

Countable Labs.

A new benchmark for
sensitivity in genomics.

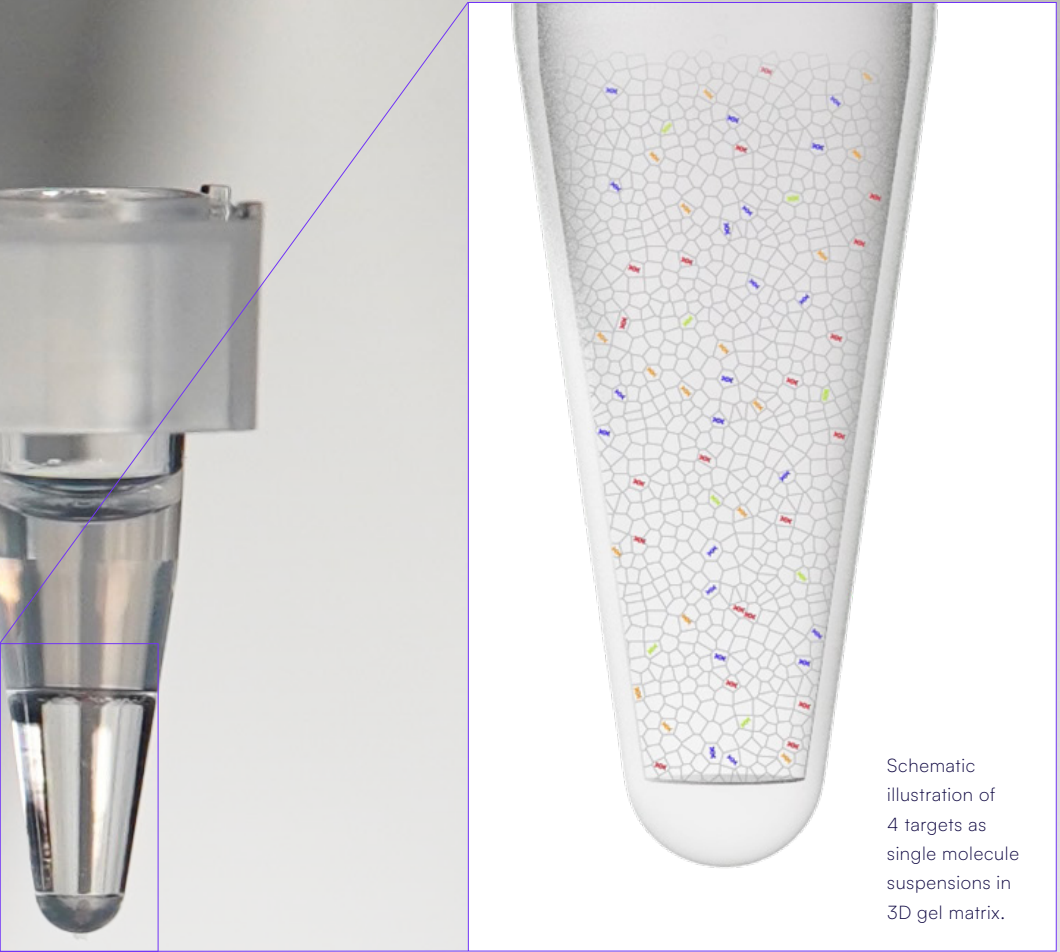
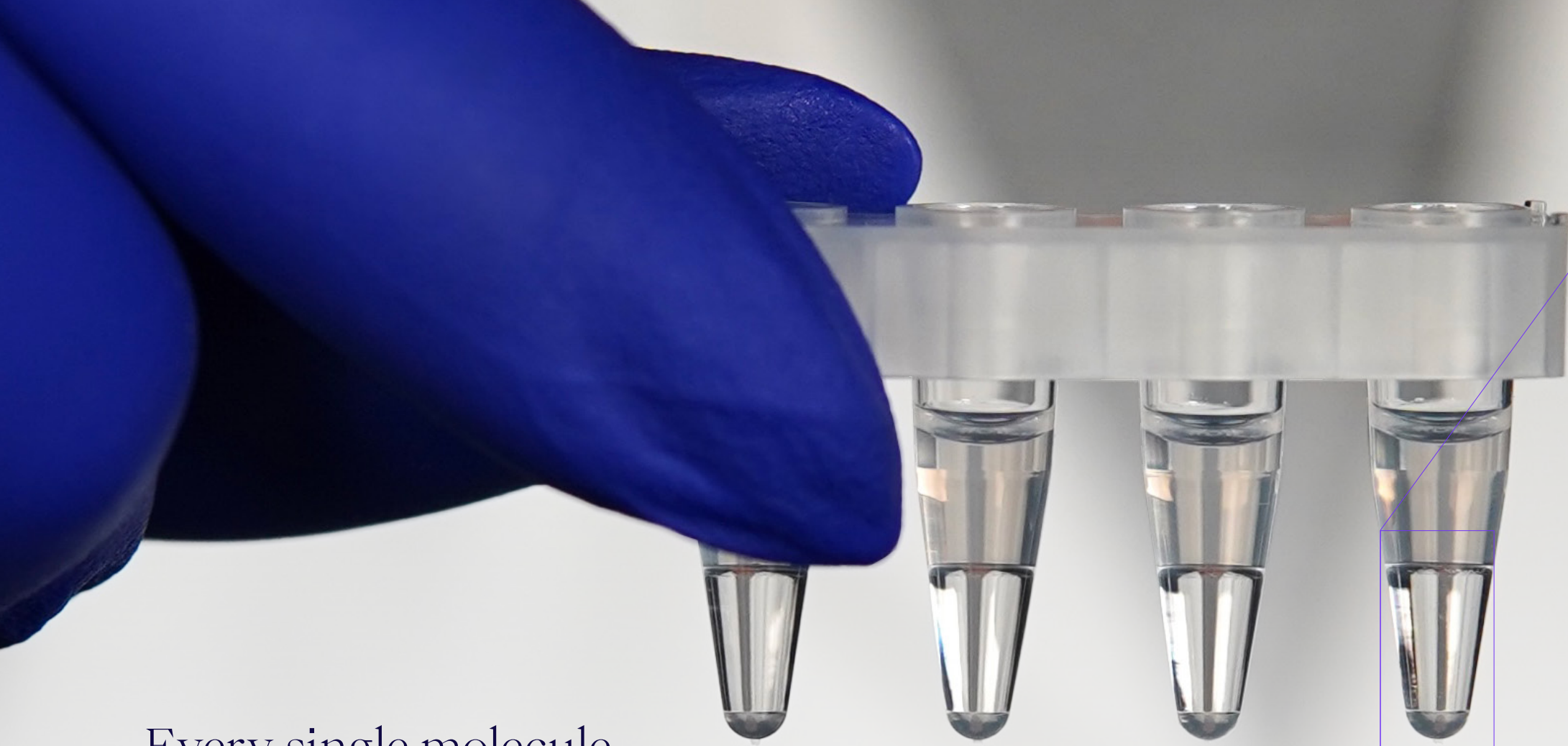
Meet Countable PCR. Built to reveal rare signals.



