NanoString® Technologies, Inc.

nCounter® Dx Analysis System

REV 2.0

For *in vitro* Diagnostic Use and Life Sciences Applications

Digital Molecular Profiling for Diagnostics *and* Translational Research

Molecules That Count®

Pathway-based Translational Research • Oncology Research • Molecular Diagnostics

nanoString TECHNOLOGIES®

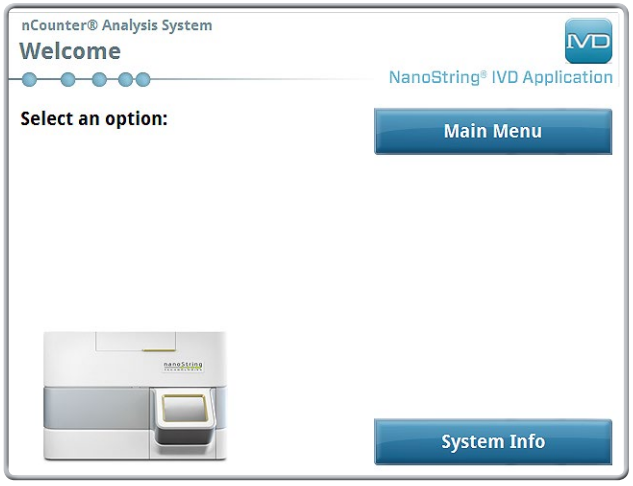
The nCounter® Dx Analysis System

for Molecular Diagnostics and Translational Research

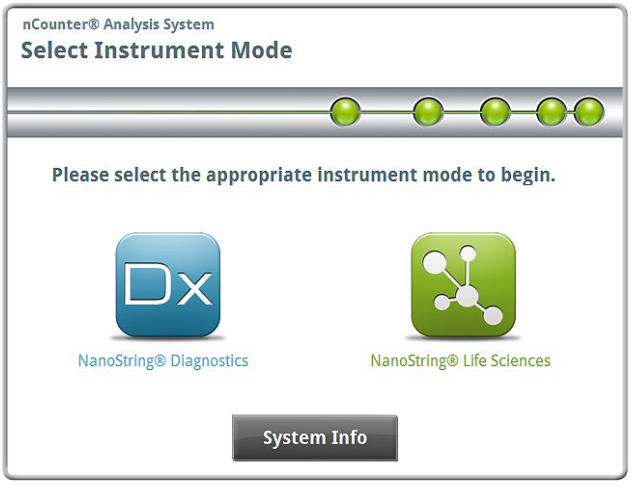
In a world rich with genomic information from projects such as the 1,000 Genomes Project and the Cancer Genome Atlas, many translational biomarkers and signatures have been identified that offer enormous potential to improve human health. The **nCounter® Dx Analysis System** is ideally suited for this dynamic environment by **providing a highly flexible solution for clinical laboratories**. Not only does the system **enable labs to implement the Prosigna™ Breast Cancer Prognostic Gene Signature Assay**, but it also **supports the translational research and pivotal performance studies that will lead to the diagnostics of the future.**

The nCounter Dx Analysis System is available in TWO configurations...

- **IVD** Configuration
  - Supports the Prosigna™ Breast Cancer Prognostic Gene Signature Assay



- **FLEX** Configuration
  - Supports the Prosigna™ Breast Cancer Prognostic Gene Signature Assay
  - Supports Life Science research applications [functions for which approval/clearance are not required]



