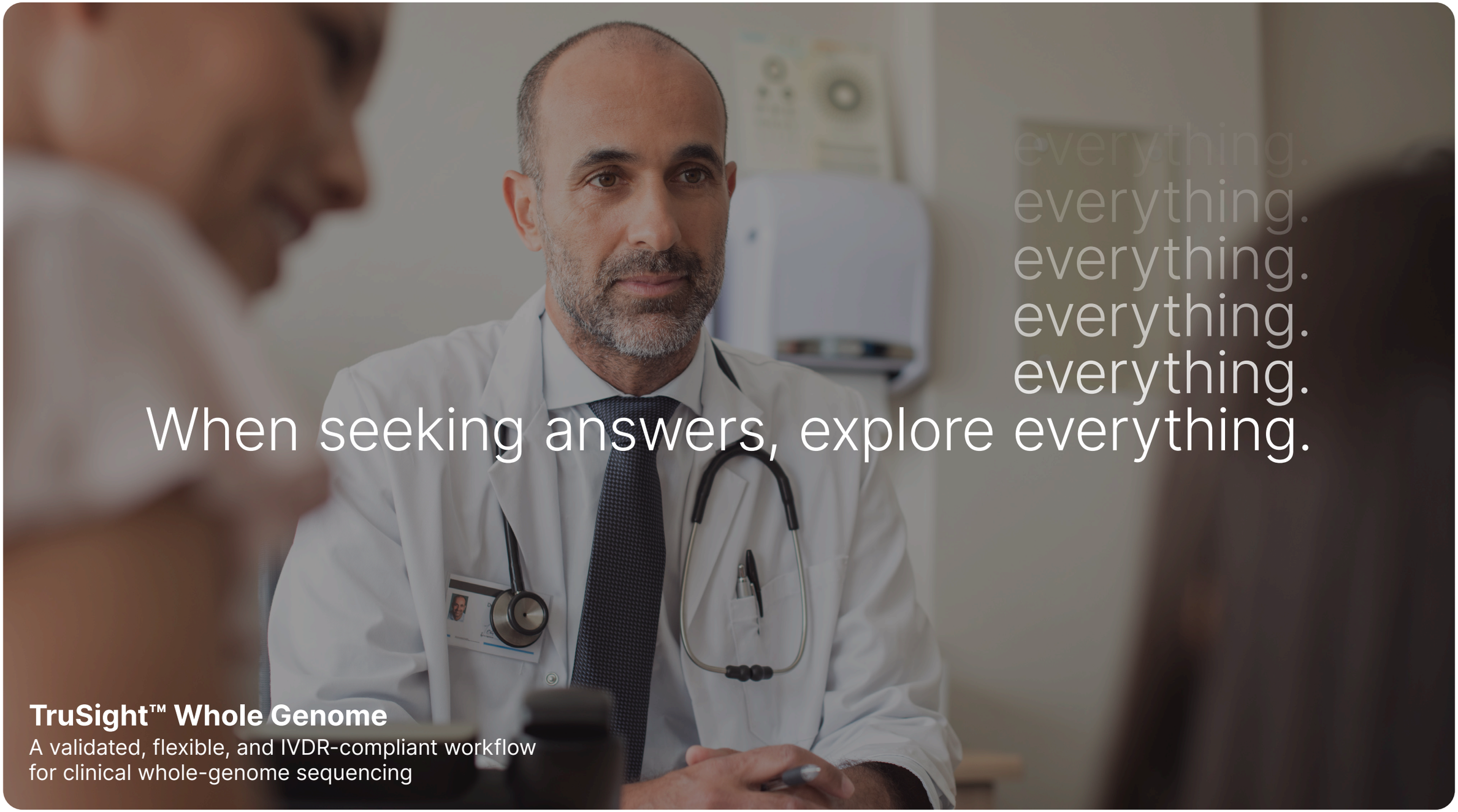

TruSight™ Whole Genome

A validated, flexible, and IVDR-compliant workflow
for clinical whole-genome sequencing

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Answers lie in the genome

Next-generation sequencing (NGS) methods are driving breakthroughs in clinical genetic testing, accelerating diagnoses. However, targeted approaches used in the clinic are limited in scope and may fail to provide much needed answers.