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countablelabs.com



Schematic illustration of 4 targets as single molecule suspensions in 3D gel matrix.

Every single molecule is now Countable.

Countable PCR is built on single-molecule resolution — every DNA molecule is physically separated into its own compartment and amplified without interference. This removes the bias and signal noise of traditional PCR, delivering rare-event sensitivity, clean multiplexing, and data that remains precise across every run.

■ **No sample loss.**

Analyze the entire sample, from trace input volumes up to one million target molecules, so even the rarest signals are detected with confidence.

■ **30 million compartments per reaction.**

Detect with higher sensitivity when you measure low and high expressing targets in the same reaction.

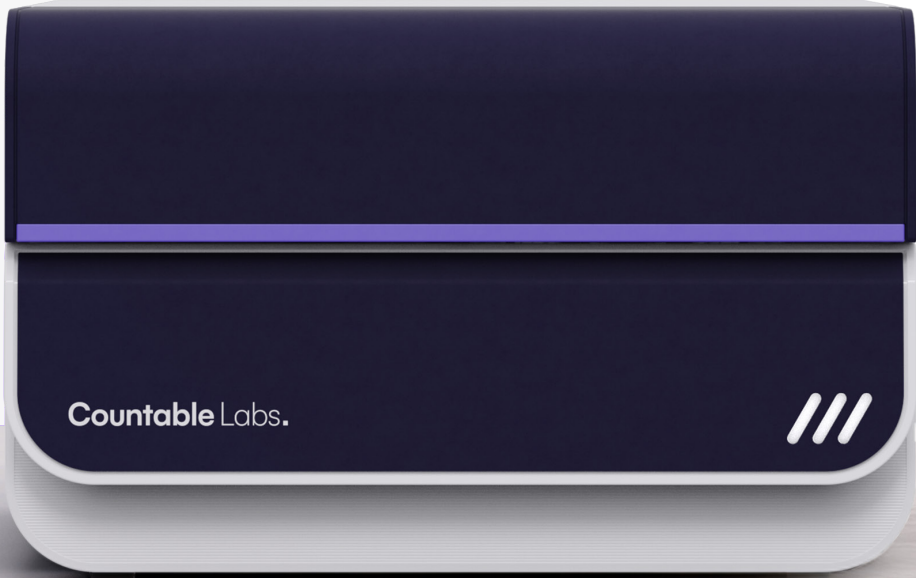
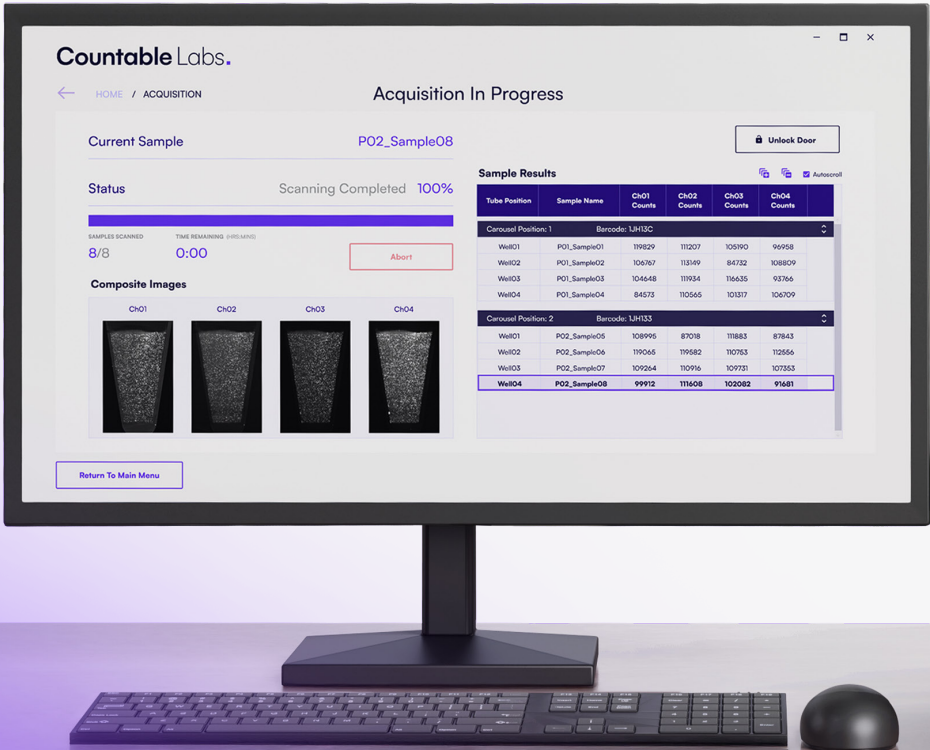
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The performance is Countable.

- 30 in 1,000,000
targets detected
- 6-log
dynamic range
- <1%
CVs
- 0%
dead volume
- 1-35 μ L
input range
- Up to 1,000,000
targets counted per reaction

Designed not just for precision,
but also for flexibility in assay
development.

- Up to 10 colors
- No PCR bias
- Up to 5 kb amplicons

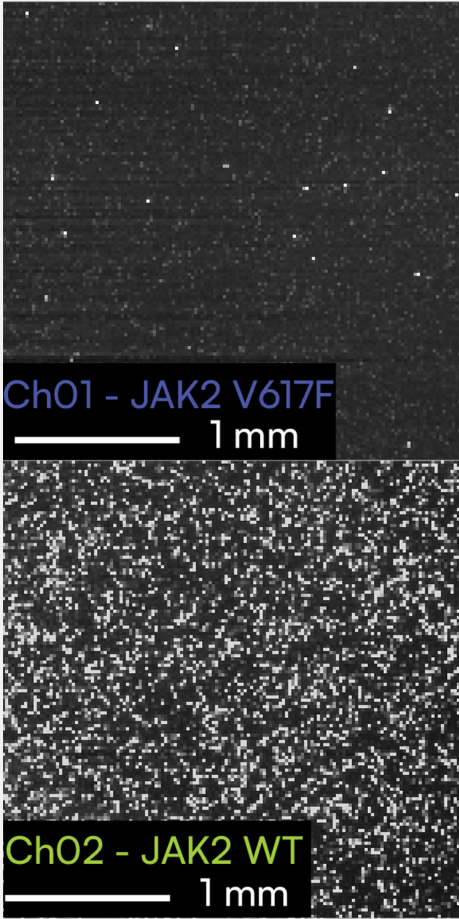
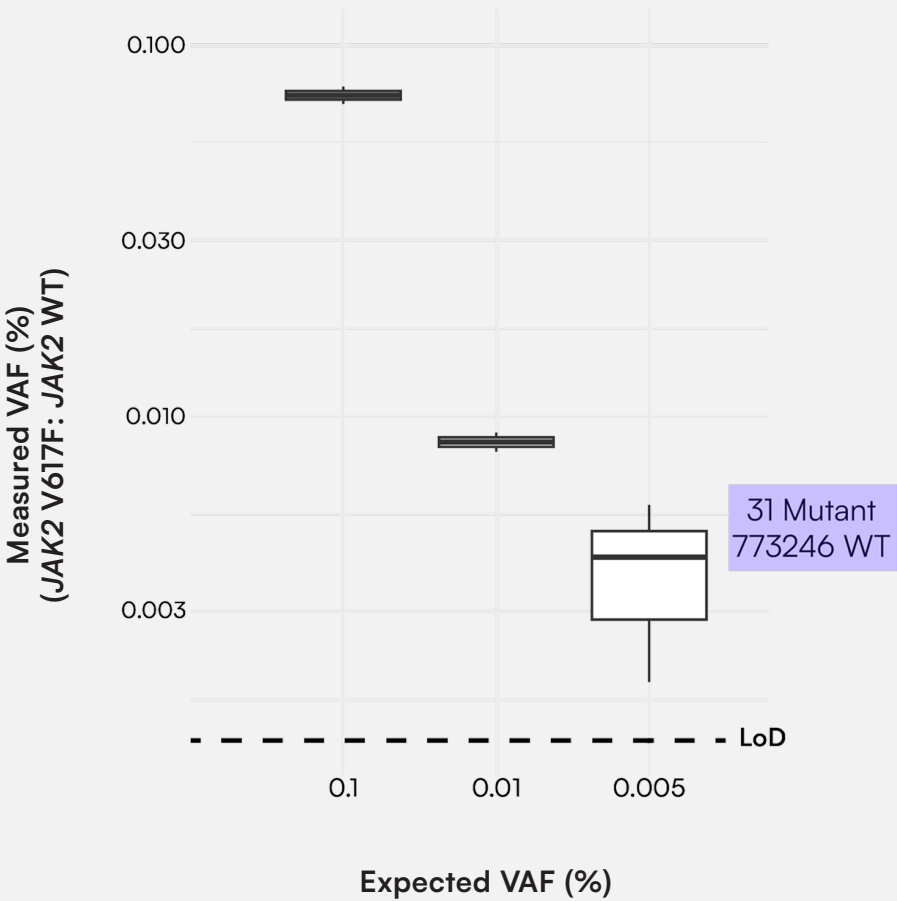