FOR *in vitro* DIAGNOSTIC USE AND LIFE SCIENCES APPLICATIONS*

** nCounter Dx Analysis System with FLEX Configuration only*

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The nCounter Advantage

510(k) Cleared *for* Diagnostic Use *with* Prosigna	» **Prosigna Breast Cancer Prognostic Gene Signature Assay received 510(k) clearance** on September 6, 2013, for use with the nCounter Dx Analysis System
FLEX-ibility	» **FLEX Configuration enables both the Prosigna Breast Cancer Prognostic Gene Signature Assay** *and* **translational research and pivotal performance studies**
Future-proofed	» **Perform research and validation** on a platform **cleared for diagnostic use with the Prosigna Assay**
Easy-to-Use	» **Highly automated workflow requires minimal hands-on time** and supports high levels of reproducibility
Digital Detection	» **Direct digital counting technology** facilitates **high levels of precision, linearity, and reproducibility**
Cancer Research	» **Assay entire pathways or multiple pathways** in a single reaction
Rapid Results	» **RNA to results in less than 2 days** *with* **as little as 15 minutes of hands-on time**

NOTE: *Prosigna can be run in as few as 3 days when starting from FFPE sample.*

For more information about the nCounter Dx Analysis System, visit **www.nanostring.com/nCounterDx.**

Fully Automated, Multi-application System

Just **add sample** and **press start**.

nCounter® Prep Station

nCounter® Digital Analyzer

Simple, fast, and cost-effective quantification of 100s of targets in virtually any sample with the PUSH OF A BUTTON.

- **Delivers 10,000s of precise data points every day**

  Digital detection of target molecules and high levels of multiplexing means no compromise between data quality and data quantity.

- **Straightforward, high-quality data with rapid results**

  Data output files include the target identifier and count number along with a comprehensive set of internal controls that can enable each assay to be highly quantitative and reproducible.

- **Sample type flexibility and low sample input**

  Directly assay tissue extracts and whole-blood lysates, total RNA, cell lysates, and FFPE samples from as little as 100ng sample input

- **Ready-to-use reagents**

  No reagent preparation or dilutions required.

- **Intuitive, easy-to-use touchscreen user-interface**

  Fully automated, simple workflow with an easy-to-use touchscreen interface provides simple instructions for each step of the automated process.

- **Manufactured under GMP/ISO 13485**

  Ensures high-standard quality and compliance and conformity with international standards for diagnostic devices.

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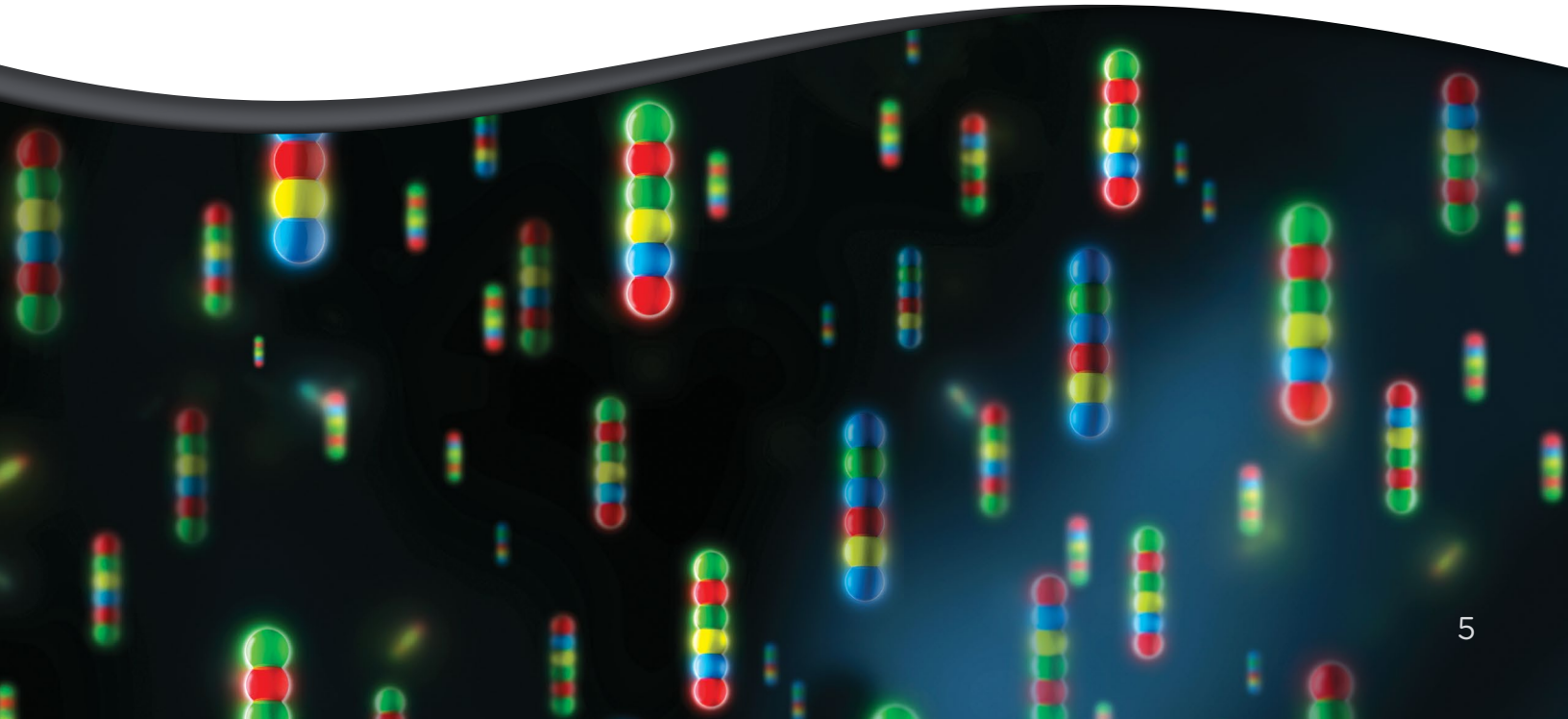
Simplified, User-friendly Workflow

