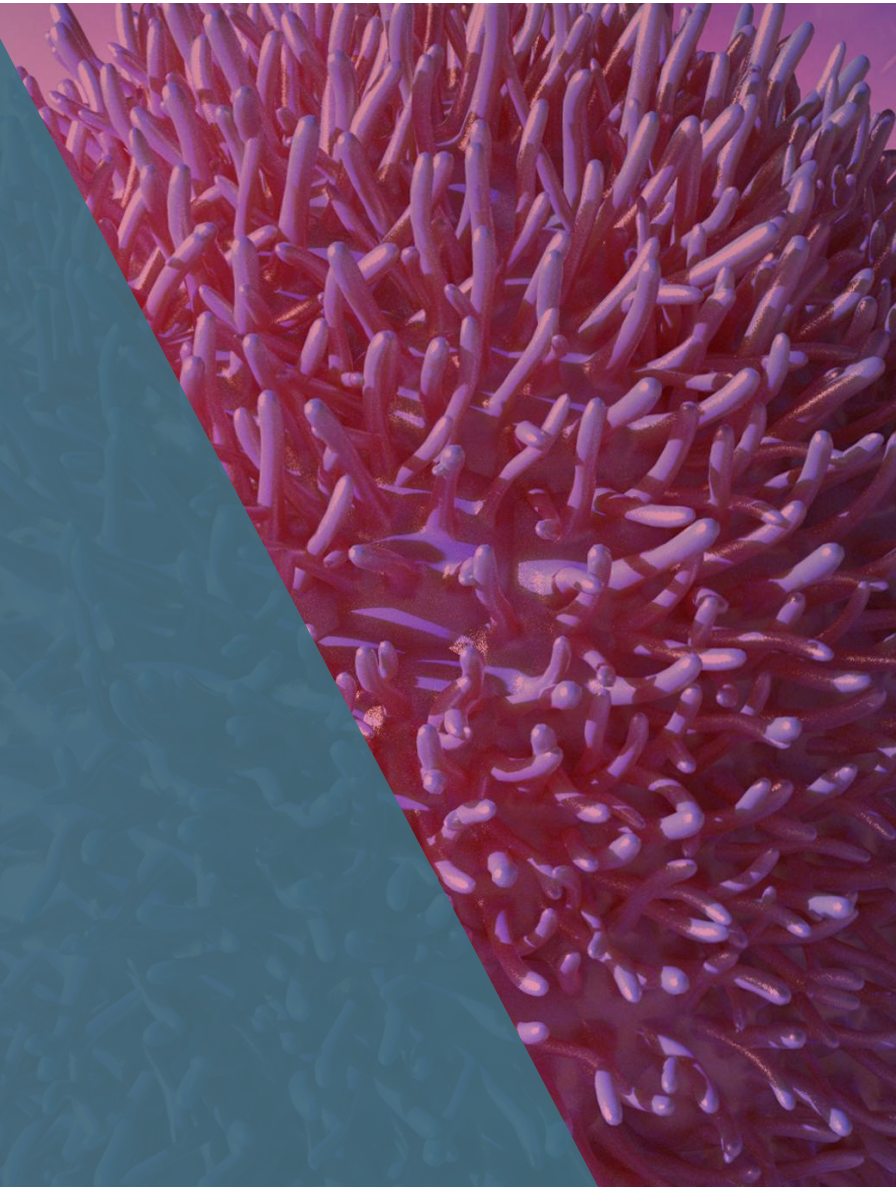
LumaCyte®

Innovate. Discover. Transform.

LASER FORCE CYTOLOGY™

Quantitative Cellular PAT Analytics Driving Improvements in Advanced Therapy Process and Production Outcomes



March 2025

Biomanufacturing Life Saving Cell & Gene Therapies and Vaccines is Complicated

Starting materials are complex, variable, and difficult to characterize, reducing process and product consistency.

Delayed and imprecise analytics result in lost process and production efficiency, delaying delivery of life saving treatments.

Large biological variability throughout manufacturing processes results in batch-to-batch variability and potential for OOS/OOT and batch failure events.

