Schedule of Accreditation

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United Kingdom Accreditation Service

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

21163

Accredited to ISO 15189:2022

Juno Genetics Limited

Issue No: 005 **Issue date:** 19 November 2024

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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 TISUES AND FLUIDS	Molecular Genetics	
Peripheral Blood, Saliva samples (in Oragene Media) and Products of conception	Extraction procedures: Automated extraction	Qiagen QIAamp kit and Qiacube
Peripheral Blood, Saliva samples (in Oragene Media) and Products of conception	Manual extraction	Qiagen QIAamp kit and Qiacube
Plasma	Extraction of cf DNA	Hamilton Liquid handler and VeriSeq workflow. Quantification using Spectramax Spectrophotometer

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Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Trophectoderm cells	Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)	Using: Repli-g SC or GenomiPi kit for DNA amplification by Multiple Displacement Amplification (MDA) Infinium SNP array/Karyomapping kit for genotyping the SNPs.Using Ilumina NextSeq 550 or Illumina NextSeq 550 DX as a scanner to "read" the genotyped SNP. Analysis using BlueFuse multi software v5.5 (Illumina) EXAM_PGT-M_Primer Design_234 EXAM_PGT_M_SOP_197
DNA extracted from Trophectoderm biopsy, Peripheral Blood or Saliva (also Genomic DNA received from an external source (mother/ father/ reference)	Direct Mutation Testing (for direct mutation site confirmation testing in PGT-M) using in house SOPs and which includes the below and analysis for all using Genemapper Fragment analysis Minisequencing Expansion analysis Fragile X	In house and kit-based methodology and analysis using ABI 3500DX /ABI 3500
DNA extracted from embryo biopsy material, blood, saliva (also genomic DNA received from samples from the mother/father)	Preimplantation Genetic Testing for Monogenic Disorders (PGT-M): testing for inherited single gene disorders using linkage based and direct mutation site testing	Illumina Next Seq 550 and Illumina NextSeq 550DX with the Applied Biosystems ViiA7 qPCR instrument EXAM_PGT_M_SOP_197

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISUES AND FLUIDS (cont'd)	Molecular Genetics (cont'd)	Hot Master-taq PCR and ABI 3500XL / ABI 3500 Hot Master-taq clean-up of PCR products using ExoSAP-IT, and Primer extension using SNaPshot and ABI 3500XL/ABI 3500 FailSafe™ one step PCR and ABI 3500XL/ ABI 3500 AmplideX® PCR/CE FMR1 AmplideX PCR kit
DNA extracted from Trophectoderm biopsy	Preimplantation Testing for Aneuploidies (PGT-A) – Chromosome copy number assessment:	PGT-SEQ kit using Juno Genetcis USA Library Preparation, Sequencing using Ilumina NextSeq 550 and Illumina NextSeq 550 DX, Analysis using NexCCsv2 analysis software EXAM_PGT-Seq SOP_149
	Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR) Products of Conception (POC) Testing – Chromosome Copy Number Assessment Including Maternal Cell Contamination Determination	
DNA extracted from Peripheral Blood and Products of Conception		PGT-Seq Kit using Juno Genetics USA library Preparation, Sequencing using Ilumina NextSeq 550 and Illumina NextSeq 550 DX, Analysis using NexCCsv2 analysis software EXAM_PGT-Seq SOP_149 EXAM_POCSOP_187

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISUES AND FLUIDS (cont'd)	Molecular Genetics (cont'd)	
Plasma	Non-invasive prenatal testing (NIPT)	Non-Invasive Prenatal Testing (NIPT) for aneuploidy and sexing using VeriSeq automated workflow using VeriSeq Solution v 2.– Automated Cell free DNA extraction from plasma and Library, Preparation using the Hamilton Star Liquid Handler and Paralleled sequencing on a NextSeq 550 DX. Analysis with VeriSeq VeriSeq NIPT Assay Software v2 (for 5 and 24 chromosomes) SOP EXAM_Neo and Neo24 test_SOP_269
END		