	1	2	3
	Hybridization	**Sample Processing**	**Digital Data Acquisition**
Only **15 Minutes** of Total Hands-on Time			
Process	**Set Up Hybridization** Add buffer, CodeSet and sample into a strip tube and hybridize overnight.	**Set Up Prep Station** Place the strip tube onto the automated **nCounter® Prep Station** with reagents and consumables from the nCounter Master Kit.	**Set Up Digital Analyzer** Take the cartridge from the nCounter Prep Station and place it into the **nCounter® Digital Analyzer** for direct digital counting.
Hands-on Time	**5 minutes**	**5 minutes**	**5 minutes**
	Day 1	**Day 2** (automated)	**Day 2** (automated)

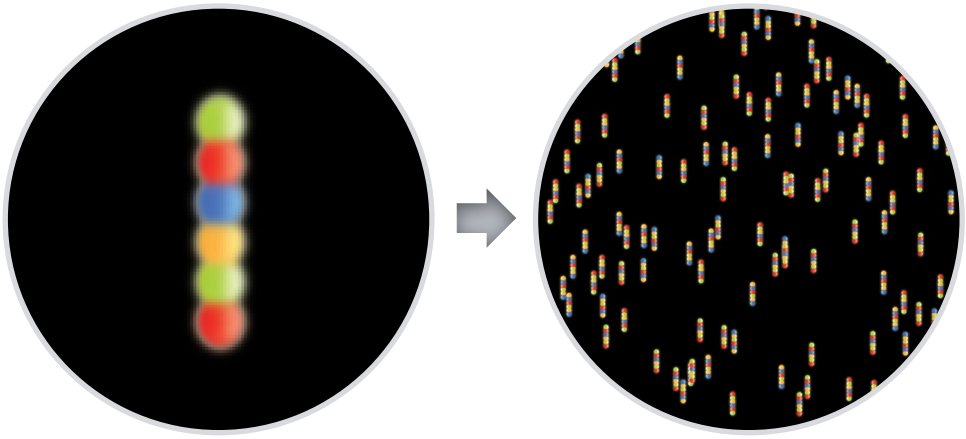


Innovation in Chemistry

NanoString's **patented technology** used in the nCounter Dx Analysis System is a **true digital detection technology** capable of **highly multiplexed, direct profiling of individual molecules in a single reaction without amplification*.**