Current Analytics → Slow + Highly Variable + Labor Intensive + Costly

Increasing Demand for Life Saving Advanced Therapies Is Driving the Need for Speed and Innovation

Real-time Label-free Single Cell Analysis Provides Solutions

- **Label-free cellular analytics** reduce the need for antibodies, provide unbiased measurements and enable the sensitive measurement of cellular changes
- **Accurate, precise and non-subjective** data comprehensively characterize complex starting materials and products
- **Real-time analytics increase process knowledge**, enable improved process controls and optimization, and maximize product quality, yield, and shelf life
- **Quantitative precision PAT analytics allows biological evidence** to be carried forward from early process development, production and QC streamlining tech transfer across resources and sites
- **Reduced labor and waste** significantly lowering costs and accelerates time to patient

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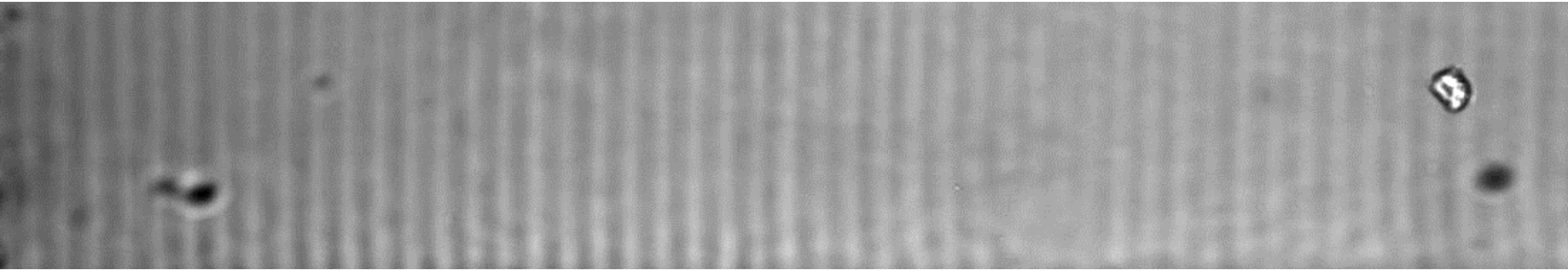
Laser Force Cytology™

Label-free, single cell analysis based on **intrinsic biochemical & biophysical properties** using a balance of optical and hydrodynamic forces in a microfluidic channel



Virally infected Vero cells

Laser (Optical Force) → Velocity ∝ $F_{Optical}$ ← Fluid Flow (Drag Force)

- An **optical force** is generated when a **laser beam reflects and refracts through a cell**
- Laser Force Cytology™ measures velocity (optical force) and other parameters to detect **subtle phenotypic changes in cells,** rapidly measuring **quantitative early indicators** of cellular response **to viral infection, activation, transfection and differentiation**
- Applications in **cell and gene therapy, vaccine development, and biomanufacturing**

