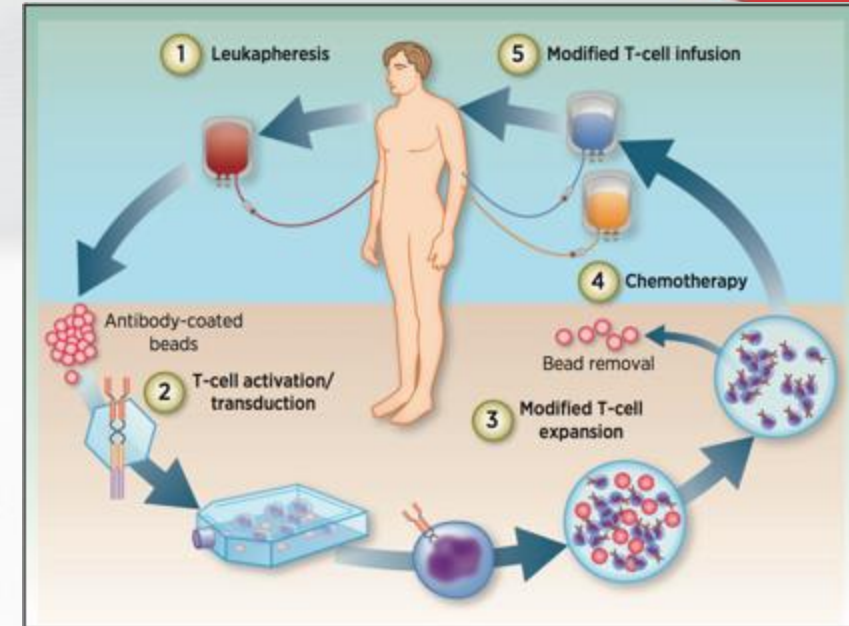




*Assay Migration & Delivery Platform for  
On Demand Process Analytics*

# Framing the “unmet need”

- The production of engineered T – Cells – A complex process.
- Regulatory approval – the process of generating the drug product.
- In this case, “process is the product”.
- A critical requirement - the control of the production process through monitoring and measurement.
- A failure in process control can have disastrous consequences.



# Regulatory: FDA Briefing Document

Oncologic Drugs Advisory Committee Meeting BLA 125646 Tisagenlecleucel  
Novartis Pharmaceuticals Corporation

- *“In order to control the manufacturing process for consistency, it is necessary to thoroughly understand the manufacturing process and critical product quality attributes unique to the autologous CAR T cell products. It is also critical to understand and address sources of variability seen in the individual products. This can be a challenging issue given the complex and labor-intensive manufacturing processes involved with making a CAR T cell product.”*

# Current Conundrum

- The methods and material currently in use
  - Lab scale infrastructure requirements
  - Highly trained personnel to operate systems
- Deploying the tests and procedures at the “processing floor”
  - A big barrier to scaling
- Accellix developed systems and solutions
  - Migrating existing assays to a format suitable for use on the production floor

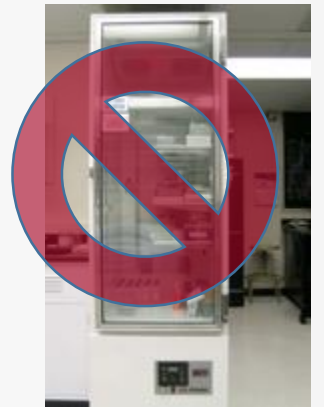




# Characteristics of Accellix system solutions

- Accellix solutions are assay delivery platforms
  - Migrate existing cell and immuno assay protocols for use on-site and on-demand – deployed in weeks
  - Deployed during clinical trials and routine manufacturing
- In migrating an assay to the delivery platform
  - Underlying science behind the assay protocol is preserved
  - Reporters and concentrations are optimized for Accellix
  - Pre-formulated, unitized, standardized, and dried reagents enable on-site, on-demand delivery of results, 24/7
- Cartridge with unitized and standardized reagents
  - No-prep, push button implementation of the solution
  - Standardization across centers and systems