Molecules That Count®

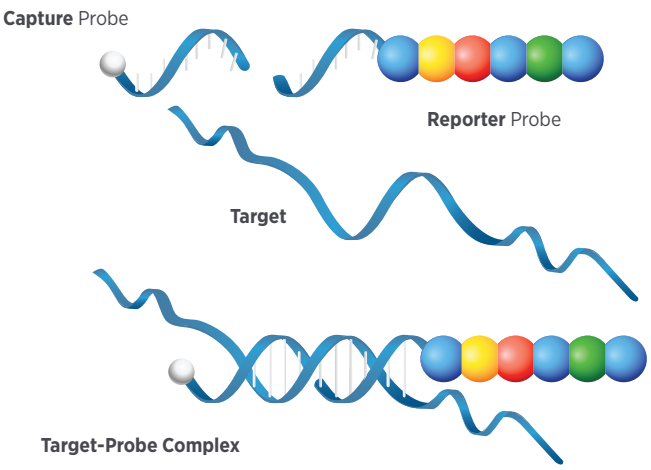
Each color-coded barcode represents a single target molecule. Barcodes hybridize directly to your target molecules and can be individually counted without the need for amplification* – **providing sensitive digital data.**

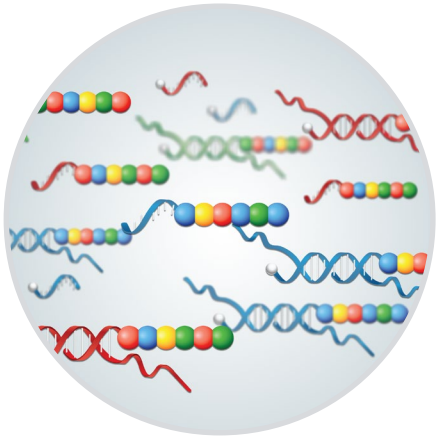


Single molecule barcodes, each attach to an individual nucleic acid.

1

HYBRIDIZE





solution phase hybridization

Hybridization

Barcoded probes hybridize directly to a target molecule in solution. The **Reporter Probe** carries the signal and the **Capture Probe** allows the complex to be immobilized for data collection.

