Yourgene Health

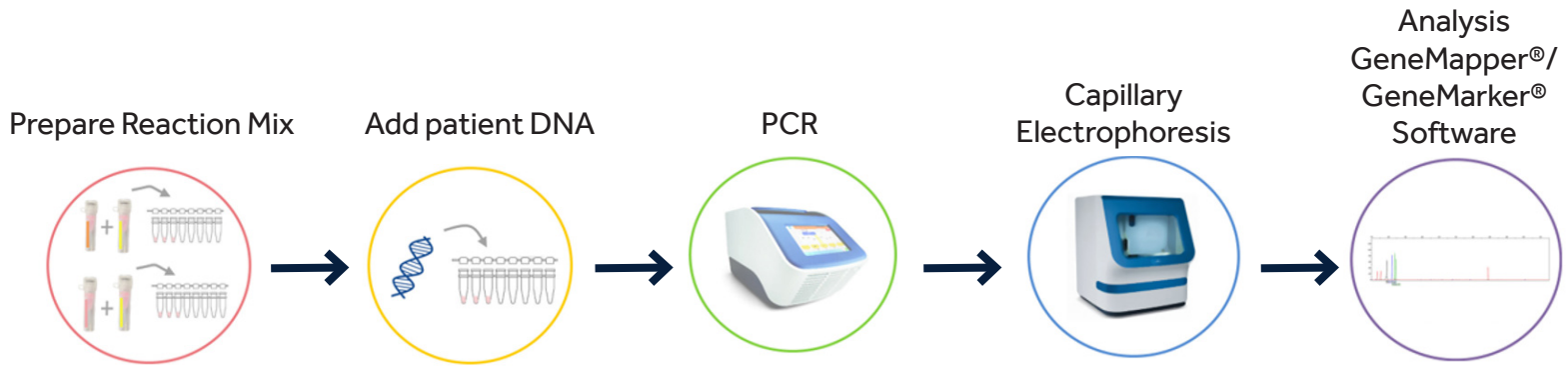
Product Catalogue (EMEA)

Nov 2022

Yourgene Health is an international molecular diagnostics group which develops integrated genomic technologies and services enabling genomic medicine.

Contents

Qualitative genotyping tests using the amplification refractory mutation system (ARMS)



- Market leading PCR assays
- Quick running time: 4-6 h
- 1 or 2 tubes per sample
- Optimised for clinical utility

- CE-IVD and registered IVD Australia and Canada
- Runs on ABI 3*** genetic analysers and SeqStudio*

Cystic Fibrosis

For the simultaneous and routine *in-vitro* quantitative detection of the human Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations. Suitable for use on DNA extracted from whole blood (EDTA preserved) and dried bloodspot samples. Intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing. CF-EU2 detects the 50 most common pan-European CFTR mutations, offering a sensitivity of 80-90%. Additional bolt-on panels are available to increase clinical utility in specific sub-populations. Standalone diagnostic panels are available to comply with specific clinical best practice and reimbursement guidelines.

DPYD

For the detection of *DPYD* gene mutations known to be associated with dihydropyrimidine dehydrogenase enzyme (DPD) deficiency, in accordance with Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines. Intended to be used in patients receiving, or due to receive, fluoropyrimidine-based medicines as part of a wider screening or diagnostic protocol. For example, 5-FU is a chemotherapy agent used to treat a number of tumour types, and is metabolized by the DPD enzyme. Patients with one of the detectable *DPYD* variants are at an increased risk of severe or fatal 5-FU toxicity.

Male Factor Infertility

For the routine *in-vitro* quantitative diagnosis of the most common sex chromosome aneuploidies (e.g. Klinefelter syndrome), as well as Y chromosome microdeletions (AZFa, AZFb and AZFc) commonly associated with male factor infertility. The devices are intended to be used on DNA extracted from whole blood (EDTA) from male patients with suspected infertility and who may be exhibiting associated features such as low sperm count. The core product exists alongside an optional bolt-on assay, covering additional Y-chromosome markers to better characterise any microdeletion detected. Both products conform to EAA and EMQN best practice guidelines.

Availability may vary by region. Please contact your sales representative for more information.

