Biotechnology Update

Dr. Kathryn Beers
Director, Material Measurement Laboratory

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

June 17, 2026

Emerging Technology Strategic Priorities

To ensure U.S. global dominance in the industries of the future, we need to act now to advance the President's stated agenda to secure the U.S. position as the unrivaled world leader in critical and emerging technologies (CETs)

Over the next four years, NIST is committed to advancing American innovation and industrial competitiveness through four interdependent strategic priorities:

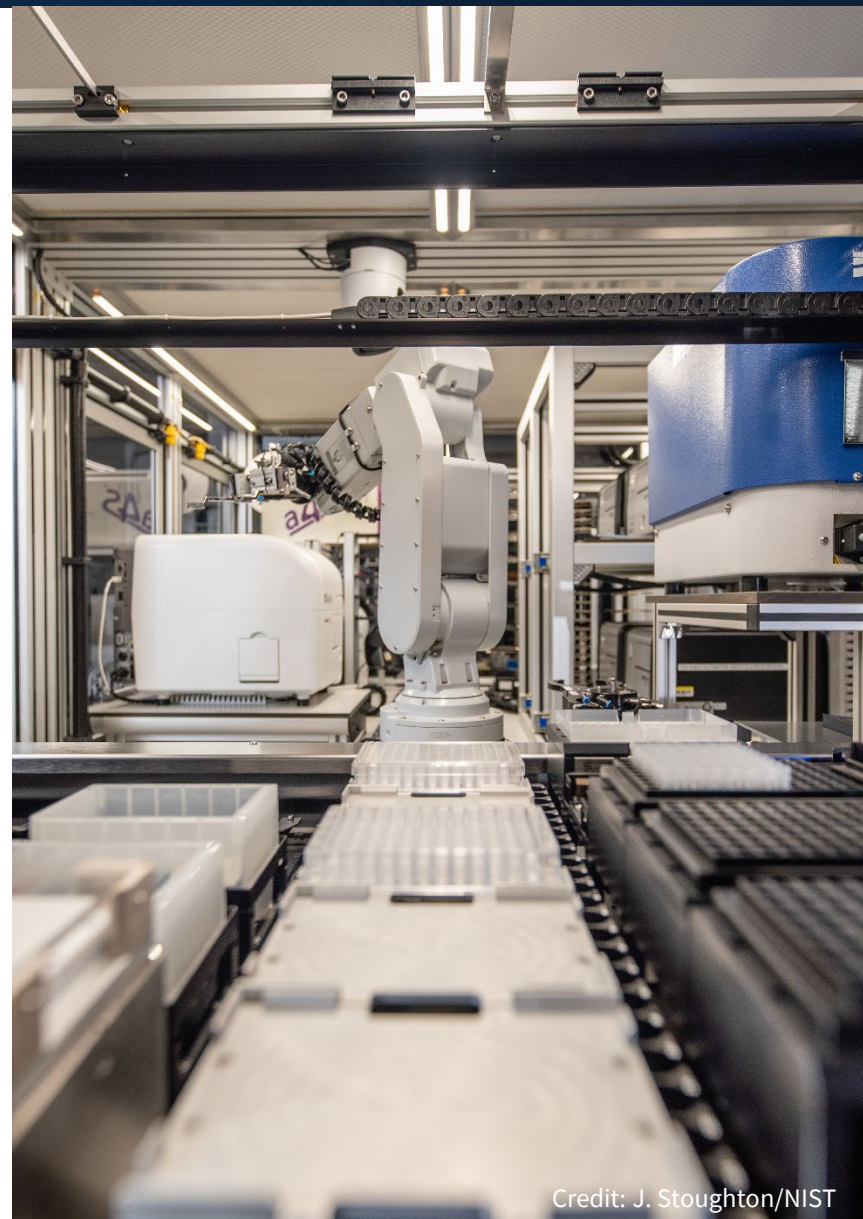
1. Accelerate Innovation in Critical and Emerging Technologies of the Future
2. Bolster American Leadership in Standards
3. Accelerate the Commercial Adoption of U.S. Innovations
4. Build 21st Century Research Infrastructure to Unleash CET Innovation

NIST Laboratory Strategy for Biotechnology

Goal: Harness the Power of Biotechnology

NIST will unlock the potential of biotechnology and biomanufacturing to solve U.S. industry challenges and partner with U.S. industry to accelerate:

- **U.S.-based adoption** of emerging biotechnologies and development of biomanufactured products.
- Development of **new fit-for-purpose biological reference materials, reference data and metrology**.
- Development of **AI-enhanced biotechnology solutions**.