Whole-genome sequencing (WGS) is the solution, providing a comprehensive view of the human genome and empowering clinical laboratories to find the answers they're looking for to impact patient outcomes directly.

Illumina offers TruSight Whole Genome, a comprehensive, validated solution for clinical WGS that delivers highly accurate and precise germline variant calling for various downstream applications.

Learn more by reading the TruSight Whole Genome data sheet

Clinical WGS, more attainable than ever

Are you struggling to maintain targeted *in vitro* diagnostic (IVD) assays, which can become outdated as new discoveries are made? Does your lab want to transition to an IVD genomic assay, but is unsure how to navigate compliance with European Union (EU) *In Vitro* Diagnostic Regulation (IVDR)?

Illumina has gone through an extensive process to validate TruSight Whole Genome for use as a wet lab-to-secondary analysis solution that is compliant with EU IVDR.

Take advantage of internal controls, automated variant calling, and analytical validation studies. With TruSight Whole Genome the work has been done, so you can focus on providing answers.

Learn more by reading the Validating TruSight Whole Genome technical note

Plug into a fast and flexible workflow

TruSight Whole Genome features a comprehensive NGS workflow.

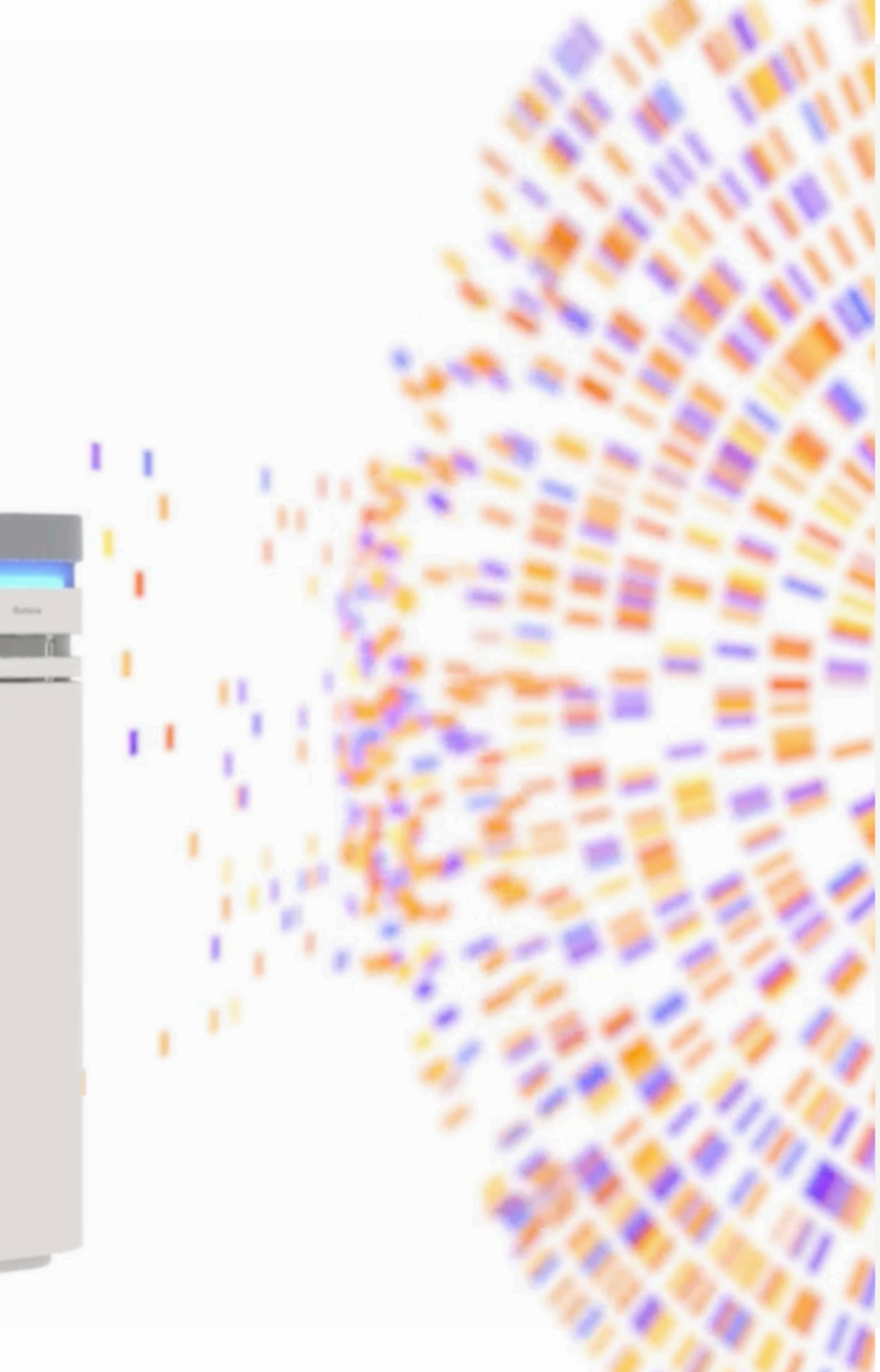
- Prepare up to 24 libraries in as little as 2.5 hours, with PCR-free chemistry to optimize coverage
- Sequence with proven sequencing by synthesis (SBS) chemistry on the the NovaSeq™ 6000Dx Instrument
- Analyze with DRAGEN™ software to output data with annotated variants, ready for interpretation