No cold storage  
Requirements



## The Accellix Platform



## The Accellix Cartridge



## Foundations of the technology

*Multispectral high sensitivity  
fluorescent event detection  
reader system*

*Pre-formulated unitized and  
dried precision reagents*



*Universal Cartridge that  
enables sample processing  
and analysis*

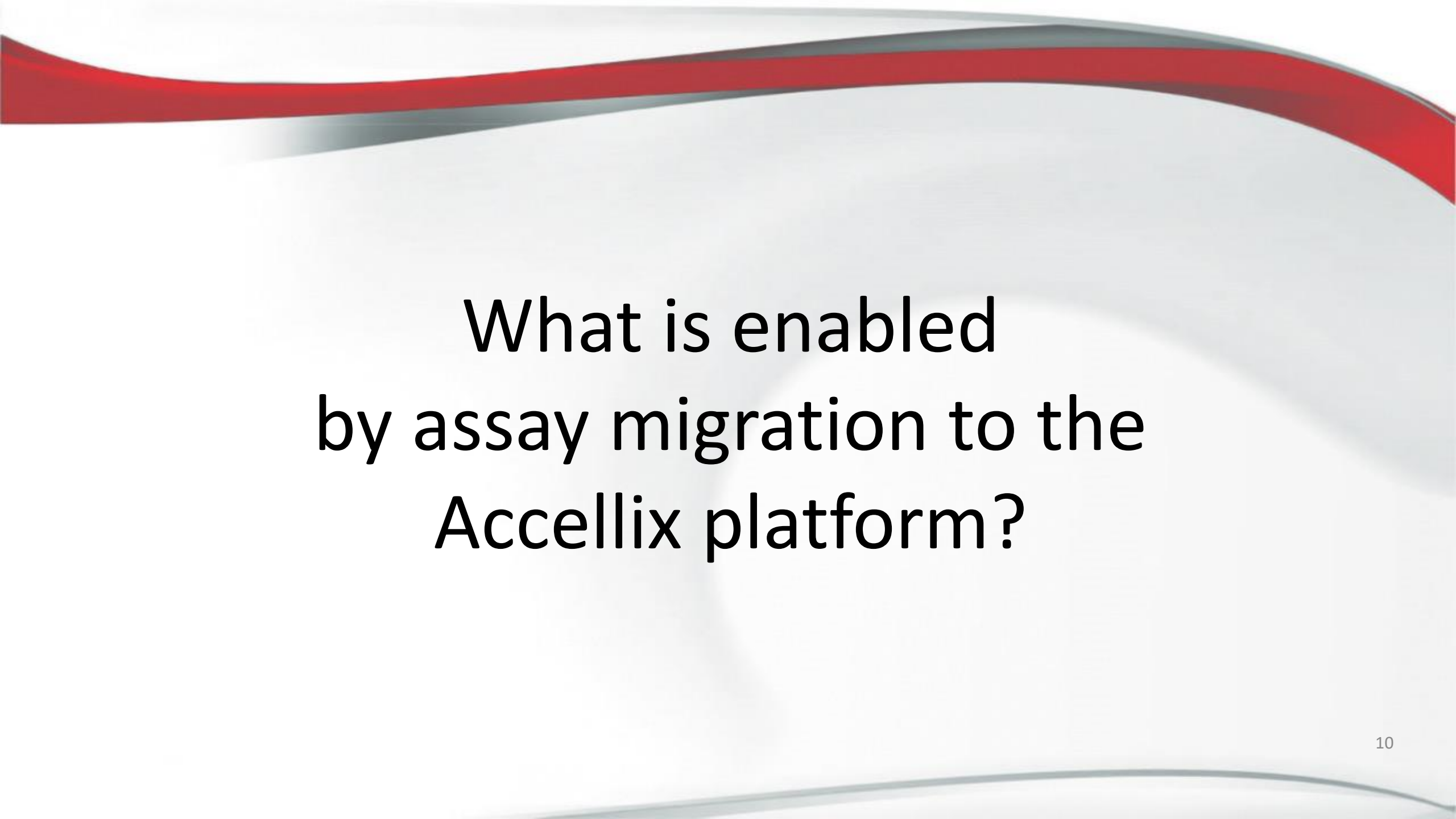
*Application specific  
automated data processing  
and result generation*

# Accellix – The Figure of Merit

- Unique Figures of Merit of the platform
  - No prep, push-button fluorescent event detection
  - On-site, on-demand, real time access to data analytics
  - Characterization and Measurement of labeled cells and beads
  - Evaluate multiple markers in a single cartridge



Please see also the Accellix Video  
@ [Accellix.com](http://Accellix.com)



What is enabled  
by assay migration to the  
Accellix platform?