Credit: J. Stoughton/NIST

Biotechnology…

technology that applies to, or is enabled by, life sciences innovation or product development

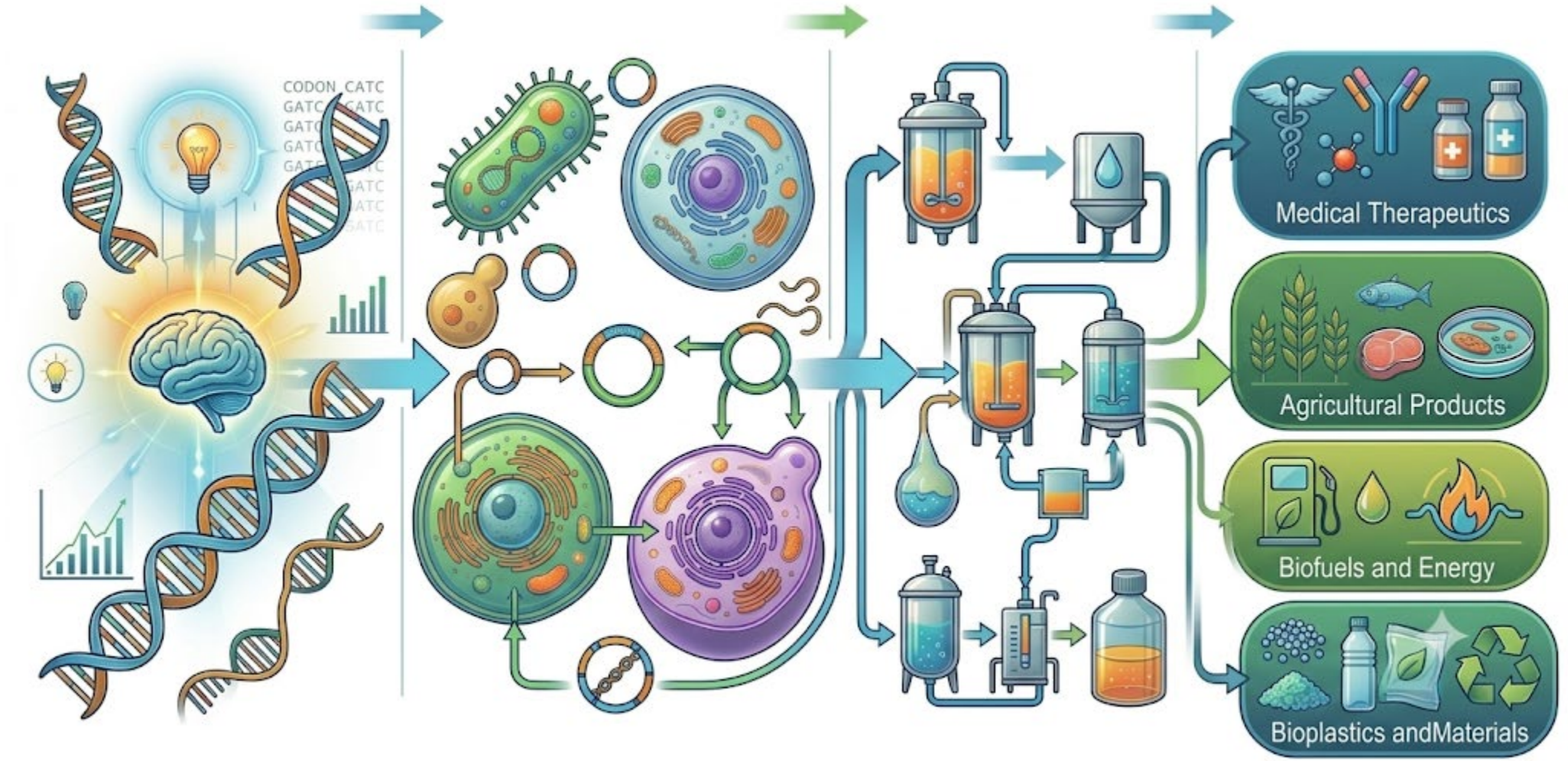


Image created with Google Gemini

NIST Biotechnology Core Competencies

Nucleic Acids

Next Gen Sequencing (NGS)
Digital PCR (dPCR)
Mass Spectrometry (MS)
NMR

Proteins

Liquid Chromatography/MS
NMR
Functional Bioassays
Chromatographic Methods
Cryo Electron Microscopy
Optical & Scattering methods

Cells

Count & Viability
Optical microscopies
Flow cytometry

Manufacturing and Process Optimization

Bioprocess Testbeds
Process Analytical Technologies (In-line/On-line monitoring of critical process parameters)