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Experience sensitivity like never before.

Push variant detection to as low as 0.004% VAF.

With over 30 million compartments, no sample loss, and high input range, you'll push the limits of detection beyond what you've dreamed possible.



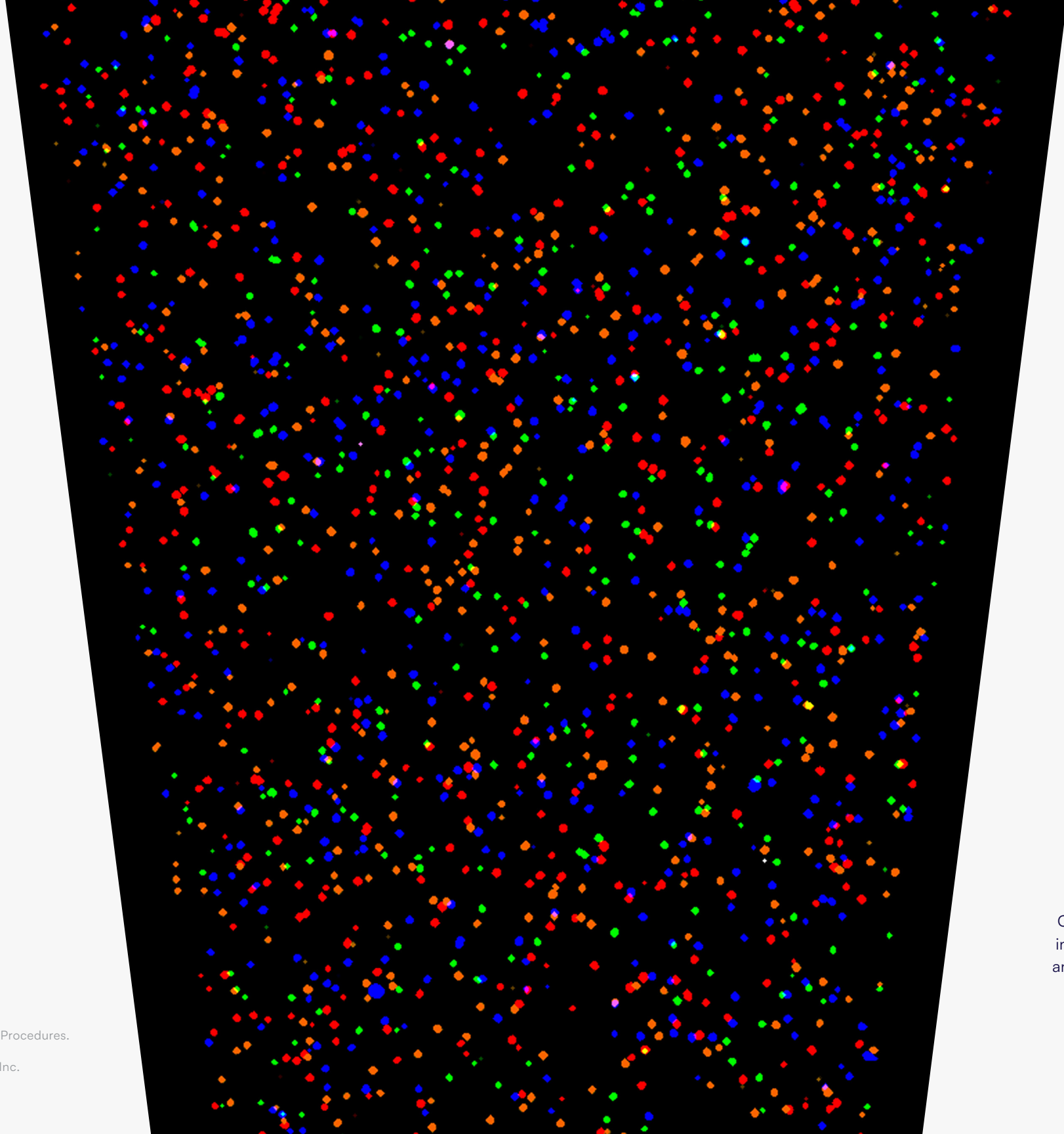
Here, 1 μ g DNA was loaded into a single Countable PCR reaction tube at decreasing presence of JAK2 V617F. Countable PCR enabled detection of mutant and WT JAK2 in parallel, counting 31 in over 700,000 molecules — all in the same reaction.