Prepare libraries > **Sequence** > **Analyze**

TruSight Whole Genome DX Library Prep

NovaSeq 6000Dx Instrument with S2 Dx (6 samples) or S4 Dx (16 samples) sequencing reagents

TruSight Whole Genome Analysis Application via paired DRAGEN server



TruSight Whole Genome at a glance

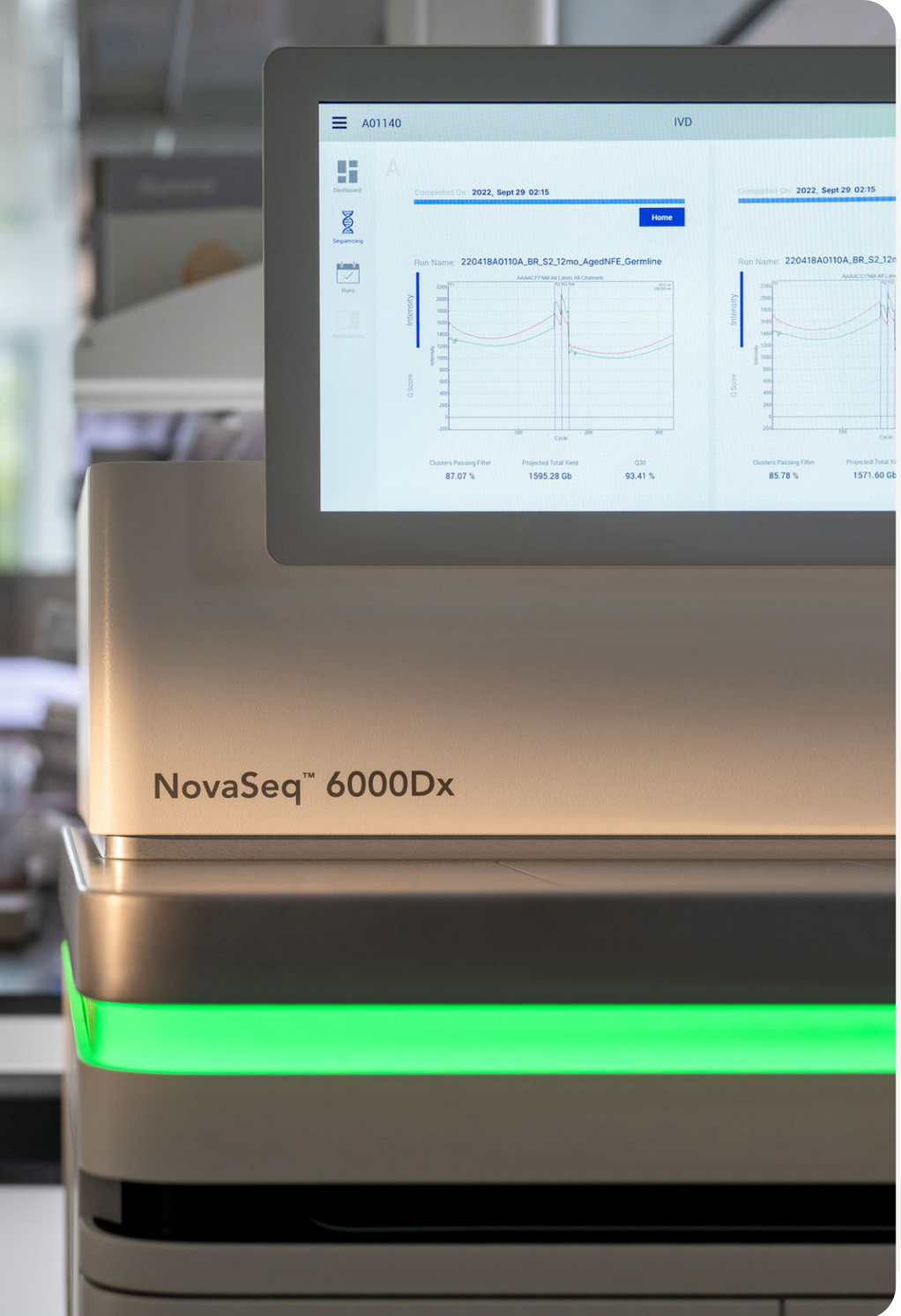
Feature	Description
Sequencing platform	NovaSeq 6000Dx Instrument
Sample type	gDNA extracted from whole blood
DNA input requirement	As little as 280 ng
Sample throughput[a]	6 samples per S2 Dx flow cell and 16 samples per S4 Dx flow cell
Total assay time	< 3 days
Library preparation time	~ 2.5-4 hrs
Sequencing run time	≤ 44 hrs
Sequencing cycles	2 × 150 bp