NIST Biotechnology Core Competencies

Nucleic Acids

Next Gen Sequencing (NGS)

Proteins

Optical Microscopies

Flow cytometry

NIST/Administration Priorities:

1. Accelerate Innovation
2. Bolster American Leadership in Standards
3. Accelerate Adoption of U.S. Innovation
4. Build 21st Century Research Infrastructure

US NMI Roles:

1. Maintain primary measurement standards and traceability
2. Represent the US to support SI for trade and science
3. Engage stakeholders and address measurement needs
4. Advance measurement science/economic competitiveness
5. Support sound documentary standards

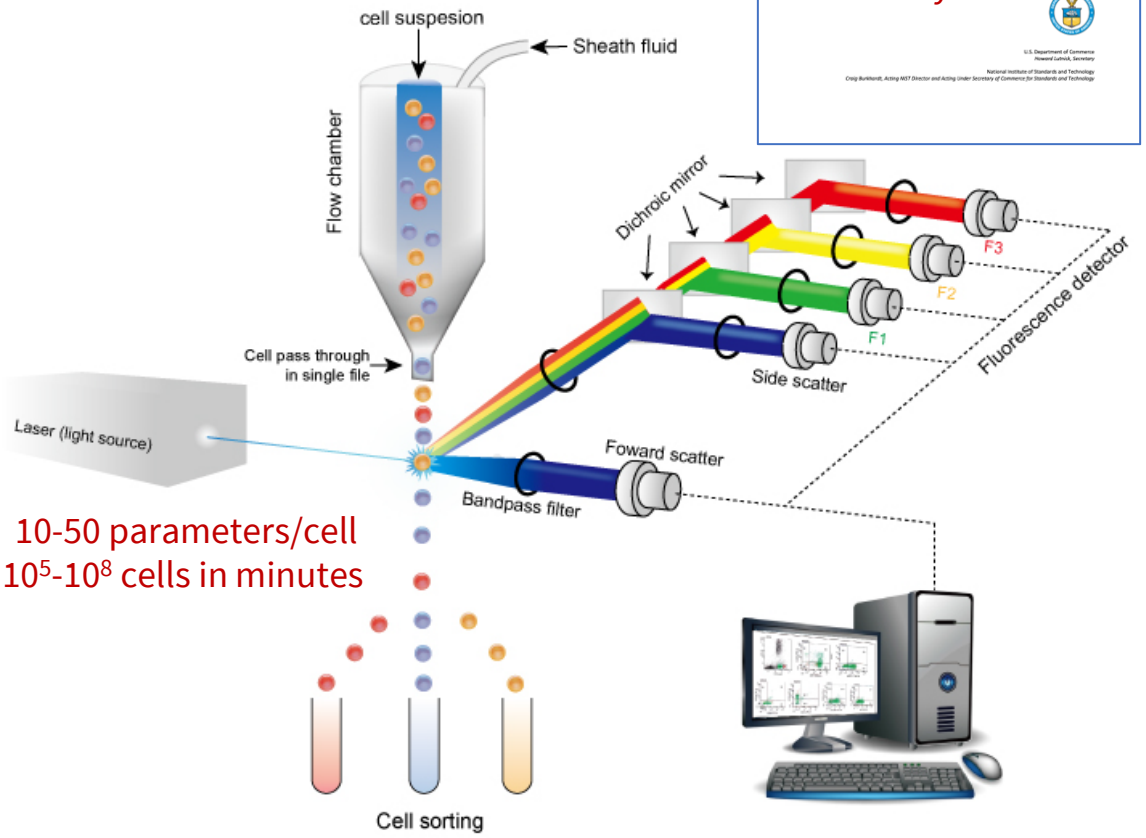
NIST-led Flow Cytometry Standards Consortium Interlaboratory Study