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A new way to do PCR.

No PCR bias.

Partition single molecules across 30 million picoliter-sized compartments in a PCR tube with only a simple centrifugation step. Amplify each molecule separately for precise and highly accurate results.

Multiplex instantly.

Avoid weeks of optimization and the expense of custom probes. Easily run 4-plex and 10-plex experiments that work the first time with our Universal Multiplexing.

Absolute counting.

Analyze data in minutes, automatically, with direct counts and objective quality control scores for better QC. Enjoy greater confidence with no Ct thresholding or Poisson statistics and with software built to support GMP environments.

Clearly distinguish each fluorophore with laser-based lightsheet detection in the Countable System. Capture clean, high-resolution signal from each and every target molecule.

Open up new opportunities for clinical assays.



With ~30 million compartments, the Countable PCR platform provides significantly higher sensitivity with fewer reactions in our oncology assays and opens new opportunities in the fields of NIPT and infectious disease. The workflow is easy, with potential for automation, and delivers highly precise results.

Tricia Zwiefelhofer
Director of R&D, **LabCorp**





Scale as you need — from 4 colors to 10 — and get sensitivity no matter what.

Countable PCR is built for both sensitivity and flexibility.

Analyze a single experiment or a full 96-reaction run without compromising data quality — no batching required and no wasted runs. Every reaction processes 100% of the sample, ensuring you never miss rare targets.

Start with 4 colors and upgrade to 10 as projects grow. Unlock richer panels and more answers per assay, all with the same instrument.

Key features for every Countable PCR bundle.

Analyze 100% of your reaction.

Catch every molecule in your sample.

Measure across a 6-log dynamic range.

Combine high- and low- expressors in the same reaction.

Rapidly develop multiplex assays.

Get accurate, precise data for multiple markers, from 1 to 1,000,000 molecules.

Automatic data output with built-in sample barcode tracking and QC metrics.

Feel confident in the quality of your results.

Prepare up to 96 samples per run.

Collect sample information with barcoded PCR tubes for tracking.

Support 21 CFR Part 11 compliance.

Aid your GMP manufacturing with software designed for regulatory environments.

System options

Countable

Detect up to 4 colors

Countable 10*

Detect up to 10 colors

Upgradable from Countable

Upgrade at any time

Countable 10 upgrade module

Start with what you need and scale as you grow. Every Countable instrument is upgradable to a 10-color system at any time.

* Product coming soon. [Contact for early access.](#)

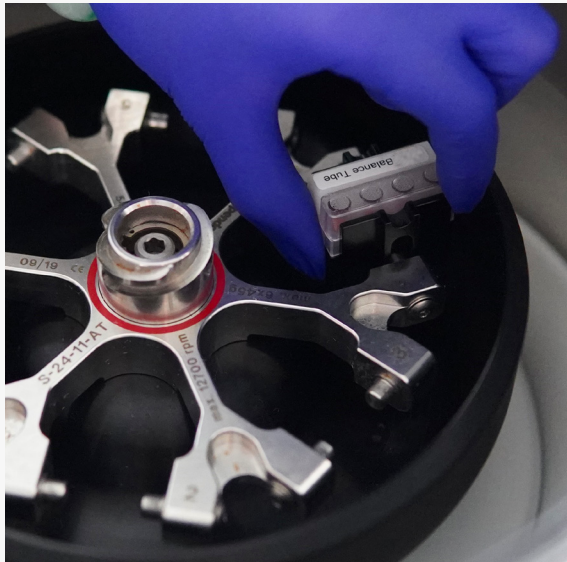
A workflow simple enough to be adopted by any lab.