** Single Cell life sciences assay requires amplification prior to analysis on the nCounter System.*

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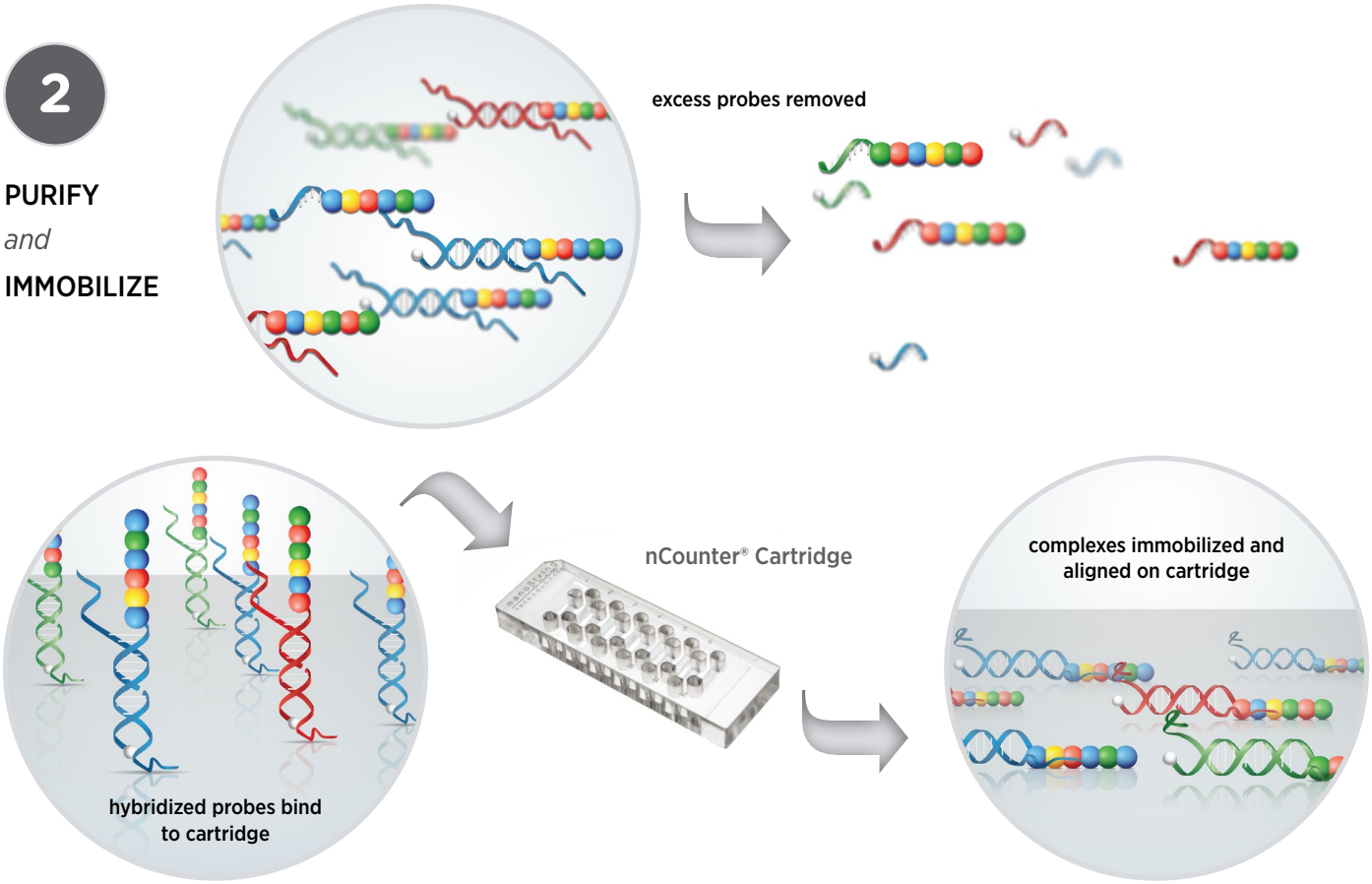
1 Molecule = 1 Count

2

PURIFY
and
IMMOBILIZE

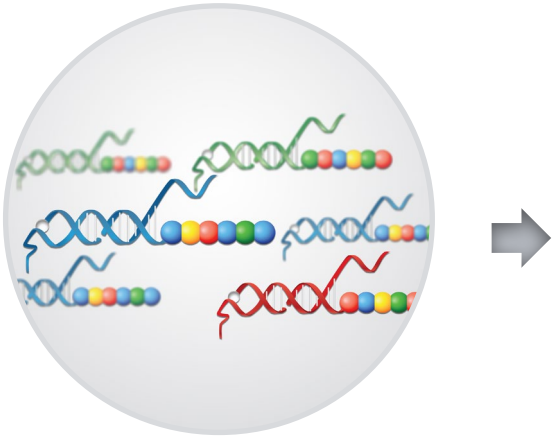


Sample Processing

After hybridization, samples are transferred to the nCounter Prep Station where excess probes are removed and probe/target complexes are bound, immobilized and aligned on the nCounter Cartridge.

3

COUNT



Barcode	Counts	Identity
	3	XLSA
	2	FOX5
	1	INSULIN

Digital Data Acquisition

Sample cartridges are placed in the nCounter Digital Analyzer for data collection. Barcodes are counted and tabulated for each target molecule.