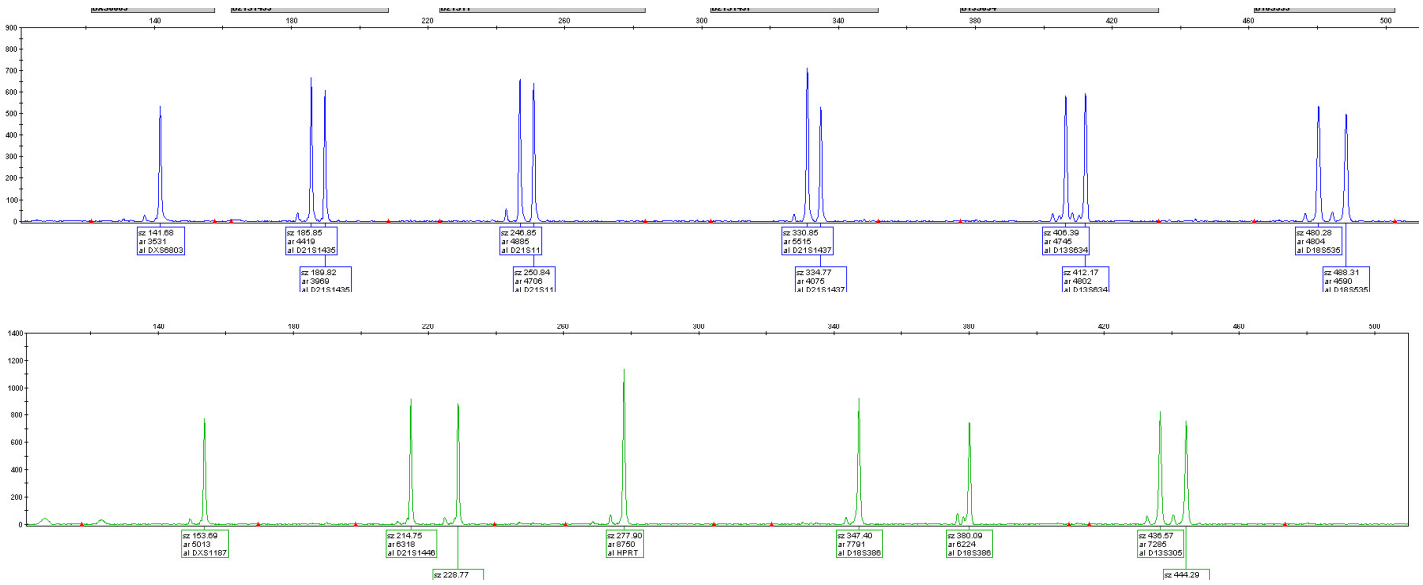
TRP-F *Plus*

For the routine *in-vitro* quantitative detection of four of the most relevant mutations implicated in the risk of developing venous thromboembolism; Factor V Leiden, Factor II, MTHFR (C>T and A>C). Intended for use on DNA extracted from whole blood (EDTA) or dried bloodspots. Testing is generally indicated in the management of patients under 50 years with venous thrombosis, or in the screening of patients with a specific family history of thrombolytic disease. Testing would additionally be warranted in relatives of individuals known to have factor V Leiden, and women with recurrent pregnancy loss, severe preeclampsia, or a previous stillbirth.

Qualitative genotyping tests using quantitative fluorescent PCR (QF-PCR) and capillary electrophoresis technology

The QST*R range from Yourgene Health utilises the analysis of short tandem repeat (STR) markers by QF-PCR technology to enable prenatal determination of aneuploidy status for the three most common viable autosomal trisomies (13, 18 and 21). Additional markers on the sex chromosomes X and Y, including a specific marker for the quantification of the number of X chromosomes, are useful in the diagnosis of sex chromosome complement disorders. The QST*R range also includes an assay specifically designed for use in recurrent pregnancy loss, which includes STR markers for chromosomes 13, 15, 16, 18, 21, 22, X and Y. Optimally balanced primers allow for the easy identification of triploidy, maternal cell contamination, mosaicism and sample degradation.

- Highly multiplexed assays
- Core product provides successful identification in 99% of samples
- Single tube per sample
- <6 hours from sample to report
- Optimally balanced primers
- CE-IVD and registered IVD Australia and Canada
- Used globally in over 30 countries
- Runs on ABI 3*** genetic analysers and SeqStudio*



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Non-invasive prenatal testing (NIPT) using whole-genome next-generation sequencing (NGS)

IONA® Nx
NIPT Workflow
illumina®

the IONA® test
non-invasive prenatal screen: safe, fast, accurate
ThermoFisher SCIENTIFIC