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REGULATORY SUPPORT FOR NOVEL CELLULAR PAT ANALYTICS

FDA

NIST

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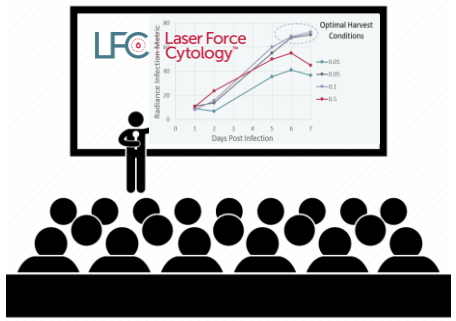
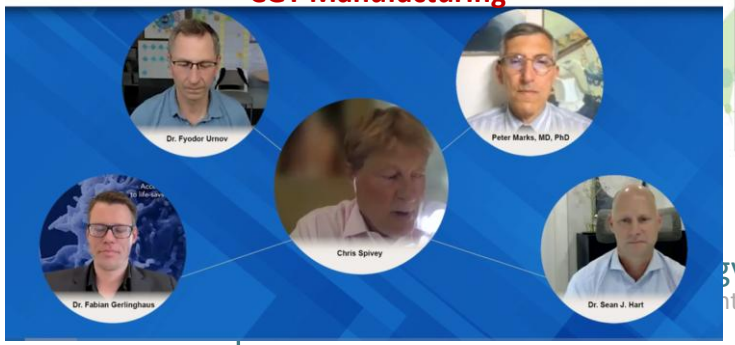
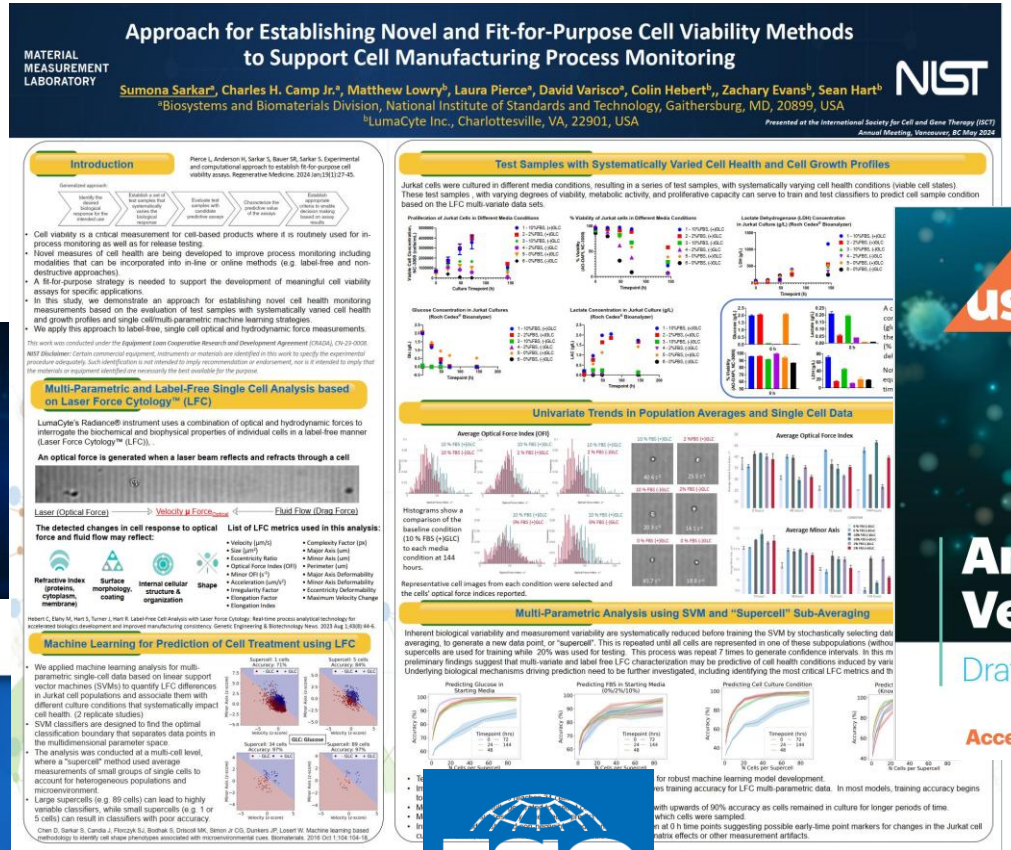