Prosigna™ Breast Cancer Gene Signature Assay

A New Way of Looking at Breast Cancer Tumor Biology

The Prosigna Assay has received FDA 510(k) Clearance and CE mark and is available for use by healthcare professionals in the United States, European Union, other countries that recognize the CE Mark and in countries where Prosigna is registered. The Prosigna Assay is NanoString's first FDA-cleared *in vitro* diagnostic test and uses the gene expression profile of cells found in a patient's breast cancer tissue to assess their risk of distant recurrence. Prosigna leverages the precision, reproducibility and ease of use of the nCounter Dx Analysis System to deliver genomic testing capabilities to qualified local labs, thus empowering local pathologists. The nCounter® Dx Analysis System is the only platform 510(k) cleared to run the Prosigna Breast Cancer Gene Signature Assay, yet it is flexible enough to support a wide range of Life Science applications.

prosigna™
Breast cancer
gene signature assay

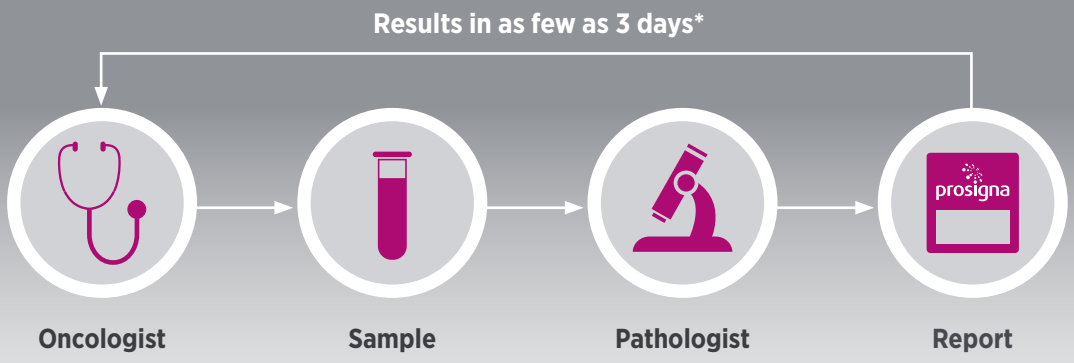
The PAM50-based breast cancer prognostic genomic signature – provides you with an individualized **Prosigna Score** for your patients with breast cancer.

Prosigna Features

- **Highly concordant results** across multiple sites, users, and lots
- Results can be obtained **in as few as 3 days***
- **Robust validation data sets** that include node-negative and node-positive patients
- Simple, efficient workflow **requires limited hands-on time**
- Decentralized model **brings the power of genomic testing to local pathologists**

Prosigna is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients.

Decentralized local lab model allows direct pathologist-to-oncologist communication



** Prosigna can be run in as few as 3 days when starting from FFPE sample.*

FOR *in vitro* DIAGNOSTIC USE

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nCounter® Translational Research Products

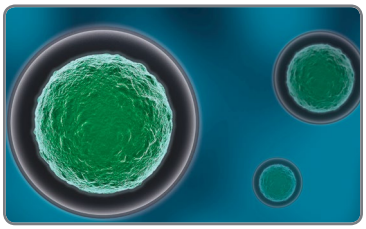
Digital Quantification of Nucleic Acids *for* Pathway-based Translational Research

NanoString offers a comprehensive portfolio of Life Science research products† which supports applications such as gene expression analysis, miRNA expression analysis and copy number variation analysis. The system can be used to digitally study pathway biology or to validate targets identified by next generation sequencing discovery experiments. Multiple pathways of up to 800 genes can be directly interrogated in a single tube experiment and the system is compatible with a range of challenging sample types including Formalin-Fixed Paraffin-Embedded (FFPE) tissue samples.