The entire process — from setup to counting — occurs in a single tube, to minimize contamination and prevent sample loss. Barcode tracking and a straightforward workflow make the system easy to adopt in any laboratory.



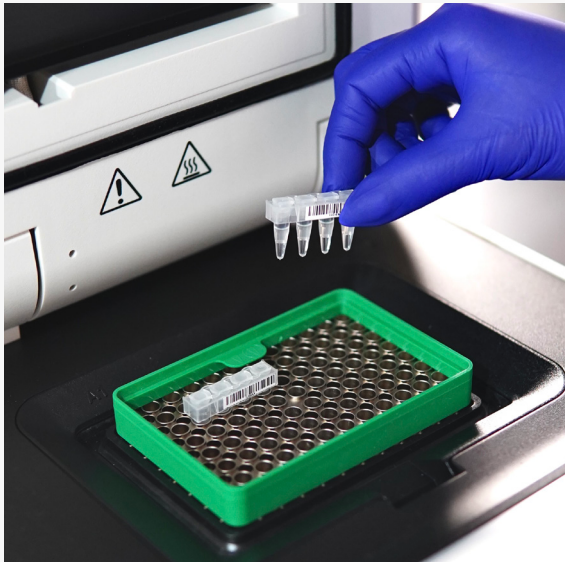
01.
Setup

Prepare PCR amplification reaction.



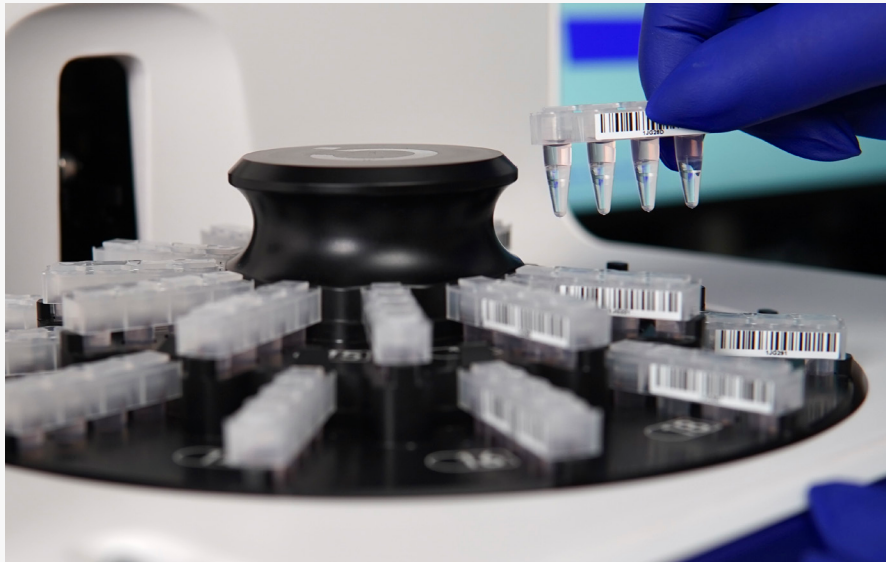
02.
Generate compartments

Load PCR reaction into spin column and centrifuge to generate compartments.



03.
Amplify

Use a standard thermocycler to amplify single molecules within compartments.