Flow cytometry measures physical and biological characteristics of individual cells at high speed, supporting diagnostics, drug discovery, cell therapy, and biomanufacturing


NIST Special Publication 260
NIST SP 260-264

Assignment of Fluorescence Intensity Values to Calibration Microspheres and Nanospheres for Flow Cytometry

January 2026



10-50 parameters/cell
10^5-10^8 cells in minutes

The $7B+ flow cytometry market lacks the measurement confidence required for regulatory use in clinical diagnostics and cell/gene therapy.

(detector-specific intensity values)
(instrument-independent scaling)

NIST-led consortium interlaboratory study to establish benchmark measurements critical for **cell and gene therapy approval.**

(17 organizations; 42 instrument models)

High quality benchmark data enables previously siloed data to be **AI ready,** accelerating discovery and manufacturing.

(1900 QC-passed, AI-ready files)
(4 SOPs prepared for documentary standards)

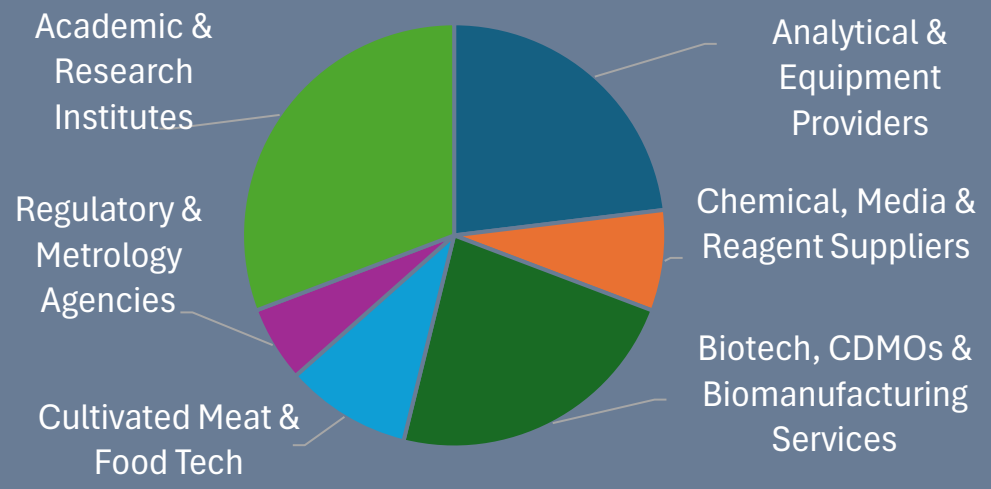
Image from https://www.creative-bioarray.com/support/principle-of-the-flow-cytometry.htm

Release of RM 8675 – NISTCHO Clonal CHO-K1 Cell Line Producing cNISTmAb

- Enables benchmarking of biomanufacturing technologies from cell growth to antibody production to downstream purification, with minimal IP constraints
- Collaboration with NIIMBL and MilliporeSigma
- ≈50 units sold/year; eased sales restrictions May '26

[NISTCHO] enables us to benchmark the performance of our current and future technologies and can give our customers confidence in the broader applicability of our products and services. –ThermoFisher Scientific