a. Dual flow cells can be run simultaneously to double throughput.

See the full picture of genomic variation

TruSight Whole Genome provides highly accurate sequence information and uniform coverage across the genome to enable a complete view of genomic variation, including detection of:

- Single nucleotide variants (SNVs)
- Insertions and deletions (indels)
- Copy number variants (CNVs)
- Runs of homozygosity (ROH)
- Short tandem repeat (STR) expansions
- Mitochondrial DNA (mtDNA) variants



Analysis made simple

Data analysis is performed automatically using the TruSight Whole Genome Analysis Application with the paired DRAGEN Server. The app delivers highly accurate variant calls in genome VCF (gVCF) files suitable for downstream germline applications.

Immense discovery power for the clinical lab

Sequencing with the NovaSeq 6000Dx Instrument delivers accurate, reliable screening and diagnostic testing. TruSight Whole Genome adds to a growing menu of Illumina and third-party clinical assays on this IVDR-compliant, high-throughput instrument of choice. Dual modes of operation enable labs to pursue clinical research applications on the same instrument, with no need for a system reboot.

Learn more: illumina.com/novaseq6000dx

Support that never stops

Illumina strives to be the best partner possible. With a global presence, you can rely on our support to facilitate your success. Technical support is available via phone five days a week or access online support 24/7, worldwide and in multiple languages, with rapid response time near most major metropolitan areas. Illumina provides excellent product consistency, supply, and quality enabled by mature global manufacturing infrastructure.

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Illumina training

Get high-quality results on Illumina technology even faster with instructor-led, hands-on courses and web-based training options at illumina.com/services/instrument-services-training/training.html

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Intended use statements

TruSight Whole Genome

TruSight Whole Genome is a qualitative *in vitro* diagnostic device intended for whole-genome sequencing and detection of copy number variants, single nucleotide variants, runs of homozygosity, insertion/deletions, short tandem repeat expansions, and mitochondrial variations in human genomic DNA extracted from blood.

TruSight Whole Genome includes the TruSight Whole Genome Dx Library Prep with UD Indexes and the TruSight Whole Genome Analysis Application Software. The device is intended to be used with compatible downstream germline applications to develop in vitro diagnostic assays, and by qualified laboratory personnel and assay developers.

TruSight Whole Genome is intended to be used on the NovaSeq 6000Dx Instrument.

NovaSeq 6000Dx Instrument intended use (European Union/other)

The NovaSeq 6000Dx Instrument is intended for sequencing of DNA libraries when used with *in vitro* diagnostic (IVD) assays. The NovaSeq 6000Dx Instrument is intended for use with specific registered, certified, or approved IVD reagents and analytical software.

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We are always available for questions, insights, and conversation.
Visit us at illumina.com.

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