# CELL ANALYSIS IN A CARTRIDGE

EASY TO USE

RAPID RESULTS

AVAILABLE 24/7

## Point of Use Analytics

### Workflow automation

Access to complex assays

### Multiplexed detection

Cell based assays up to 6 markers

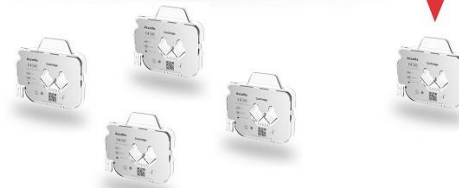
### Single use cartridge

Built in controls

### Dried reagent technology

Stable ambient storage

  
Accellix



## Migrate Your Assay

### Your protocol

Implemented in the cartridge

### Standardized reagents

System to system uniformity

### Automated results

Available on demand and on time

### Standardized analytics

In weeks not months

ACCELLIX: THE AUTOMATED QC PLATFORM FOR CELL THERAPY

[accellix.com](http://accellix.com)

# Customized Assay migration

## Implemented and in use

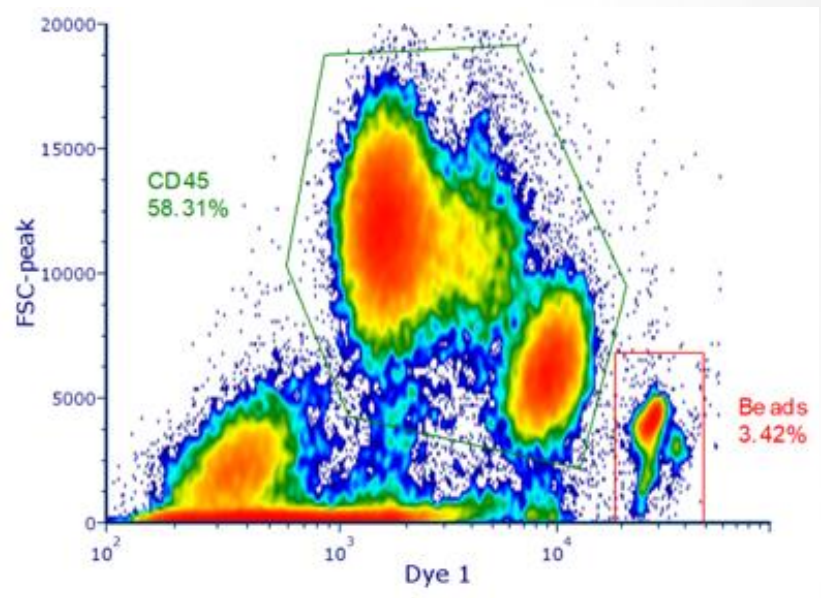
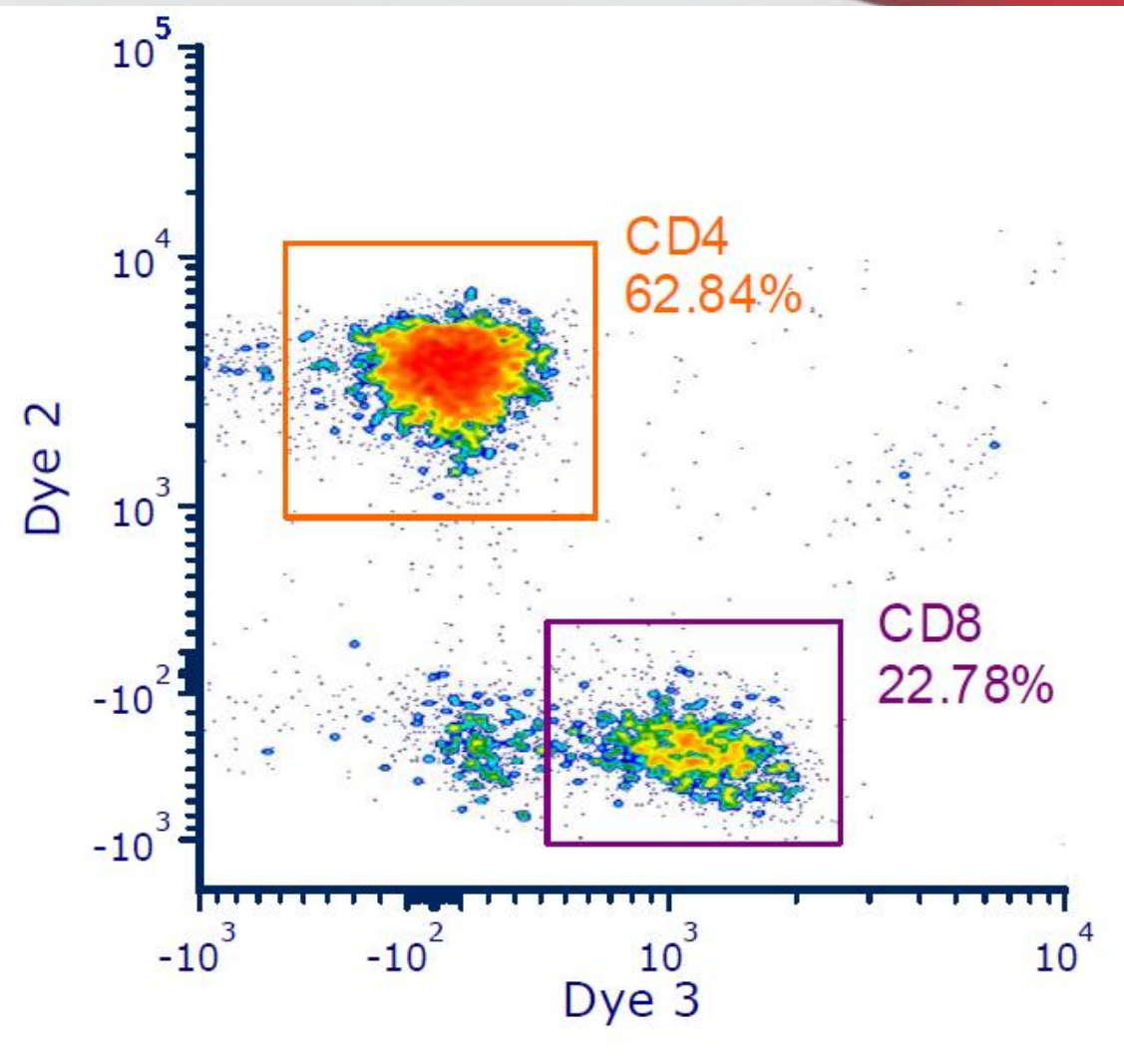
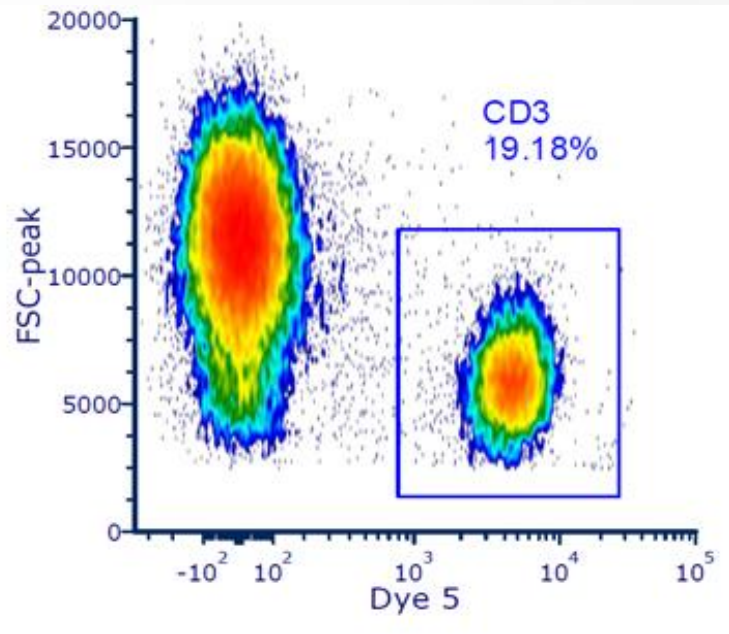
- T– Cell subset enumeration – 5 color assay
- CD34+ Stem Cell enumeration in whole blood and Aphaeresis product – Absolute count