Distribution Throughout the Bioeconomy



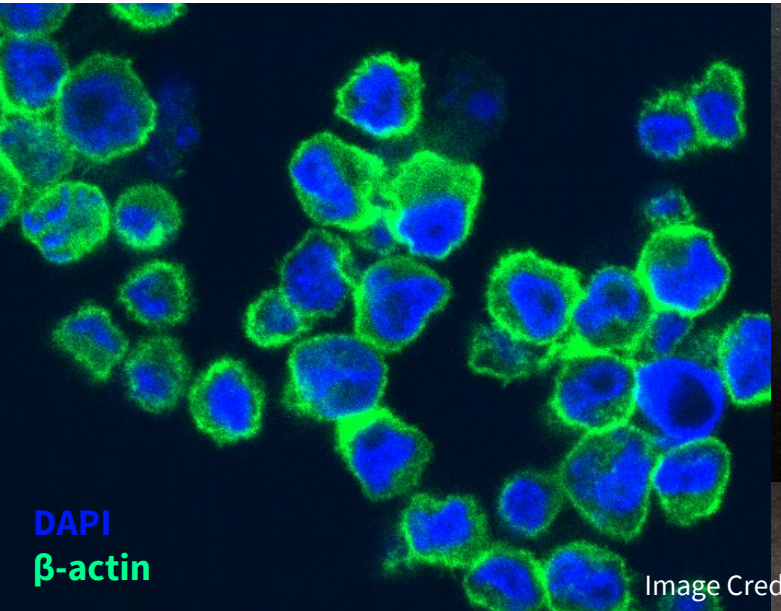


Image Credits: NIST

In Production:

cNISTmAb RM being produced by a Contract Development and Manufacturing Organization (CDMO)

MilliporeSigma

Gemini

New Biotech Reference Material Products

Human ID Testing Benchmark

Credit: NIST

Reference Material 8043 Forensic DNA Resource Samples (2/26)

- A set of eight human DNA extracts, including DNA mixtures (more than one contributor) and degraded/damaged samples
- Designed for forensic DNA Testing Labs (Federal/State/Local) to validate and benchmark testing methods for law enforcement

Quality Control for Visual Inspection

Standard Reference Material 1989 Monodisperse Irregularly Shaped Particles (7/25)

- A set of epoxy-based photolithographic particle dispersions in three sizes (nominal 100 µm, 150 µm, 220 µm)
- Biotech laboratories use the RM to train and qualify inspectors and validate automated visual inspection processes

Validation of Bird Flu Testing

Credit: NIST

NIST RM 8038: H5N1 (Avian Influenza) Synthetic RNA Fragments (1/26)

- CDC collaboration in response to highly pathogenic avian influenza A (H5N1) outbreaks in humans
- Non-hazardous, quantified materials to support new assay development, validation, and harmonization of diagnostic/screening tests

World's Most Complex Multi-omics Living Reference Material

RM 8048 – Gut Microbiome Reference Material (released March 2025)

Need

Benchmark for reproducibility and comparability in microbiome analyses

Impact

"A standard stool product will allow for greater comparability in preclinical studies and later clinical trials testing interventions to alter the microbiome." - Lori Holtz, MD, MSPH Washington University School of Medicine (Medscape Medical News)

Community Adoption

73 units sold to date across industrial, federal, and academic sectors globally

Image Credit: IAFNS

"This tool will be 100% useful for microbiome research." - Sudhir K. Dutta, MBBS, MACG, Johns Hopkins University School of Medicine (Medscape Medical News)

Highly characterized

Metagenomic sequencing, Mass spectrometry, nuclear magnetic resonance (NMR), Flow cytometry