IONA® - A Flexible Sequencing Solution

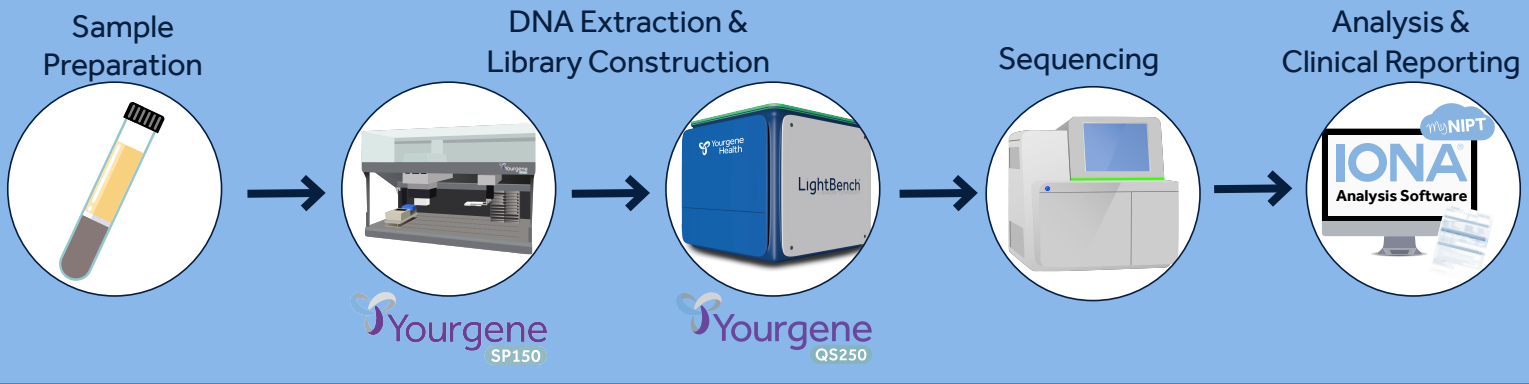
Enabling analysis of fetal cfDNA from a maternal blood sample to screen for autosomal and gonosomal aneuploidies, including trisomy 21 (Down's syndrome), trisomy 18 (Edwards' syndrome) and trisomy 13 (Patau's syndrome). In addition to this, solutions are customisable to allow for the optional screening of microdeletion syndromes* and fetal sex determination.

IONA® has been developed on the Ion Torrent systems from Thermo Fisher via the IONA® test, and the Illumina NextSeq 550dx via the IONA® Nx NIPT Workflow.

Test features:

- Confidence with CE-IVD marking for manual & automated workflows
- Simplicity; no added run controls during sequencing
- Scalable from 24 to up to 48 samples/flow cell
- Wrap-around solution from sample to report
- State-of-the-art on-site analysis software
- Complete training, support and maintenance
- Customisable, with bespoke solutions available

IONA® Nx NIPT Workflow



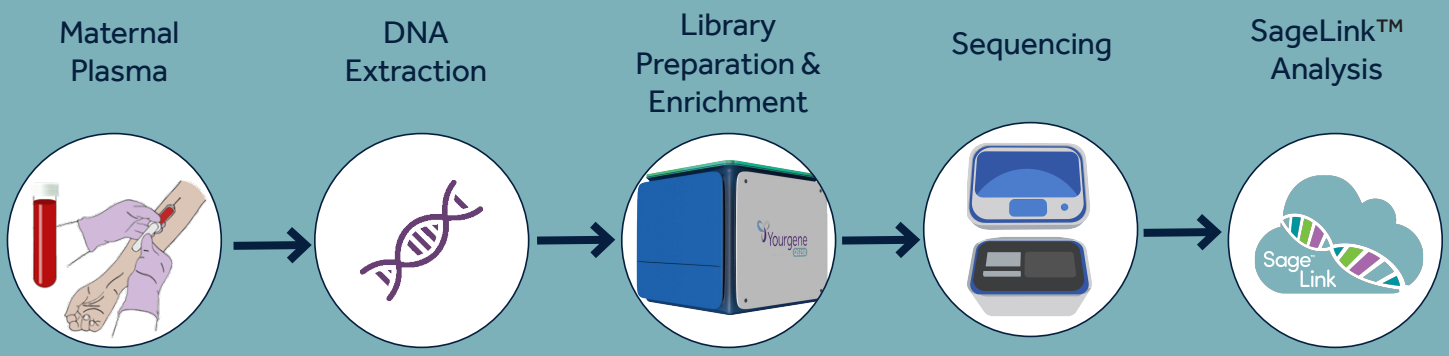
Atlas Workflow Manager - Tracks samples through the entire workflow

Availability may vary by region. Please contact your sales representative for more information.

The Sage™ Prenatal Screen

Developed alongside the IONA® solution, the Sage™ prenatal screening workflow employs the latest advances in NGS for laboratories wishing to establish an in-house offering. Like IONA®, Sage™ enables assessment of fetal cfDNA from a maternal blood sample to screen for trisomies 13, 18 and 21. Sage™ also offers the additional detection of other autosomal trisomies and monosomies, sex chromosomes aneuploidies and 5 microdeletions. The Sage™ workflow has been developed on the Thermo Fisher Sequencing Ion Torrent™ System.