## Ready for customized migration

- Cell Health Panel

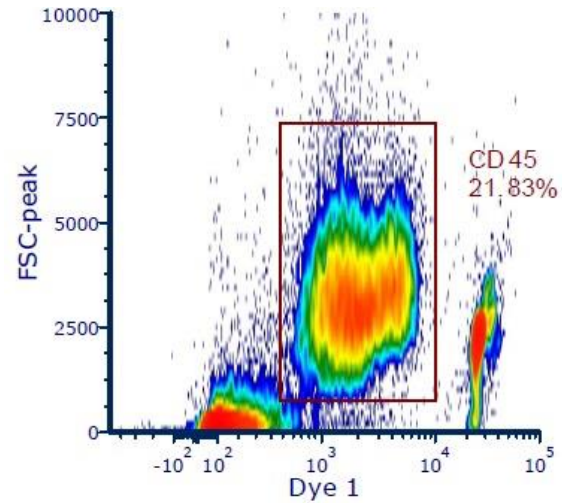
## Customized assays under development

- CAR Specific T– Cell subset analysis
- Functional release testing

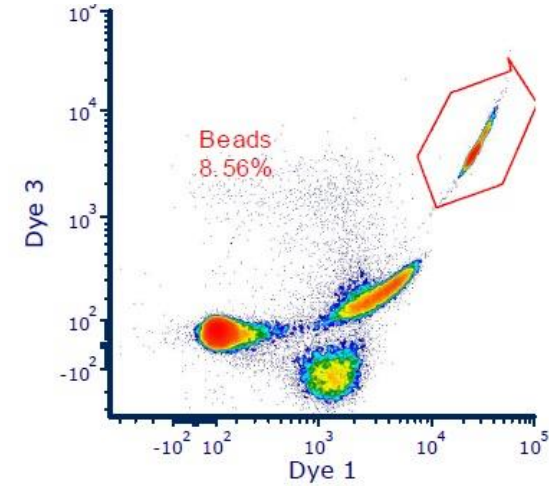




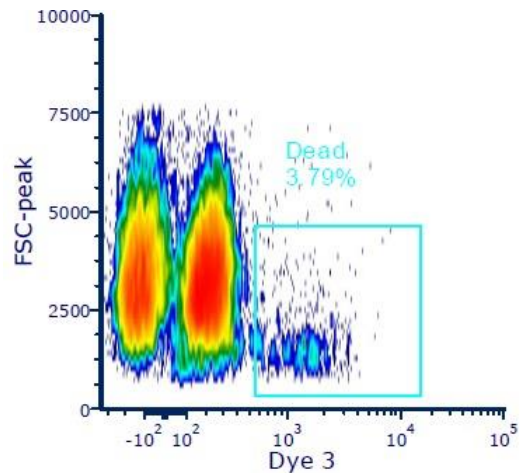
## Identification of CD45+ cells from all events



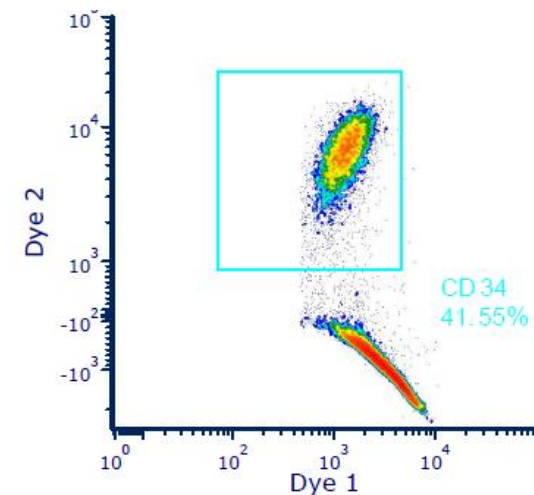
## Counting bead determination from all events