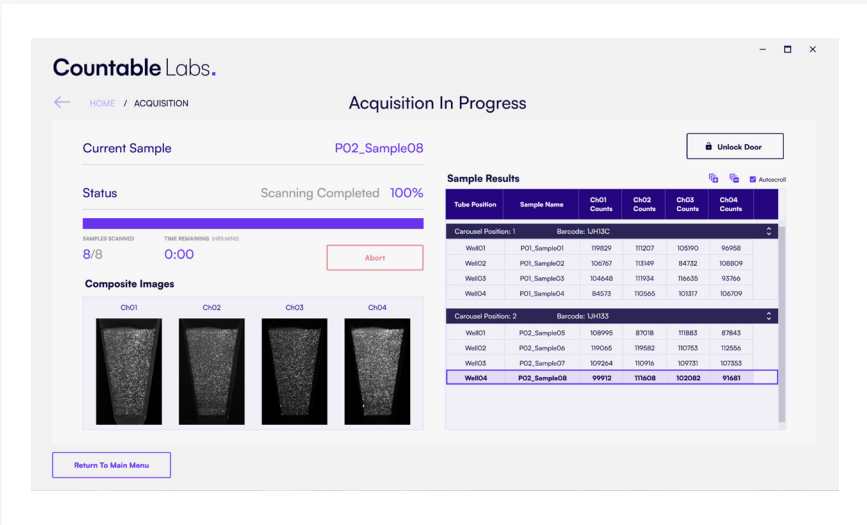
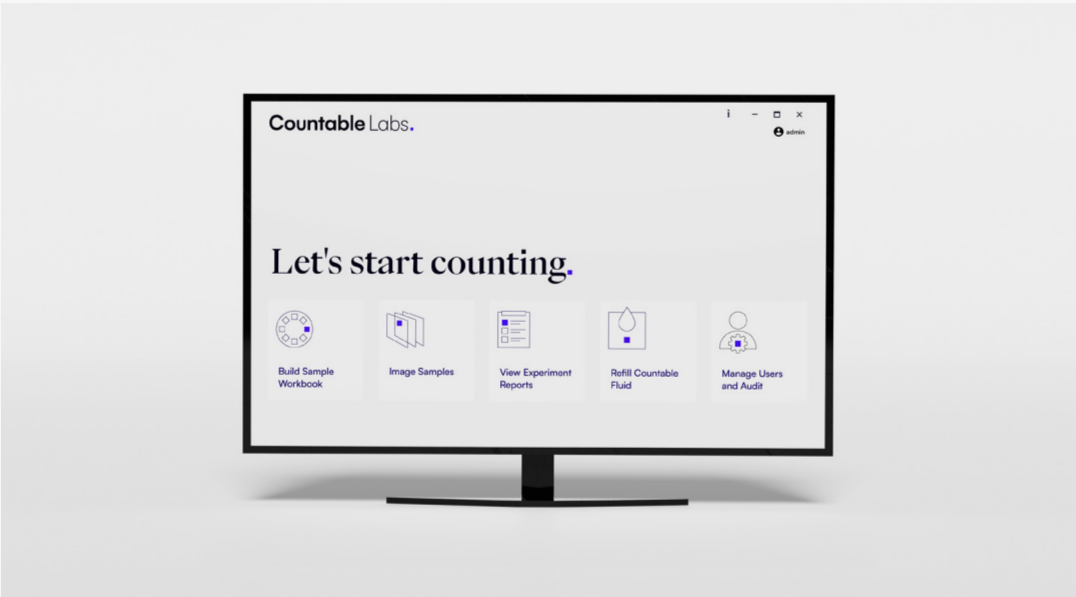
04.
Count

Count single molecules using the Countable system.

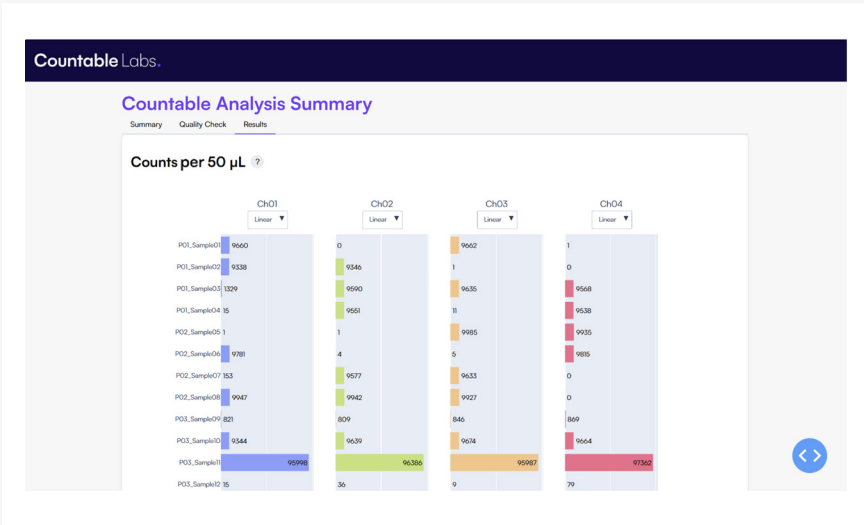
Meet a user-friendly workflow built for GMP.

Intuitive software with a straightforward user interface makes getting direct counts of your targets easy.

Built with regulated environments in mind, Countable PCR combines contamination-free workflows with end-to-end barcode tracking, automated QC, and 21 CFR Part 11 compliance support. Get the objectivity and reproducibility you expect for high-quality results.



Monitor data acquisition in real time.



Get direct, automated counts, ready to use immediately, with no thresholding or bioinformatics.



Receive objective, automated QC on every amplification event via Sample ID score.

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Countable Labs.

System Initialization

← HOME / ACQUISITION

1 Unlocked Door



Initializing Hardware



The door is unlocked! Please lock by raising the door lid and then firmly closing.

Select Sample Workflow

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Implement high-sensitivity PCR detection — for every application.

Implement Countable PCR for diverse applications. Experience sensitive and precise quantification that supports your research in oncology, cell and gene therapy, and beyond.

