Trust

**Issue No:** 004 **Issue date:** 29 October 2021


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**Testing performed at the above address only**

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN TISSUE AND FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in-house methods incorporating manufacturer's instructions (where relevant) |
| NGS Sequence data (RPKM analysed data) received from an external source | Determination of copy number changes* [ *definitive list of targets assessed to be held by this laboratory] | Dosage interpretation using RPKM analysed data<br>GEN-MOL-LAB-41 Interpretation of RPKM analysed data<br>GEN-MOL-GEN-01 – molecular genetics analysis, checking and reporting. |
| Sequence data (raw) received from an external source | Detection of nucleic acid sequence variant - SNVs and Indels* [ *definitive list to be held by this laboratory] | Sanger sequencing analysis using Mutation Surveyor and Alamut<br>GEN-MOL-LAB-14 – analysis of sequencing data<br>GEN-MOL-LAB-15 – Alamut software<br>GEN-MOL-GEN-01 – molecular genetics analysis, checking and reporting<br>GEN-MOL-GEN-04 Research Confirmations |
| NGS data (raw) received from an external source | Detection of point mutations and small insertions and deletions of nucleotides* [*definitive list to be held by this laboratory] | NGS Analysis using Alamut and Congenica software<br>GEN-MOL-GEN-01 – molecular genetics analysis, checking and reporting.<br>GEN-MOL-LAB-15 – Alamut software<br>GEN-MOL-LAB-40 NGS data analysis using Congenica<br>GEN-MOL-LAB-36 Interpretation of sequence variants |

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|---|---|---|
| HUMAN TISSUES AND FLUIDS cont'd<br><br>Cell Free DNA extracted from maternal blood | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer<br><br>Non-invasive prenatal screening test :<br><br>• Detection of trisomy 21,18 and 13 and fetal sexing | Documented in-house methods incorporating manufacturer's instructions (where relevant)<br><br>CE Marked IONA NX test using<br><br>Yourgene SP150<br>Yourgene QS250<br>Illumina NEXTSeq 550 Dx<br>IONA computer – Atlas Workflow Manager Software<br>MyNIPT Portal<br><br>SOPs<br><br>GEN-SAFE-LAB20 Automated IONA Nx Extraction using the SP150<br><br>GEN-SAFE-LAB21 Automated IONA Nx Library Preparation using the SP150 and QS250<br><br>GEN-SAFE-LAB22 IONA Nx Sequencing using the NextSeq 550Dx |
| END | | |