## Separation of Dead cells in the CD45+ cell population

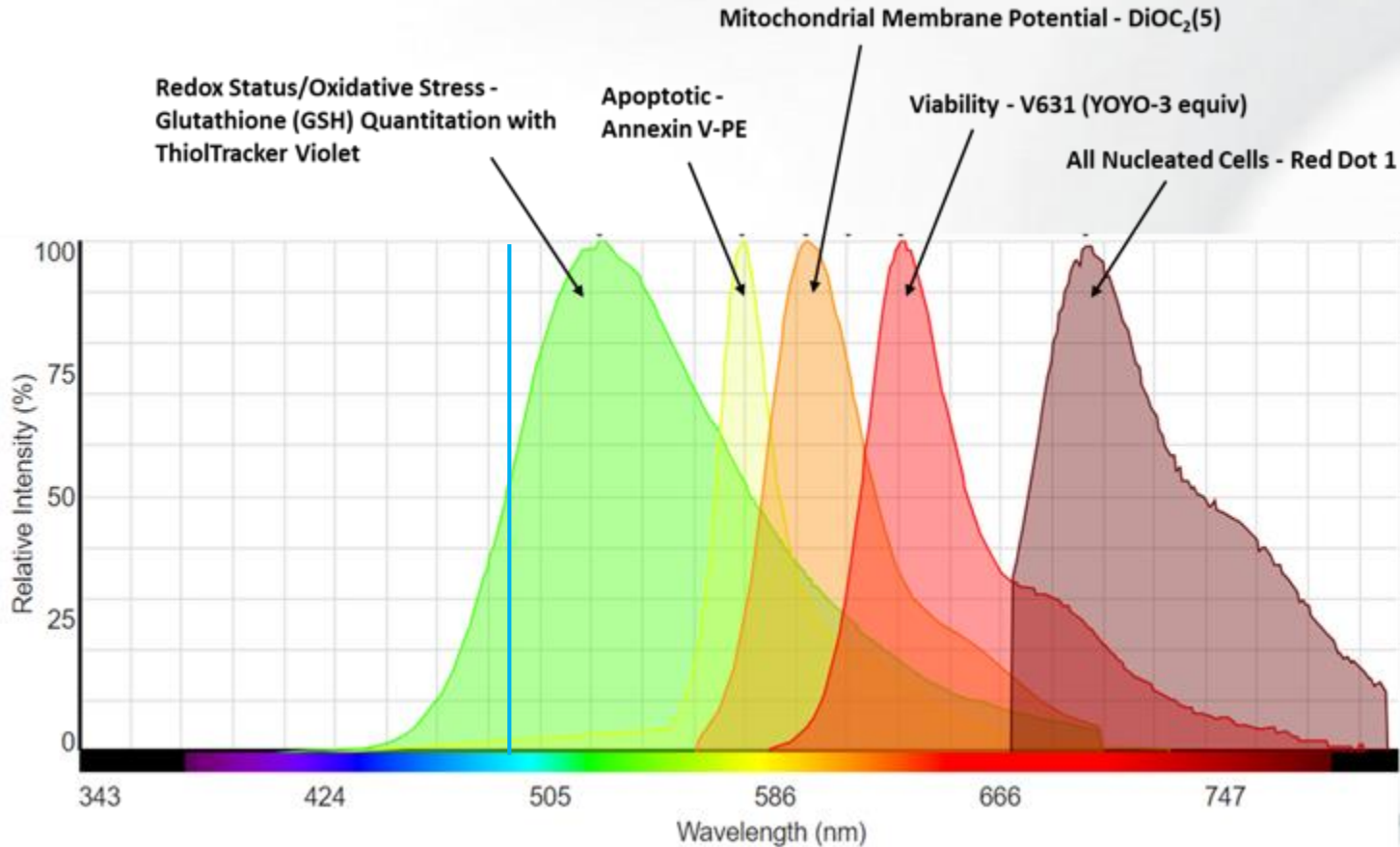


## Identification of CD34+ cells from CD45+ cells



# Cell Health Panel Assay

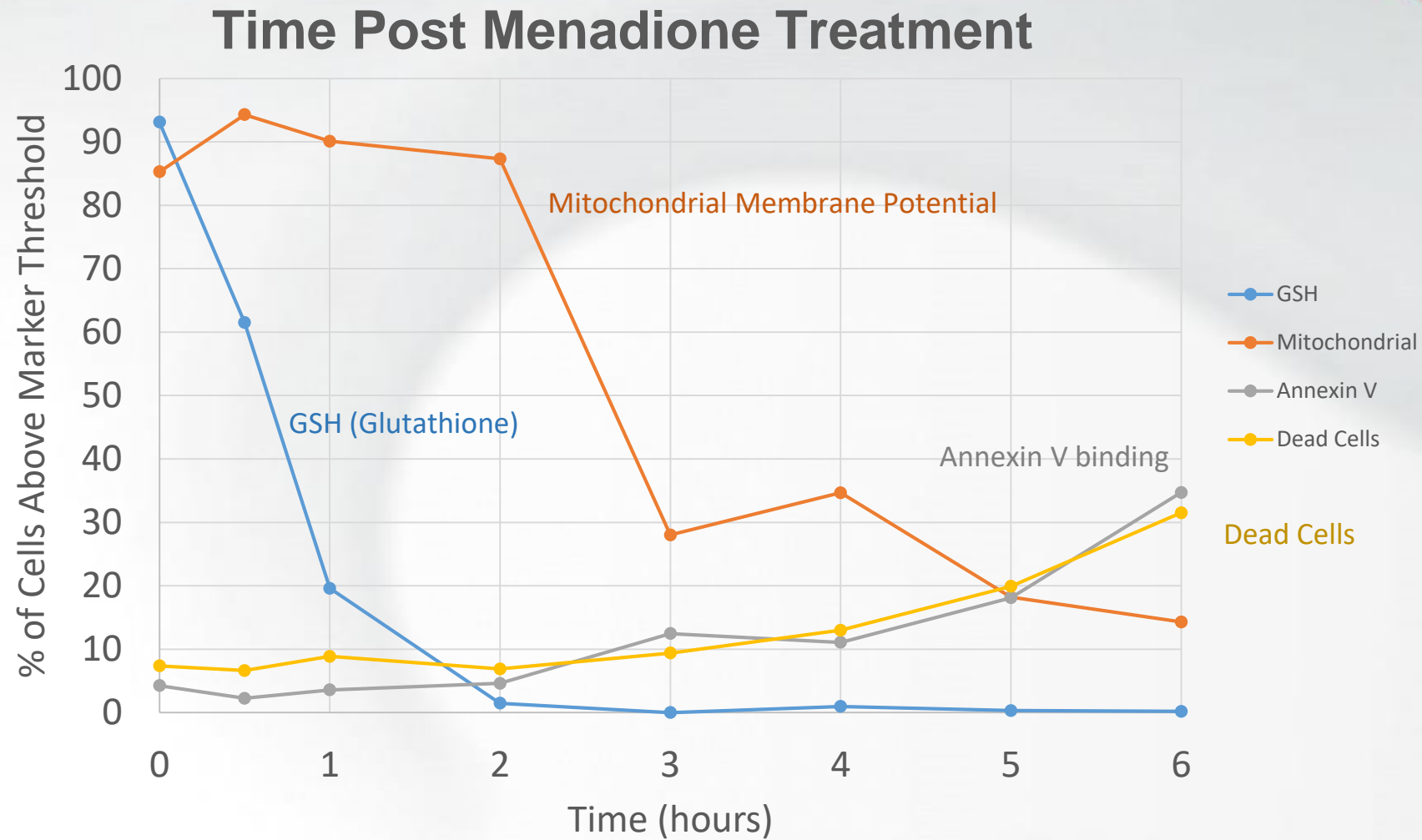
## Simultaneous 5 Parameter Cell Health Assessment



## Parameter Description

- 1) All Nucleated Cells Identification
- 2) Intracellular Glutathione (GSH) Quantitation
- 3) Mitochondrial Membrane Potential
- 4) Annexin V – Apoptosis
- 5) Viability – Membrane integrity

# Time Course Results Tracking Cell Health Panel Markers



# The Opportunities enabled by Accellix

- Accellix technology enables
  - Complex set of QA and QC tests on the cell processing floor
  - Point of need “characterization of the immune system” at the point of acquisition of the input material
  - Near patient real time monitoring during and after transfusion
- The unification of
  - Measurement platform
  - Universal capillary cartridge
  - Dry reagents
  - Automated data analysis
- Delivery of “turnkey point of use” solutions when and where needed



# Thank You

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