RNA Analysis

Gene Expression Analysis

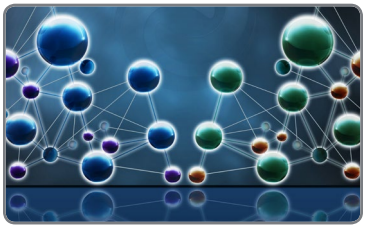
- Analyze up to 800 genes simultaneously
- No RT, no amplification*, no enzymes
- Directly assay tissue, cell and blood lysates, and FFPE extracts in a simple workflow



Single Cell Gene Expression Analysis

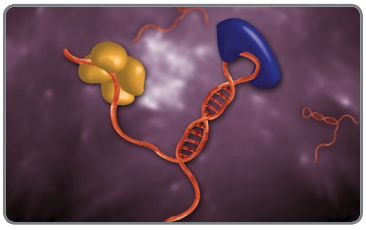
** Single Cell assay requires reverse transcription and amplification prior to analysis on the nCounter System.*

- Analyze multiple pathways for up to 800 genes
- Flexible format allows interrogation of exact gene number of interest
- Obtain single cell sensitivity while minimizing amplification



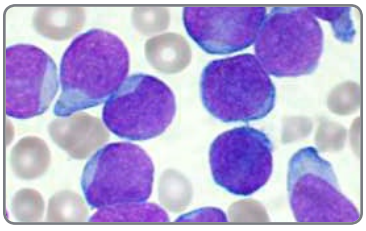
Plex²™ Expression Analysis

- Multiplex hundreds of targets and multiple samples in a single tube
- Customizable to study size
- Digital data in a high throughput format



lncRNA Expression Analysis

- High precision, digital quantification of lncRNAs
- Analyze up to 800 lncRNAs in a single reaction with no amplification
- Compatible with FFPE, crude cell lysates and other challenging sample types



Leukemia Fusion Gene Analysis

- Profile a comprehensive set of fusion genes in different leukemia subtypes
- Includes probes for 11 wild-type translocation partners and 12 leukemia-related biomarkers
- 15-minutes of hands-on time per run

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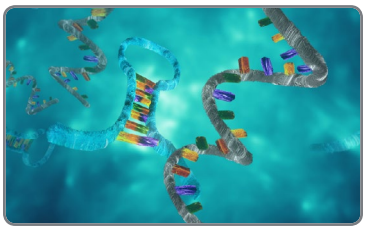
Not for use in diagnostic procedures.

High-precision, Digital Quantification *of* Nucleic Acids

miRNA Analysis

miRNA Expression Analysis

- Multiplexed target profiling of miRNA transcriptomes in a single reaction
- miRNA discovery and validation on one platform
- High specificity - accurately distinguish between highly similar miRNAs



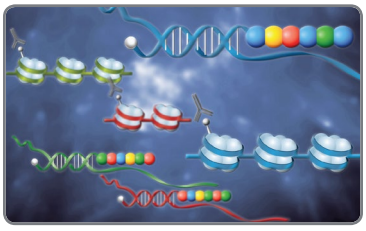
miRGE™ Expression Analysis

- Simultaneously profile miRNA and mRNA expression in a single reaction
- No RT, no amplification, fewer pipetting steps
- Profile FFPE samples and other difficult sample types