BioPharm International PEER EXCHANGE

Fixing The Potholes in CGT Manufacturing





ISO

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Laser Force Cytology™

Cellular Fingerprinting

Biological/Cellular Processes Affecting the LFC Fingerprint

Potency

Viral Infection and Neutralization

Oxidative Stress

Apoptosis

Cell Health/Viability

Contamination

Donor variability

Activation

Differentiation

Transfection

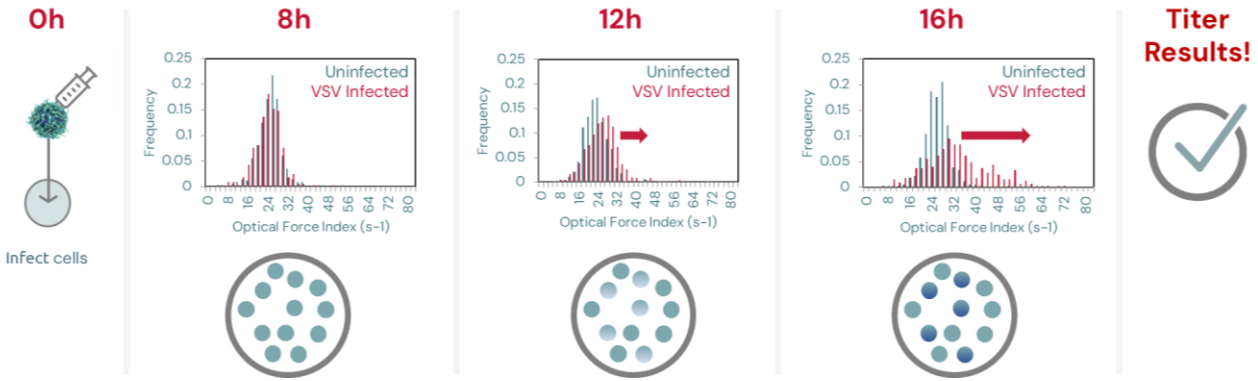
Media Composition

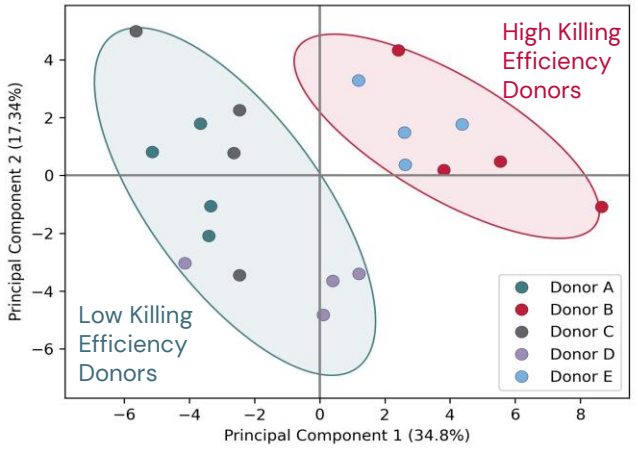
Transduction

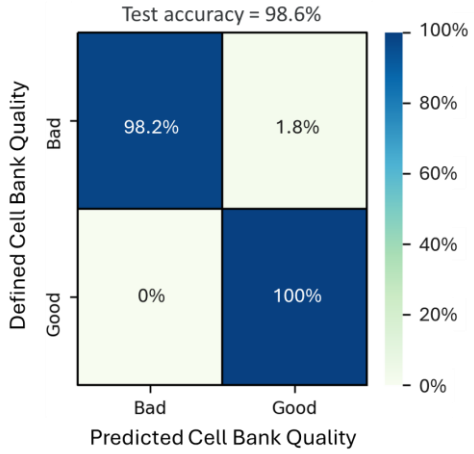
Electroporation

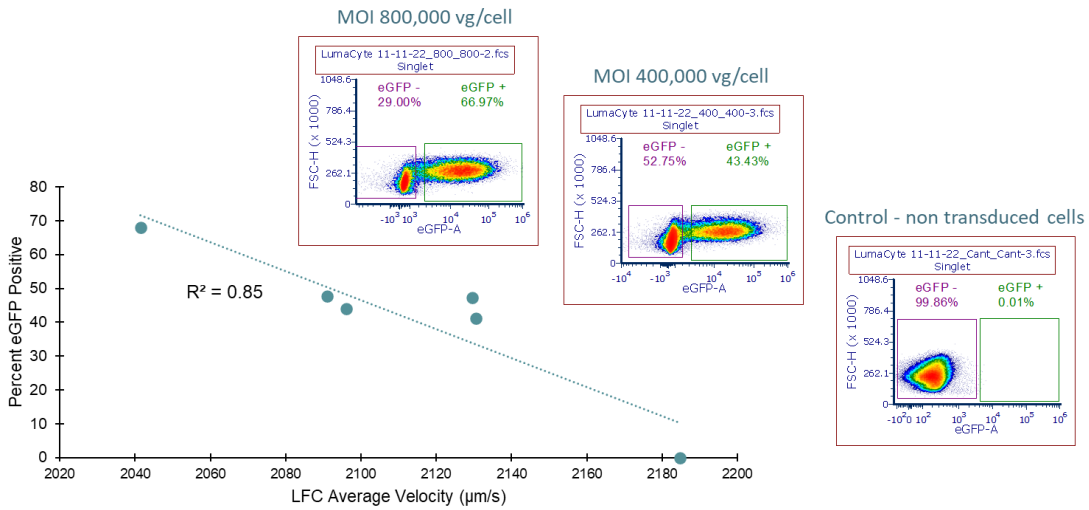
Metabolites

Cryopreservation Formulation/Processing









Laser Force Cytology™