Sage™ NIPT Workflow



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Standalone software solutions

MyNIPT®

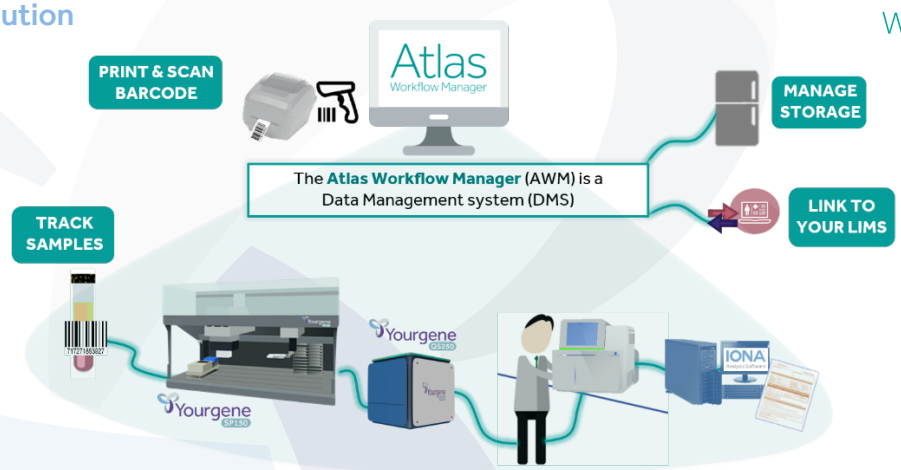
MyNIPT® is a data exchange portal provided by Yourgene to enable the seamless exchange of patient results easily and securely between the laboratory and the clinician.

- Intuitive and simple interface
- Secure
- Enhance traceability
- Efficient communication
- For IONA® solution

Atlas Workflow Manager

The Atlas Workflow Manager is a custom, comprehensive Data Management system (DMS) capable of interfacing with multiple LIMS for end-to-end tracking of samples and reagents.

- Track samples securely
- Manage storage
- Exportable data for auditing purposes
- Efficient communication
- For IONA® solution



Sage™ Link

Sage™ Link is a cloud-based bioinformatics data exchange portal for fast results analysis and test report generation.

- Secure
- Enhance traceability
- Efficient communication
- For Sage™ solution

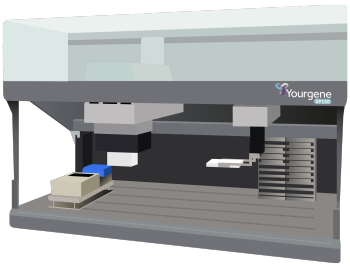
Availability may vary by region. Please contact your sales representative for more information.

Instrumentation

Yourgene® SP150

Developed in conjunction with the IONA® solution, the Yourgene® SP150 liquid handling system provides unlimited solutions in one instrument, streamlining sample processing and tracking.

The preconfigured instrument automates routine tasks to efficiently manage laboratory work, improving turnaround times and providing greater control and consistency across runs.



Ranger® Technology

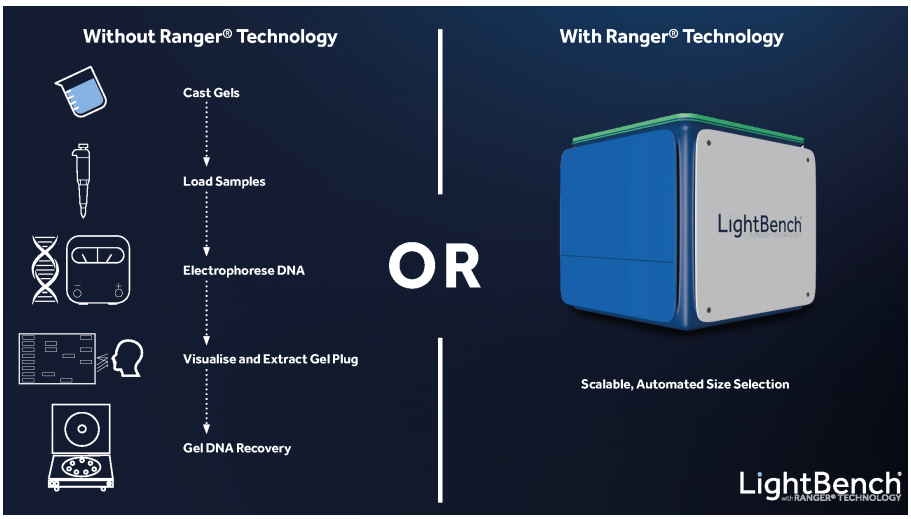
Ranger® Technology is the target enrichment technology that we incorporate in our next generation size selection instruments to provide automated gel electrophoresis. This technology enables industry-leading scalability and precision for the size selection process, ensuring maximum and repeatable enrichment every time.