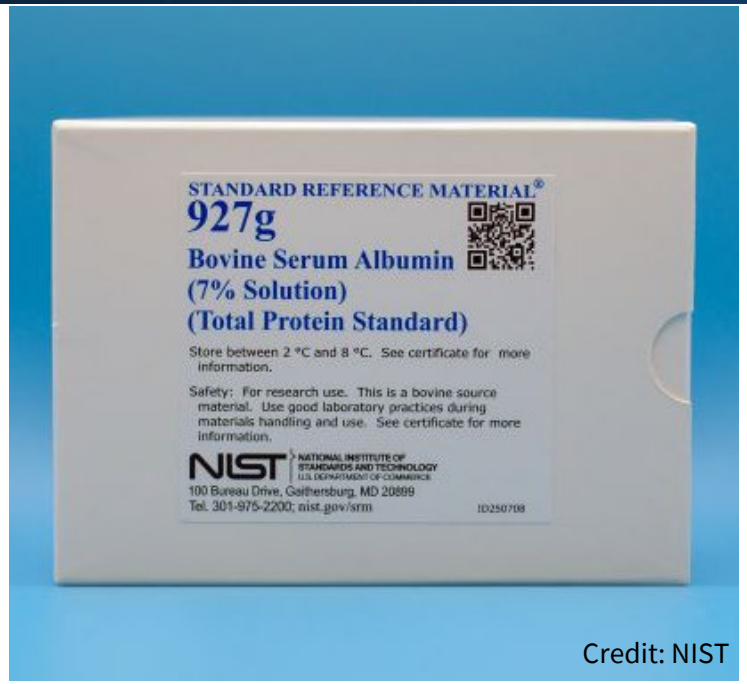
AI Readiness

Accompanied by a custom metagenome-assembled genome (MAG) database to enable data standardization and integration for AI applications

Catalyst for NIST Microbiome Program

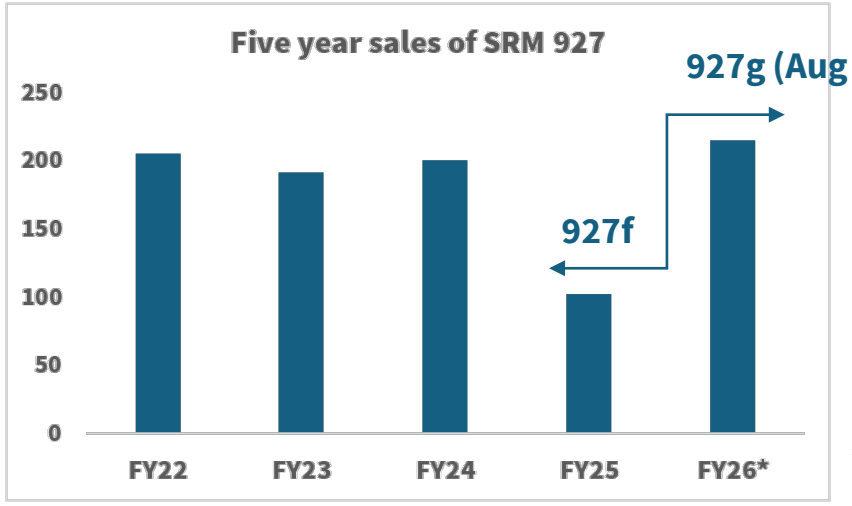
Human Virome measurements; RGTM 10212 Fecal Metabolite Mixture - Kit of 50, defined, quantified metabolites

Supporting Biotherapeutic Quality Testing



Credit: NIST

- SRM 927g Bovine Serum Albumin (7% Solution) is a total protein standard
- Essential SRM for biopharmaceutical production and characterization
- Used in FDA filing requirements for many biopharmaceutical products



"…we rely on the NIST 7% BSA to be able to help supply the market with important health products to those in need. When we cannot supply the market, we endanger those individuals at risk."