Cellular Fingerprinting

Biological/Cellular Processes Affecting the LFC Fingerprint

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Transfection

Transduction

Electroporation

Media
Composition

Metabolites

Cryopreservation
Formulation/Processing

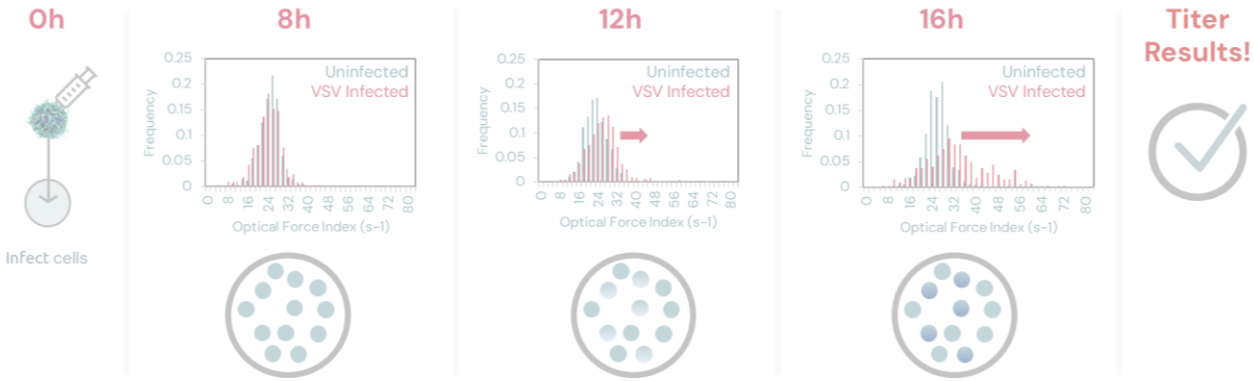
Single Analytic Spanning Every Stage of Production

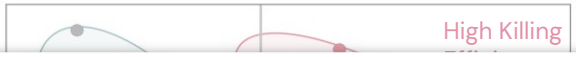
Accelerate Development

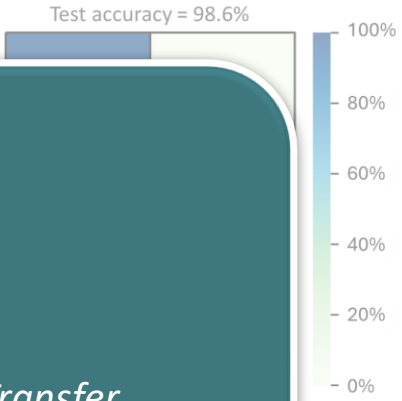
Enable Discovery

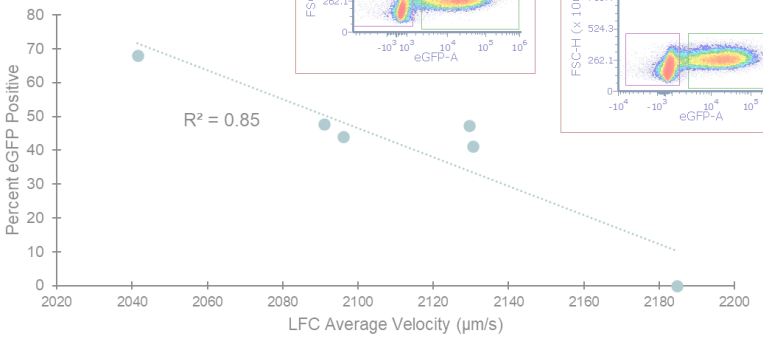
Ensure Process Consistency

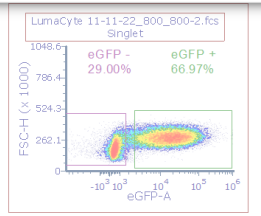
Streamline Tech Transfer



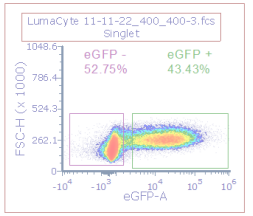








MOI 400,000 vg/cell



Control - non transduced cells