DNA Analysis

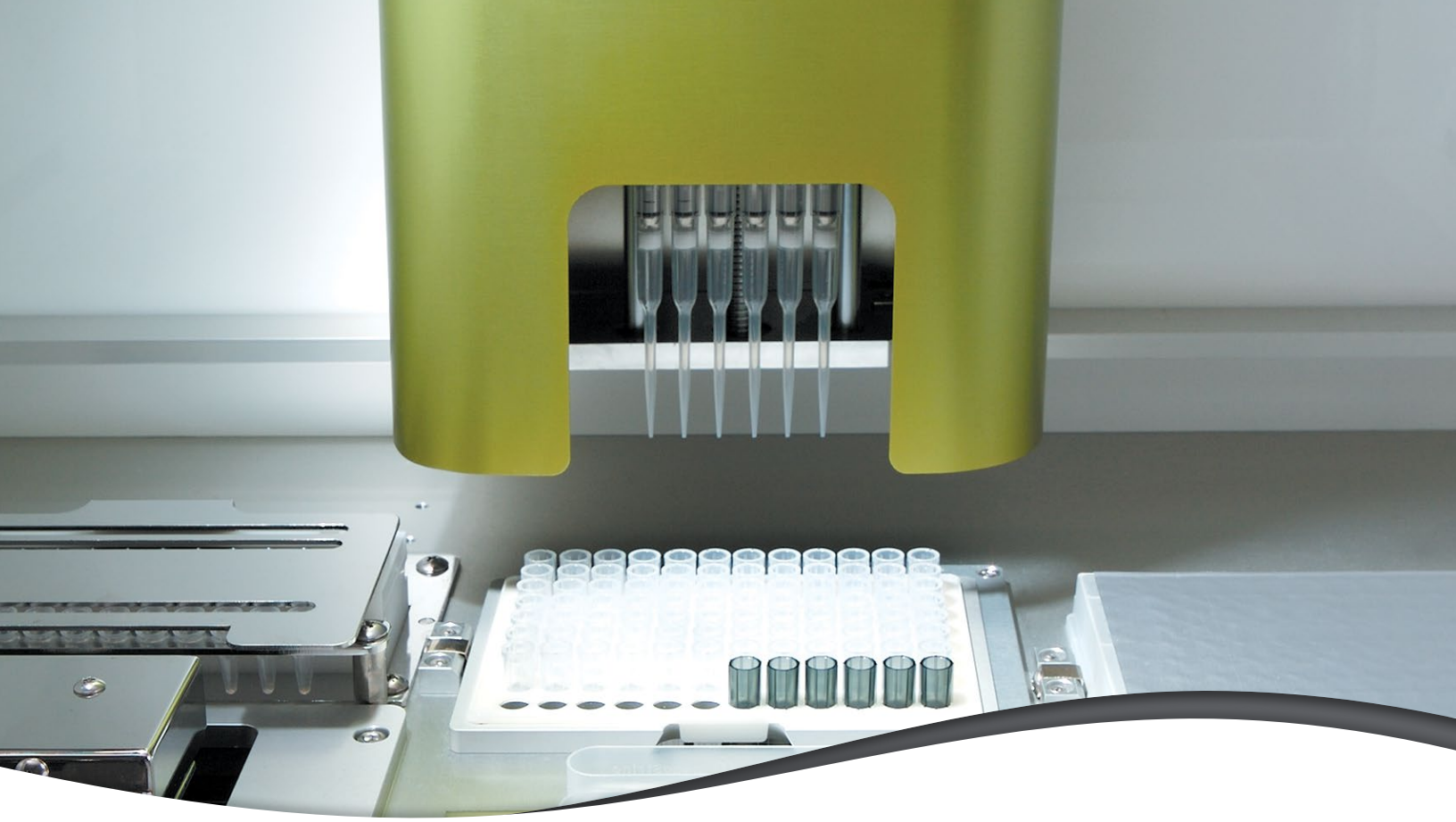
Copy Number Variation Analysis

- Multiplex up to 800 target regions in a single reaction
- Just 25-minutes of hands-on time per 12 samples
- High accuracy for multiallelic CNVs



ChIP-String Expression Analysis

- Analyze up to 800 loci with 15-minutes of total hands-on time
- Excellent correlation with ChIP-Seq results
- No library prep or amplification required



Ordering Information

	Product Description	Unit(s)	Catalog Number
SYSTEM	**nCounter Dx Analysis System (US)** Includes both Prep Station and Digital Analyzer.	System	NCT-SYST-DX-US
SYSTEM	**nCounter Dx Analysis System (EU)** Includes both Prep Station and Digital Analyzer.	System	NCT-SYST-DX-EU

nCounter® Dx Prep Station

nCounter® Dx Digital Analyzer

CONTACT INFO

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