- A top 5 global biopharmaceutical company

* Reflects sales for FY26 as of June 9, 2026

World's Most Sequenced Cancer Genome

Cancer Genome in a Bottle: Measurement Infrastructure

Need

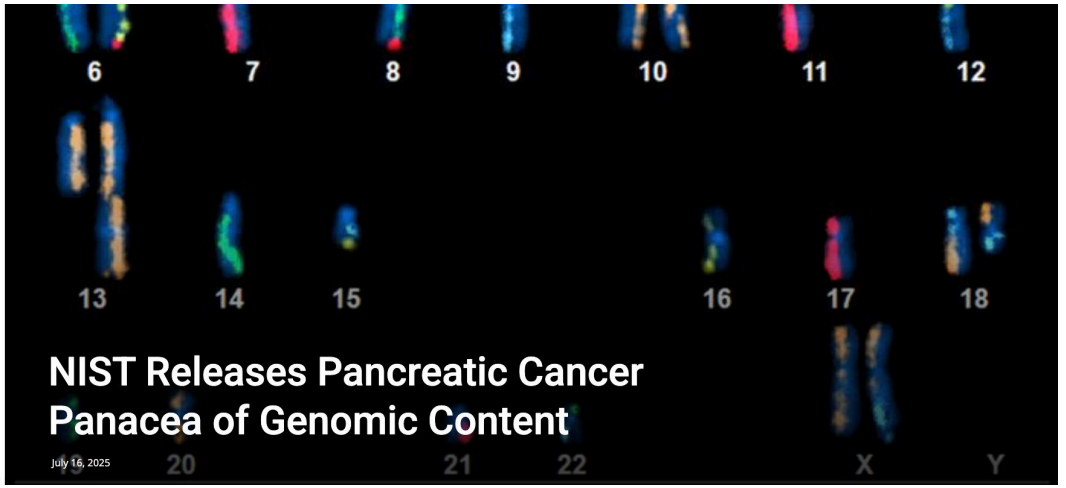
Public reference data for complex somatic variants and difficult cancer genome regions.

NIST-led collaborative measurements

"This is probably the most well-characterized cancer cell line in the world right now."
- Giuseppe Narzisi, New York Genome Center (GenomeWeb)

Impact

A shared reference enables platform comparison and faster assay and algorithm development.



Method developers now have "something to refer back to" for evaluating new approaches.
- Winston Timp, Johns Hopkins University (GenomeWeb)

Scientific Data paper

Open, broadly consented HG008 tumor-normal data across 17 distinct measurement technologies. (July 2025)

Benchmark preprint

Near-complete tumor/normal assemblies and curated somatic benchmark datasets. (May 2026)

Industry use

Validate assays, demonstrate sequencing platforms, and improve cancer algorithms.

NIST26 Mass Spectral Libraries: SRD 1A

More than 5000 libraries delivered to end users each year

General Purpose Libraries

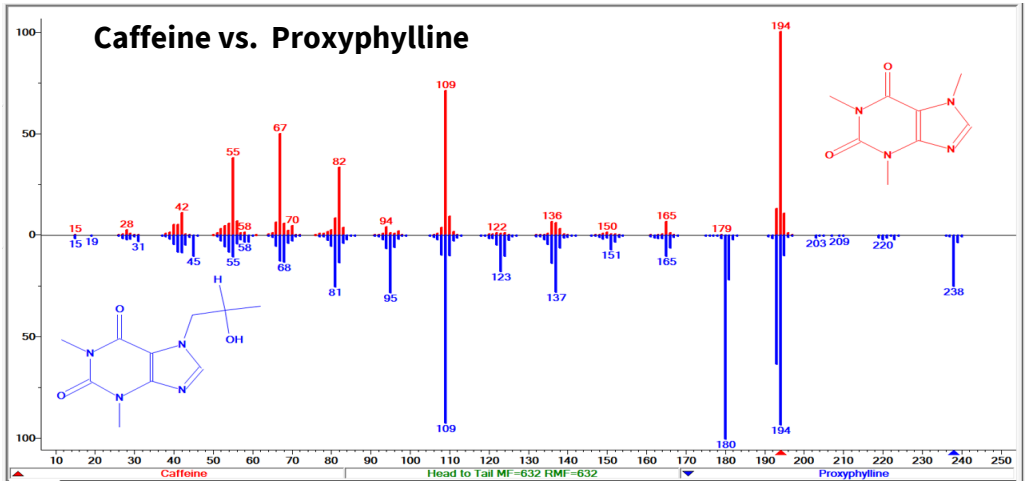
- GC-MS: 382,280 compounds
- LC-MS: 68,635 compounds
- Primary focus areas:
  - Plant & animal metabolites
  - Food
  - Drugs
  - Industrial compounds

