PRODUCT DATASHEET

Interpretation of Next-Generation Sequencing Panels

FABRIC GENOMICS

Launching and Scaling NGS Testing for Diagnostics or Risk Screening

Advances in next generation sequencing (NGS) coupled with decreased costs and growing reimbursement are opening the door for broader clinical use of NGS. With the efficiencies gained leveraging technologies such as Fabric ACE and current sequencing costs, clinical labs can achieve scale and profitability with genomic panel testing. Clinical utility and reimbursement are driving high volumes, particularly for hereditary risk screening for breast and gynelogical cancers and cardiac conditions. Newborn screening and carrier screening as well as broader screening for cancers and neurological diseases are also improving clinical care. Panels are used to analyze specific mutations, sets of genes, or gene regions associated with a disease or phenotype.

Fabric ACE

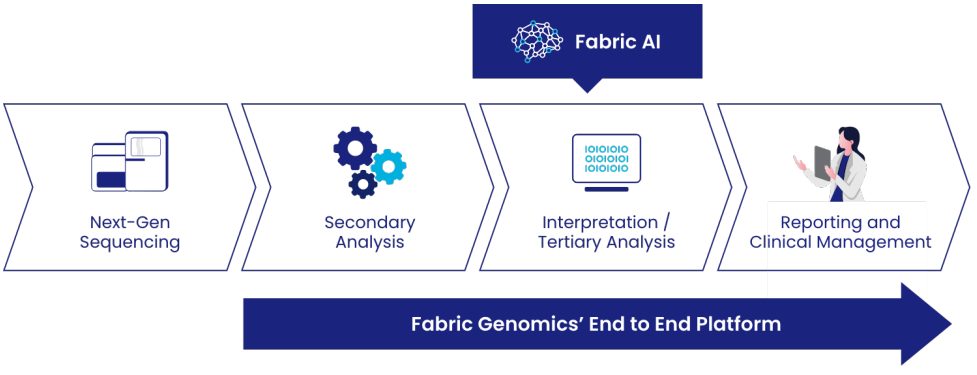
As NGS testing volume in your lab increases, interpretation efficiency and turnaround times become critical. However, a significant part of the cost involves the manual and time-consuming assessment of variant pathogenicity by trained clinical geneticists. Fabric optimizes this process with ACE – an extensively validated, AI-based inference engine implementing the ACMG-AMP criteria. ACE leverages deep gene and variant annotation for highly accurate ACMG variant classification, providing a complete FASTQ-to-clinical report workflow. Fabric ACE is available for over 1,000 genes in the most-used genetic testing panels and has been validated across more than 100,000 variants in a broad range of genes, including ACMG incidental findings, inherited cancers, and newborn screening tests. Fabric ACE enables labs to scale up testing, looking comprehensively at even the rarest variants while reducing processing effort and cost.

Fabric Enterprise

Fabric Enterprise is the leading analysis software for genomic testing, providing best-in-class variant interpretation from raw sequencing data to clinical report. Fabric Genomics offers diagnostic labs the flexible tools to quickly interpret genomic data and minimize turnaround time with standard step-by-step workflows. Fabric provides comprehensive product support from FASTQ or VCF data to clinical reports, including secondary and tertiary analysis. Fabric Enterprise is modular and enables labs to offer a more extensive diagnostic menu of reimbursable tests quickly by providing tools to create custom panels, workflows, and physician-ready reports easily.

Fabric Clinical Services

Fabric Genomics possesses the genomics expertise and a deep bench of experts to help your lab quickly launch and scale NGS testing. We work with many labs that are new to NGS and help them get up and running and testing quickly. We offer a range of services to take our customers from test planning and assay selection and validation to certified, scaled testing. We work with both labs that are new to NGS and the largest testing organizations in the world.



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Fabric Enterprise: A Complete Solution for Hereditary Panels, Somatic Cancer Panels, and Whole Genomes

Rapid and Accurate Testing

- Comprehensive solution from FASTQ or VCF file to the clinical report
- Works with any NGS sequencer and any validated assay
- Customized or off-the-shelf assay and genetic test
- Best practices alignment and variant calling pipelines deliver high-quality analysis 20-50x faster at a lower cost
- Robust and fast annotation from >90 public and proprietary data sources
- Custom clinical reporting solutions

ACMG Classification Standards

- Easily adopt the ACMG standards for variant classification with Fabric ACE – AI Classification Engine
- Standardize your institution's classification methodology with a fully auditable history of scoring decisions

Flexible Clinical Reporting

- Fully customize your clinical report with desired formats, content, and brand
- Export clinical report content directly to Electronic Medical Record (EMR) or other systems

Full LIMS and EMR Integration

- Easy integration with Laboratory Information Management Systems (LIMS) or EMR to ensure automated and consistent transfer of lab and patient information
- Upload of patient and test information, as well as export of results and clinical reports

Streamlined Interpretation and Classification

The 2015 ACMG guidelines were developed to provide clinical labs with a consistent, standard method for interpreting genetic variants. Fabric Enterprise delivers automated ACMG-compliant classification powered by ACE, Fabric's AI variant Classification Engine.

Classified Variant Database

Underlying evidence and annotations are easily accessible for rapid review by variant scientists. In addition, as laboratories classify variants, Fabric Genomics' platform automatically stores this information and builds a comprehensive genomic knowledge base. This enables laboratories to leverage publicly available data, the lab's historical variant classification data, and new knowledge created through the classification process. Leveraging this database, the vast majority of cases are classified automatically.

Accelerated Turnaround Times with Increased Efficiency and Consistency

Fabric Genomics' platform allows labs to configure standard workflows for their unique testing protocols, providing scientists a step-by-step procedure for triaging and classifying variants. Flexible workflow configurations enable labs to quickly identify negative reports for batch approval, introduce multiple levels of review, and specify read or read/write access to cases at various stages of interpretation, review, or report generation.

Fabric's dashboards and notifications enable lab directors and variant scientists to take immediate action on cases as they move through the interpretation, review, and reporting workflow. Colleagues can easily collaborate through case-level and variant-level notes.

Secure and Cloud-Based

Fabric Enterprise is a cloud-based application that scales seamlessly as your lab grows. Fabric Genomics matches or exceeds regulatory requirements, guidelines, and standards for the privacy and security of patient data.

- Accessed via 128-bit SSL encryption; hosted in a secure data center with 24/7 monitoring
- Cloud architecture includes redundant server and backup for all annotated variant, report, and patient data
- HIPAA, ISO-27001, CAP, and CLIA compliance programs
- US FDA Code of Federal Regulations 21 Part 11 compliant programs for electronic signatures

About Fabric Genomics

Fabric Genomics is making genomics-driven precision medicine a reality. The company provides clinical-decision support software that enables clinical labs, hospital systems, and country-sequencing programs to gain actionable genomic insights, resulting in faster and more accurate diagnoses and reduced turnaround time. Fabric uniquely provides a comprehensive AI-based solution that spans the range of NGS applications from targeted panels to exomes and whole-genome sequencing. Fabric was the first to offer a commercial algorithm for diagnostic genomic interpretation and has partnered with leading NGS labs and major hospital systems to bring these groundbreaking advances to patients at over 50 sites running tens of thousands of tests per year. Headquartered in Oakland, California, Fabric Genomics was founded by industry veterans and innovators with a deep understanding of bioinformatics, large-scale genomics, and clinical diagnostics.

Learn more at **www.fabricgenomics.com** ■ **demo@fabricgenomics.com** ■ **510.595.0800**

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