Instrumentation from Yourgene powered by Ranger® Technology offers turnkey automation across three core processes:

- Size selection
- Fragment length analysis
- Quantification protocols using fluorescence assays

Ranger® Technology offers a fast, effective and efficient automated solution for separating DNA, providing clinical and research laboratories walk away time, reducing workflow costs and improving yields.

Yourgene offer a range of platforms powered by Ranger® Technology: Nimbus Select, LightBench®, LightBench® Detect and Yourgene® QS250.



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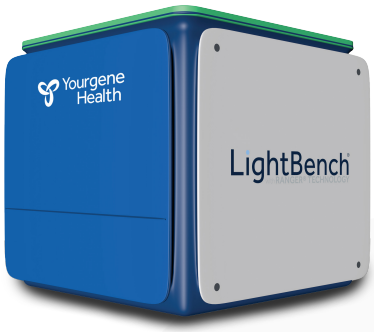
LightBench® and LightBench® Detect

The LightBench® and LightBench® Detect, powered by Ranger® Technology, automate gel electrophoresis in sample preparation for next generation sequencing applications, including non-invasive prenatal testing (NIPT), liquid biopsy for oncology and infectious disease detection, amongst many others.

The LightBench® can run 12 samples in 45 minutes; these quick turnaround times make it ideal for research applications.

The LightBench® Detect is ideal for clinical applications where the compatibility with EDTA blood collection tubes for size selection offers reduced workflow costs.

LightBench with RANGER® TECHNOLOGY



Research grade platform

LightBench Detect with RANGER® TECHNOLOGY

Clinical grade platform

Yourgene QS250®

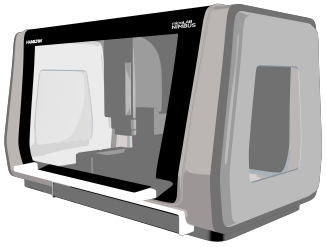
The QS250® instrument is available exclusively for use in Yourgene's NIPT workflows (IONA® Nx and Sage™). The QS250 integrates with other automated robotics and has been shown to improve the efficiency of fetal DNA enrichment to achieve an average recovery yield of over 70%. Not only does the QS250 help you achieve greater efficiency in your NIPT workflow, but it also increases the discrepancy between unaffected cases and those with trisomies, allowing you to provide greater confidence to your patients.

Yourgene QS250

NIMBUS Select

The NIMBUS Select is a fully integrated automated platform, ideal for high-throughput laboratories. This instrument combines automated electrophoretic fragment analysis, size selection, and liquid handling in one compact footprint. Up to 96 DNA samples can be processed in two hours.

NIMBUS SELECT with RANGER® TECHNOLOGY



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HELPING MAKE INFORMED HEALTHCARE DECISIONS TO IMPROVE PATIENT OUTCOMES

Yourgene Genomic Services

Yourgene Genomic Services are specialists in Next Generation Sequencing solutions for Research andClinical applications, including Oncology and Reproductive Health Testing. We are an ISO 15189 accredited medical laboratory focused on enabling genomic medicine, working with pharmaceutical organisations, biotechnology, research institutes, clinicians and various types of health care professionals.

OUR TESTS

Reproductive Health

- Prenatal Screening
- Trisomies by NIPT
- NIPT Extended menu

Oncology

- Cancer Precision Medicine Panel
- Comprehensive Genomic Profiling
- Whole Exome Sequencing
- Hypoxia Risk Score
- Chemotherapy Resistance
- CancerNext® powered by Ambry Genetics
- RNAinsight® powered by Ambry Genetics

OUR RESEARCH SERVICES

- Biomarker Discovery
- Clinical Trials
- Research Programs

OUR CAPABILITIES

Technologies

Our Manchester HQ hosts a high-volume, automated genomics testing facility. Capacity to process thousands of samples a day.
NGS • PCR • Microarray

Fetal Fraction & Liquid Biopsy

Expertise in cell-free DNA enrichment methods, with Yourgene Health's size selection Ranger Technology.

Bioinformatics

Bioinformatics and clinical interpretation capabilities for NGS analysis using GATK best practices.

Please contact us if you have any questions on our services or would like to learn more about how we can support your work on: genomics@yourgene-health.com

Yourgene Health

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