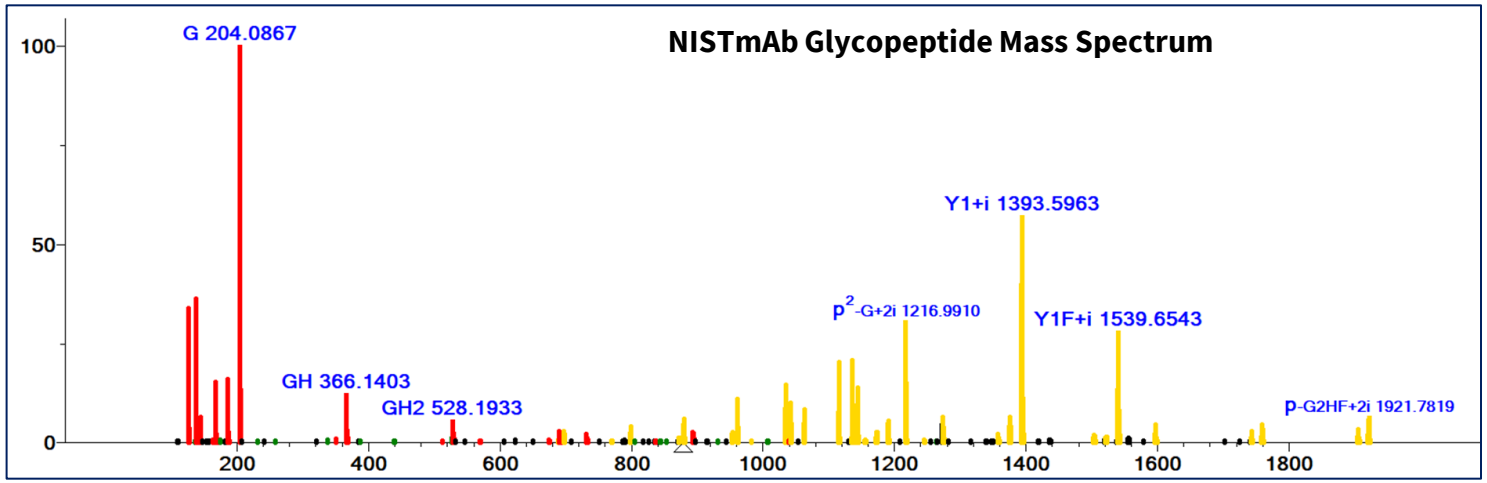
Example Specialty Libraries

- Protein/peptide
  - NISTmAb; Influ. A vaccine
- Substance specific
  - Human blood, urine, milk
- Material specific
  - Polymer extractables
- AI generated
  - Peptides; GC ret. index

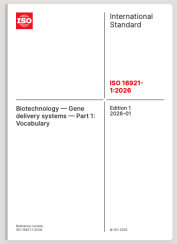
Software

- NIST MS Search
  - Library search program
- MS Interpreter
  - Thermochemical prediction tool
- Polymer Pyrolysis Search
  - Microparticle identification





Bolster American Leadership in Biotechnology
STANDARDS – Gene Delivery Systems



ISO 16921-1:2026

Biotechnology — Gene delivery systems

Part 1: Vocabulary

Read sample

Published (Edition 1, 2026)

ISO 16921-2:2026

Biotechnology — Gene delivery systems

Part 2: Quantification methods for viral vectors

Read sample

Published (Edition 1, 2026)

ISO/WD 16921-3

Biotechnology — Gene delivery systems

Part 3: Guide for Methods for the Quantification and Characterization of Lipid Nanoparticles

Under development

A working group has prepared a draft.

Viral and nonviral gene delivery systems are widely used in modern biotech and as emerging therapeutics.

NIST led the drafting of a series of ISO standards with the input of industry leaders from its Consortia and other stakeholders.

Part 1: *Vocabulary* provides urgently needed terms and definition to specify key attributes, Part 2: *Quantification methods for viral vectors* and Part 3: *Quantification methods for lipid nanoparticles* (under development) focus on specific measurement solutions

NIST continues to coordinate with FDA for the development and adoption of science-based standards for advanced therapy (include FDA Standards recognition program) to promote U.S. trade.

Thank you

www.nist.gov

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE