



Cytek[®] Guava[®] easyCyte[™] and Cytek[®] Guava[®] Muse[®] Solutions for Cell and Gene Therapy

Turnkey solutions to fit into your cell and gene therapy workflows

Cytek® Guava® Systems Provide Complete Solutions for Cell and Gene Therapy Labs

Cell Analysis Is Effortless and Fast

The Guava® systems are a perfect fit for cell and gene therapy workflow with their robust and reliable instrumentation combined with optimized software solutions and validated assay kits.

More than 20 years ago, Guava® technologies introduced the first compact benchtop flow cytometers. Today, the Guava line offers flexibility, sensitivity, and high-throughput capabilities. Powered by intuitive software, Guava flow cytometers are some of the most dynamic and flexible benchtop systems available. The Guava line offers:

- Accurate and informative cell viability and health measurement
- Highly accurate cell counting
- Walk-away automation and robotics compatibility

Turnkey solutions for cell and gene therapy are critical for in process analysis. Cytek offers multiple options with our Guava® easyCyte™ and Guava® Muse® platforms.

Guava® Systems	Guava® Software Options	Installation Qualification and Operational Qualification	Daily System Quality Control	Guava® Count and Viability Assays
• Single loader and high-throughput formats • Minimal fluidic usage and waste • Small footprint	• 21 CFR Part 11 enabling features facilitate compliance for electronic tracking of samples • Cytek® GuavaLink for fully automated workflows on your easyCyte™ high-throughput systems	• Trained Cytek staff to perform installation and operational qualifications documentation	• Optimized beads for daily quality control to ensure instrument performance for count and fluorescent measurements that meet manufacturing specifications • Tracking for quality control to evaluate performance over time	• Simplified mix-and-read reagents optimized to determine accurate and precise cellular counts and viabilities • Easy to use software that includes optimized assay setup and results

Figure 1. Guava® easyCyte™ and Muse® systems add reliability in various stages of cell and gene therapy

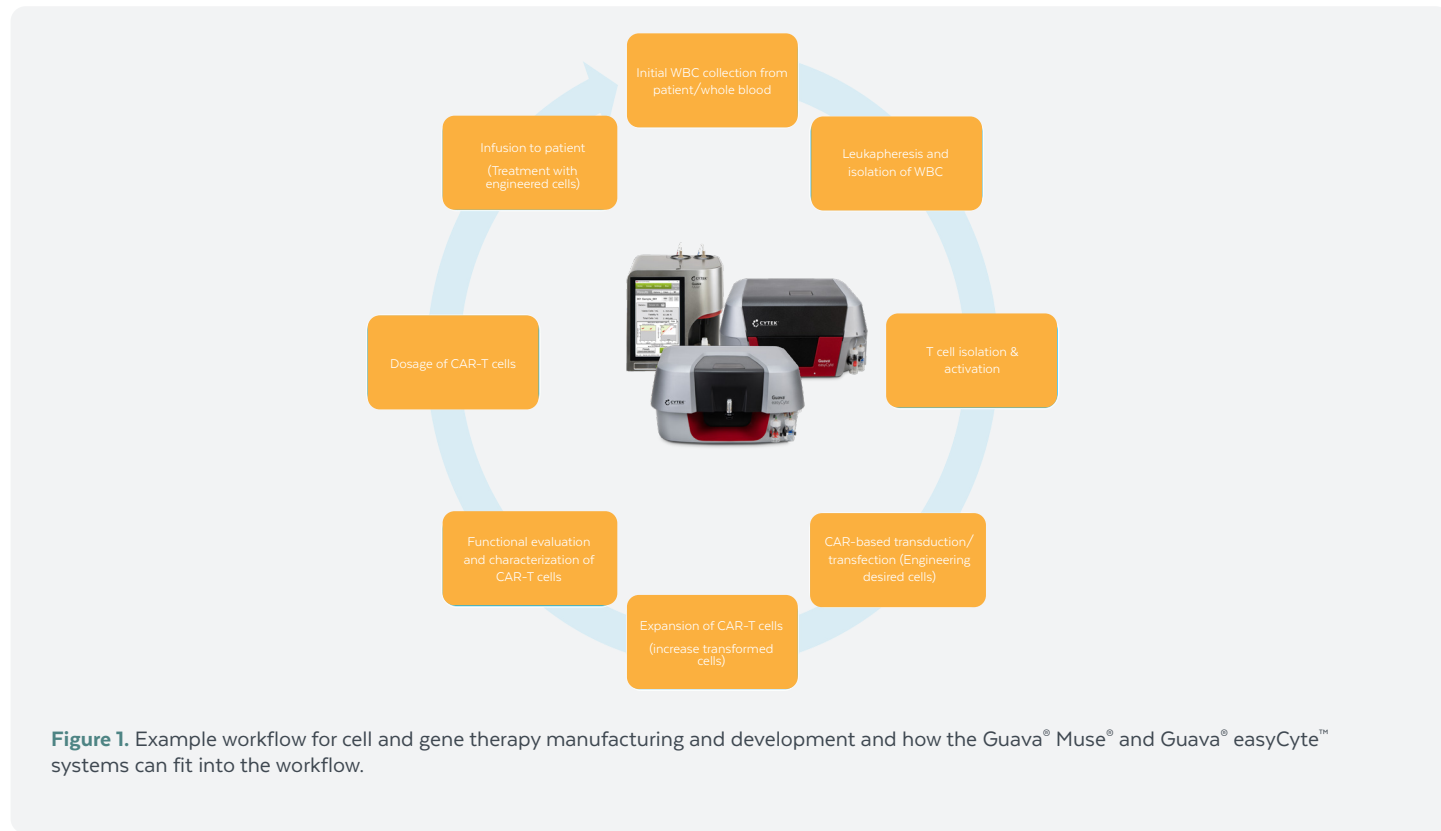


Figure 1. Example workflow for cell and gene therapy manufacturing and development and how the Guava® Muse® and Guava® easyCyte™ systems can fit into the workflow.

21 CFR Part 11 Compliance Enabling Features

The Guava® easyCyte™ and Guava® Muse® systems include features that are designed to facilitate users to be 21 CFR Part 11 compliant.

21 CFR Part 11, Electronic Records and Electronic Signatures, is the United States Food and Drug Administration's (US FDA) regulation directing electronic record and signature management in open and closed systems. The regulation, which became effective in March 1997, specifies the criteria under which the agency considers electronic records and signatures equivalent to paper records and handwritten signatures. Software facilitates compliance with the following areas:

- Central storage of data files for tracking and monitoring
- Secure login for administrator and user login
- Audit trail tracking for acquisition and analysis

A closed system is controlled by persons responsible for the content of the electronic records generated on the system. In addition to software system technical controls, 21 CFR Part 11 requires that user facilities have established procedural and administrative controls. These include defined and documented lab policies, standard operating procedures, personnel training, and notification and management controls.

Installation Qualification and Operational Qualification (IQ/OQ)

Our trained and certified Field Service Engineers (FSEs) and/or Technical Applications Scientists (TASs) will conduct the installation and operation qualification services to ensure your instruments are installed, operating, and performing according to manufacturer's specification. This provides added peace of mind that your instrument is producing high-quality data.

The Cytex field team will conduct comprehensive testing of your instruments using verified tests, certified tools, and developed standards to verify instrument performance. Reliable, audit-style documentation is provided to help you meet regulatory requirements and industry standards.

Installation qualification checks include:

- Determining that the Cytex system is installed with proper supporting services and components.
- Installation evaluation data is documented in reports provided.

Operational qualification checks include:

- Determining that the Cytex system operates to design criteria, as installed.
- Cytex personnel will test the system to ensure its accuracy and functionality.
- The system test includes various equipment checks to ensure that the Cytex system operates as designed by cycling through a series of tests to ensure operation.
- Operational evaluation data will be documented in reports provided.

Robotic Integration – Cytex[®] GuavaLink

Integrate Your Guava[®] easyCyte[™] System with an External Robotic Arm or Liquid Handler

GuavaLink API (Application Programming Interface) and GuavaLink Acquisition software allow robot-scheduling software to control and integrate Guava[®] easyCyte[™] systems with all physically compatible robotic arms and liquid-handling systems—resulting in streamlined workflows and enhanced productivity.

Verified with multiple robotic arms and liquid handlers however, our Cytex Experts are available to assist in integrating with your custom robotic arm or liquid handler.

*****NOTE:** Robotic Integration is only available with Guava[®] easyCyte[™] HT systems

Figure 2. GuavaLink API Workflow



Daily System Quality Control

Providing confidence in assay results

Guava® easyCheck™ and Guava® System Check Kits

The Guava® systems have been designed with a daily quality control to ensure the instruments are performing within the manufacturer's specifications.

The Guava® Check Kits are used to verify the performance of your Guava® system by assessing the counting accuracy and fluorescence detection using a standardized fluorescent bead reagent. The kits contain beads and diluent. Running the procedure for daily quality control (QC) and maintenance ensures you are getting consistent, reliable, and accurate results with failure modes displayed on screen.

Figure 3. Instrument performance is automatically tracked over time and can be exported in PDF or CSV format

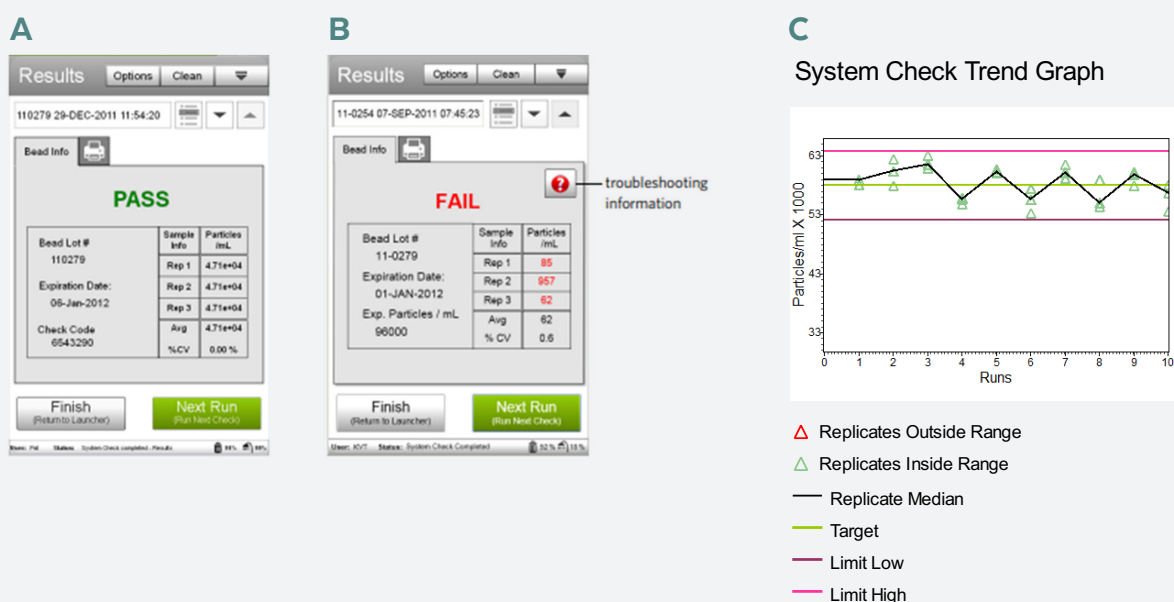


Figure 3. Example Data: System Check bead data obtained with the Muse® System Check software module and acquired on the Muse cell analyzer. **Figure 3A** shows passing results, while **Figure 3B** shows results that failed. Results include the bead count for each replicate, average bead count, and %CV. Bead counts (particles/mL) that fall outside $\pm 10\%$ of the expected value appear in red.

Guava® System Clean and Shutdown Procedures

Following the recommended Guava® system cleaning protocols, instruments will be cleaned and ready to perform per the manufacturers specifications. The Guava systems utilize the Guava® Instrument Cleaning Fluid (ICF) for all cleaning procedures to allow for thorough cleaning of the Guava systems.

Guava systems also allows for tracking and export of cleaning protocols executed to CSV and PDF files.

Guava[®] ViaCount[™] and Viability Assays

Robust and reliable count and viability measurements on a simplified flow platform

The Guava[®] ViaCount[™] Reagent and Muse[®] Count & Viability Kit allow for the quantitative analysis of cell count and viability. The reagents provide rapid, precise, and accurate assessments on a wide variety of cell lines, even those with unusual culture conditions or a tendency to aggregate.

The reagent distinguishes viable and non-viable cells based on differential permeabilities of two DNA-binding dyes in the Guava ViaCount Reagent. The nuclear dye stains only nucleated cells, while the viability dye brightly stains dying cells. This proprietary combination of fluorescent dyes enables the assay to distinguish viable, apoptotic, and dead cells. Debris is excluded from results based on negative staining with the nuclear dye. The software automatically provides outputs on total and viable cell concentrations and viability measurements. Results can be printed on a per sample basis or exported as a CSV or PDF for batched analysis.

Using as little as 20 μ L of sample, the Guava ViaCount Reagent provides the following:

- Total absolute cell counts
- Cell viability counts and percentages
- Apoptotic cell percentages and counts

The assay has proven to be more accurate than hemocytometer counting and impedance-based counting over a wide range of cell concentrations without the use of expensive reference beads. By providing data on viable, dead, and apoptotic cell populations in a single measurement, the Guava ViaCount Reagent enables a more precise evaluation of culture conditions and cell viability to better optimize culture conditions.

Precise, accurate cell counts provide consistent results for experiments that depend upon accurate determination of viable cells for success such as ELISpot, cell-based fluorescence assays, and cytokine production assays.

Figure 4. Muse[®] Count & Viability Reagent Workflow

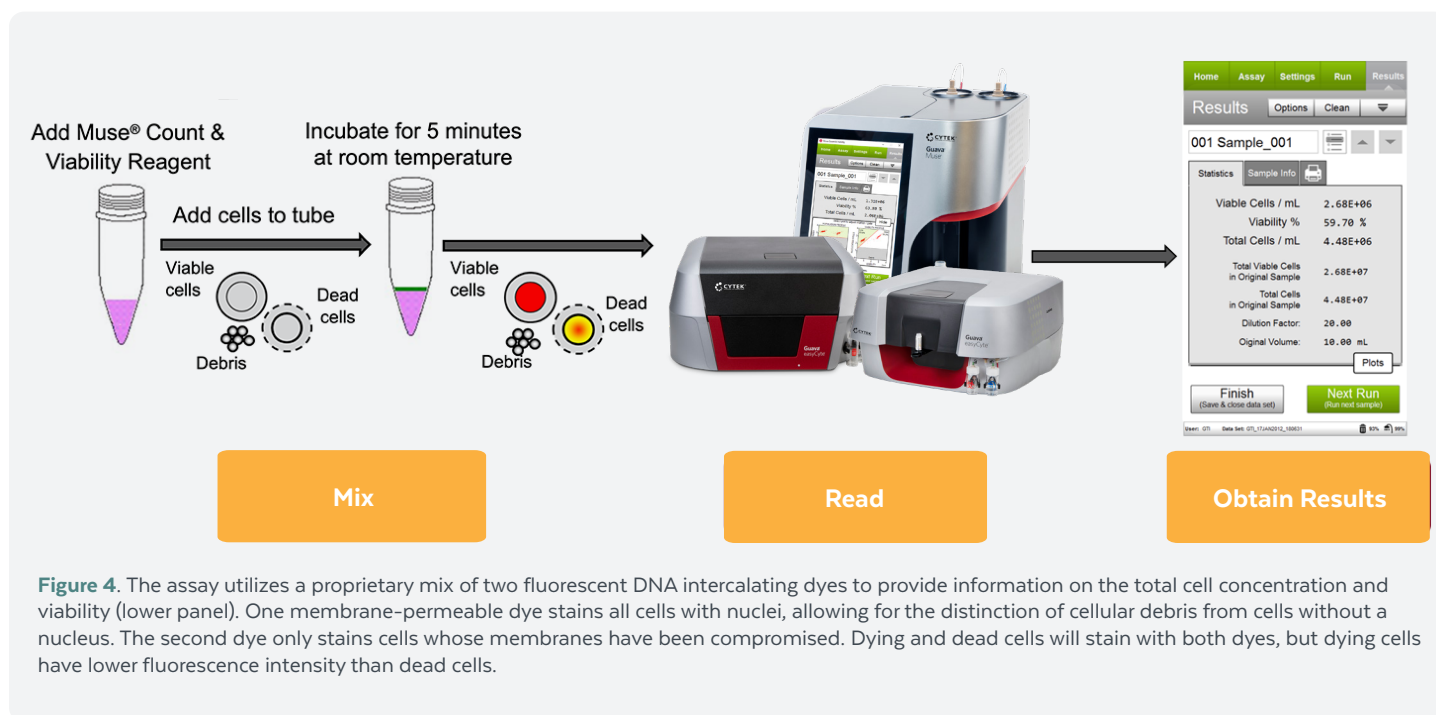


Figure 4. The assay utilizes a proprietary mix of two fluorescent DNA intercalating dyes to provide information on the total cell concentration and viability (lower panel). One membrane-permeable dye stains all cells with nuclei, allowing for the distinction of cellular debris from cells without a nucleus. The second dye only stains cells whose membranes have been compromised. Dying and dead cells will stain with both dyes, but dying cells have lower fluorescence intensity than dead cells.

Trustworthy Results

Figure 5. Accurate and Precise Count and Viability Measurements

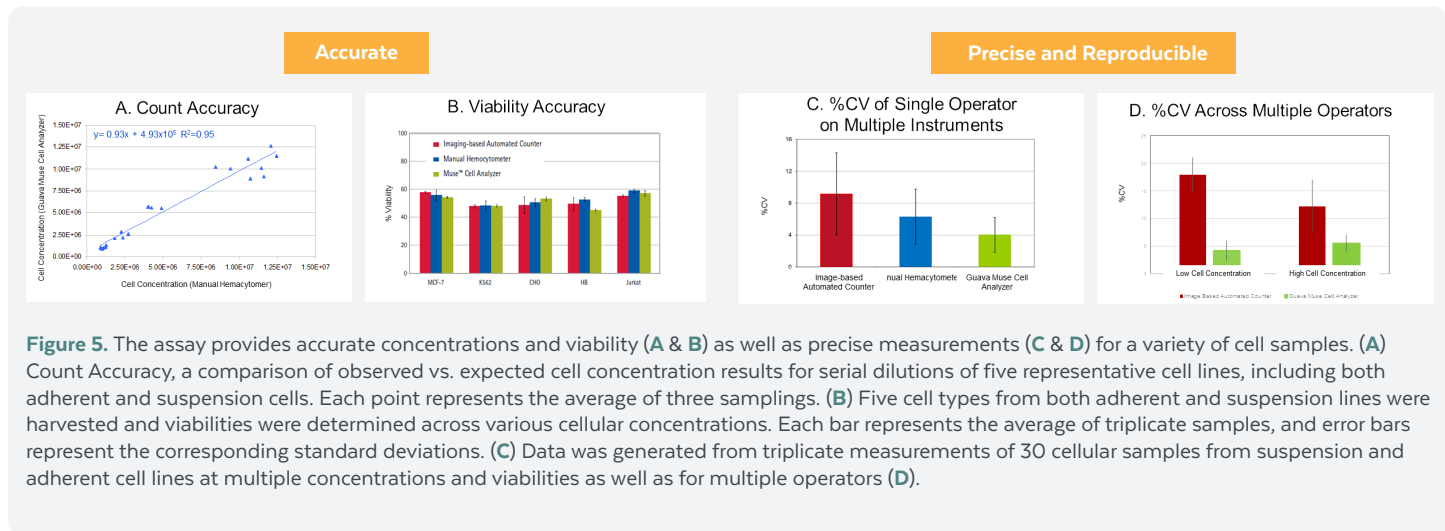
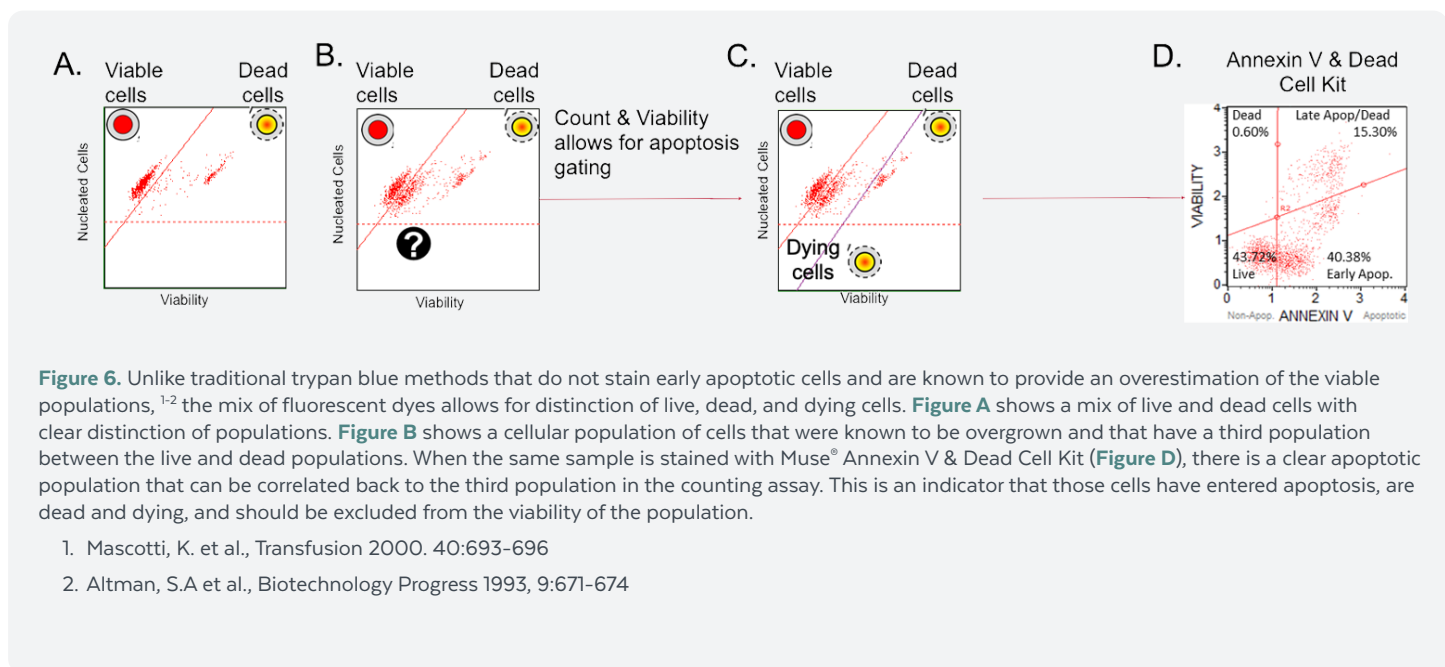


Figure 6. Guava viability results offer insights to apoptotic cells



Ordering Information

Product Name	Part Number
Instruments	
Cytek® Guava® easyCyte™ 5 Base System	0500-5005
Cytek® Guava® easyCyte™ 5HT Base System	0500-4005
Cytek® Guava® Muse® Cell Analyzer	0500-3115
Services	
Guava® easyCyte™ IQ/OQ	8000-1998
Guava® Muse® IQ/OQ	CN-0474-01
Reagents	
Muse® Count & Viability Kit (40mL)	MCH100102
Muse® Count & Viability Kit (240ml)	MCH600103
Guava® ViaCount™ Reagent (40mL)	4000-0040
Guava® ViaCount™ Reagent (240mL)	4000-0041
Muse® Count & Viability (200X) (100 tests)	MCH100104
Guava® ViaCount™ Flex Kit (100 tests)	4500-0110
Guava® ViaCount™ Flex Kit (500 tests)	4700-0060
Muse® Annexin V & Dead Cell Kit (100 tests)	MCH100105
Guava® Nexin® Kit (100 tests)	4500-0450
Guava® Nexin® Kit (500 tests)	4500-0455
Muse® Cell Cycle Kit (100 tests)	MCH100106
Guava® Cell Cycle Kit (100 tests)	4500-0220

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