nCounter™ Customer Assay Evaluation Kit

Package insert for the nCounter™ Customer Assay Evaluation Kit

Product Description

The nCounter™ Customer Assay Evaluation Kit is designed to provide fast and easy access to our technology. The nCounter Customer Assay Evaluation Kit components consist of the probes or CodeSet and all the reagents and consumables needed to run the assay. The CodeSet targets 48 genes included in the Microarray Quality Control study (MAQC). Each of the sequences is targeted by two different probes, the Reporter and the Captures probes.

Reference Documents

- *nCounter™ Gene Expression Assay Manual - Total RNA and Cell Lysate Protocols*
- *nCounter™ CodeSet Design Manual*
- *nCounter™ Analysis System Brochure*
- *nCounter™ Prep Station User Manual*
- *nCounter™ Digital Analyzer User Manual*
- *nCounter™ Data Analysis Guidelines for Gene Expression*

nCounter™ Customer Assay Evaluation CodeSet

Component	Volume per Tube	Assays per Tube
Reporter ProbeSet (48 genes and controls)	130 µL	12
Capture ProbeSet	70 µL	12

Storage Conditions: Up to 6 months at –80°C.

The nCounter CodeSet kit also includes a USB drive that contains:

- Three read-only folders for Cartridge Definition files (CDFData), Reporter Library files (RLFData), and Reporter Code Count files (RCCData)
- A CDF template
- A PDF copy of the *nCounter™ Gene Expression Assay Manual - Total RNA and Cell Lysate Protocols*, the *nCounter™ Prep Station User Manual,* the *nCounter™ Digital Analyzer User Manual,* an RCC collector tool, *nCounter™ Data Analysis Guidelines for Gene Expression* and this product insert.
- Material Safety Data Sheet(s)

Testing and Quality Control

All nCounter CodeSets are functionally tested.

Specifications

Level of Multiplexing	48 Gene Targets per Assay
Recommended Amount of Starting Material	100ng of total RNA, or lysate from ~10,000 cells
Sample Types Supported	Total RNA, Cell Lysates in GITC, FFPE derived total RNA and PAXgene lysed whole blood
Reaction Volume	30 µL
Limit of Detection	0.5fM spike-in control (~1 copy per cell); 90% of the time
Fold Change Sensitivity	>1.5 fold (>5 copies per cell) >2 fold change (>1 copy per cell)
Hybridization Spike Correlation	$R^2 \geq 0.95$
Linear Dynamic Range	7 X 10^5 Total Counts
nCounter Prep Station Throughput	12 samples <2.5 hours
nCounter Digital Analyzer Throughput	12 samples/4 hours (up to 72 samples per day unattended running in continuous mode)
Controls	6 Positive Controls 8 Negative Controls

nCounter™ Master Kit Components

All reagents and consumables required to process nCounter Gene Expression Assays are supplied in the nCounter Master Kit. Kits for 12, 24, 48 assays are available. Orders for 96 Assays will be shipped to 48 assay Master Kits. Master Kit components include:

- nCounter Cartridges
- nCounter Prep Plates
- nCounter Prep Packs

The nCounter Master Kit components are shipped in separate boxes under different shipping conditions[1].

nCounter™ Cartridge

Twelve samples can be processed in a single nCounter Cartridge.

Component	Assay Pack	Cartridges per Pack
nCounter Cartridge	12	1
	24	2
	48	4

Storage Conditions: Store for up to 6 months at –20°C.

nCounter™ Prep Plates

The Prep Plates are foil sealed 96-well plates that are used by the Prep Station. Do not remove the foil seals.

Component	Assay Pack	Plates per Pack
Contains wash buffers, magnetic beads, immobilization, and imaging reagents.	12	4
	24	4
	48	8

Storage Conditions: Store for up to 6 months at 4°C.

1 Individual components may be purchased separately if required.

nCounter™ Prep Pack

Component	Assay Pack	Units per Pack
Racked Tips & Foil Piercers	12	2 racks
	24	2 racks
	48	4 racks
12-Tube Strips	12	4 strips
	24	8 strips
	48	14 strips
Tip Sheaths	12	2 sheaths
	24	4 sheaths
	48	8 sheaths
12-Strip Tube Caps	12	4 strips
	24	8 strips
	48	14 strips
Cartridge Well Seals	12	2 seals
	24	3 seals
	48	6 seals
Hybridization Buffer*	12	1 tubes
	24	1 tubes
	48	2 tubes

** If Hybridization buffer has been stored in cold conditions and precipitate is observed, warm tubes at 37°C until salts have dissolved.*

Storage Conditions: Store at room temperature. No expiration date.

Safety Information

Material Safety Data Sheets are included on the USB drive packaged with the nCounter CodeSets. Safety information for operation of the nCounter System is included in the *nCounter™ Prep Station User Manual* and the *nCounter™ Digital Analyzer User Manual*.

Precautions

1. The NanoString nCounter System and Consumables are for Research Use Only; not for Diagnostic Procedures.
2. Avoid microbial contamination, which may negatively affect the quality of the results.
3. All biological specimens and materials should be handled as if the potential exists of transmitting infectious agents and disposed of with proper precautions in accordance with federal, state and local regulations. This includes adherence to the OSHA Blood Bourne Pathogens Standard (29 CFR 1910.1030) for samples derived from blood and other sources governed by this act.
4. Never pipet by mouth.
5. Avoid specimen contact with skin and mucous membrane and always wear gloves.
6. Exercise caution when handling and disposing of carcinogenic reagents.
7. Avoid cross-contamination of samples which may negatively affect results quality.

Contact Information

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