Therapeutic QC

- Multiplexed viral titer and genome integrity
- Vector copy number
- Gene editing efficiency
- Biodistribution studies
- Contamination detection

Rare Event Detection

- Minimal residual disease tracking
- Low frequency variants (SNP, indel, CNV)
- Rare isoform
- Somatic mutation
- Rare pathogens

Orthogonal Validation

- Gene expression
- Splice isoform profiling
- Variant/mutant allele frequency quantification
- Structural or copy number variation
- Quantify unconventional DNA/RNA

Compatible Sample Types

Cell free DNA	Tissue DNA	FFPE DNA	RNA	cDNA	Plasmids	Nucleosomal DNA
Genomic DNA, digested	Genomic DNA, undigested	Genomic DNA, sheered	Crude cell lysate	Virus with capsids	Viral DNA	Viral RNA



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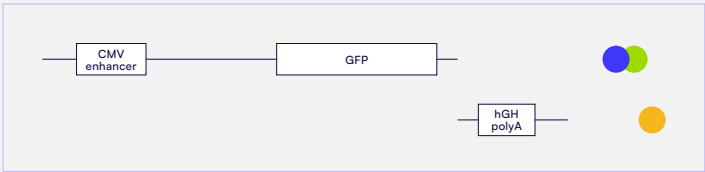
Make linkage analysis easy with single-molecule isolation.

30 million compartments and targets locked spatially in a gel matrix give you the most accurate linkage analysis yet. Investigate vector genome integrity, probe linked targets, and probe isoform splicing.

Quantitate DNA linkage.

Here, mixtures of either full-length or partial viral vector genomes were mixed, amplified, and counted via Countable PCR. Since targets are physically separated in space, automatic analysis enables direct and precise identification of co-occupied (linked) targets.

Partial Viral Genome Examples



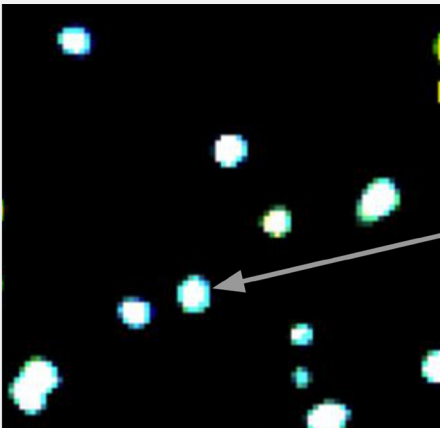
Full-Length Viral Genome



A.

“Complete” proxy sample

Representative lightsheet



Single molecule signals

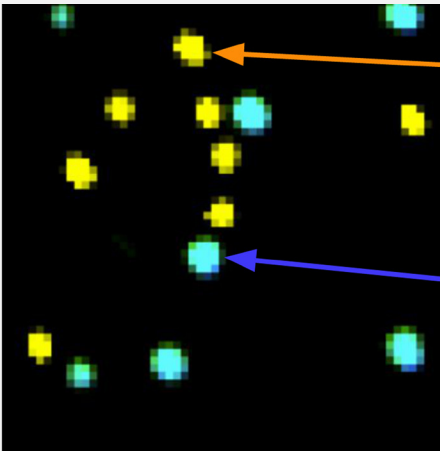


Complete genome

B.

“Partial” proxy sample

Representative lightsheet



polyA partial



CMV enhancer + GFP partial

A platform built for reliable performance.

Countable PCR includes design tools, Universal Multiplexing, reagents and consumables, and the Countable System with automated software for direct target counting.

Easily go from DNA sample to target counts with bias-free amplification and highly reproducible results.



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Countable PCR specifications at a glance.

Performance

Total detectable dynamic range	6 logs (1 to 1,000,000 molecules)
Limit of detection (LoD)	As low as 0.004% MAF*
Reproducibility (%CV)	<1% across replicates
Channels available for detection	4 and 10 (coming soon)

Sample Processing

Partitioning method	Centrifugation into gel matrix
Number of compartments	Approximately 30 million per reaction (tube)
Reaction volume (per tube)	50 µL up to 35 µL input DNA
Sample loss / dead volume	0%
Fluorescent chemistry supported	Universal Multiplexing, TaqMan, or combined
Fluorophores	Up to 4 channels per reaction Ch01 - FAM, Alexa488, Atto488 Ch02 - HEX, VIC, Atto532 Ch03 - TEX615, Atto590 Ch04 - Cy5, Atto647N

Data Processing

Detection method	Laser lightsheet 3D imaging
Throughput	96 reactions per run
Scan time	40 seconds per reaction
Result output	40 seconds per fluorophore
Time to results	~5 hours for 4 channels x 96 reactions, shorter if fewer channels and sample number
Data analysis	Direct counting, fully automated
Data output	CSV, HTML reports + ID score for per-channel QC
21 CFR Part 11 support	Included in software

To learn more about Countable PCR,
visit us at countablelabs.com.

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Have questions? We're here to help.
Email us at hello@countablelabs.com.