



# CELL THERAPY QUALITY CONTROL WITHOUT COMPLEXITY

Bringing the power of flow cytometry  
to GMP manufacturing.



Accellix

PIONEERING DIAGNOSTICS



# Fully Automated Flow Cytometer

Bring automated sample preparation, flow cytometry and data analysis into the GMP manufacturing suite.

**30  
MIN.**

**Total assay  
running time**



Small footprint bench-top platform



Manufacturing suite compatible  
fan-less operation



24/7 accessibility



Plug-&-play



Minimal maintenance  
and no calibration



1 hour setup and operator  
training



# Cartridge-Based Assays

COMPACT MICROFLUIDICS. COMPREHENSIVE QC.

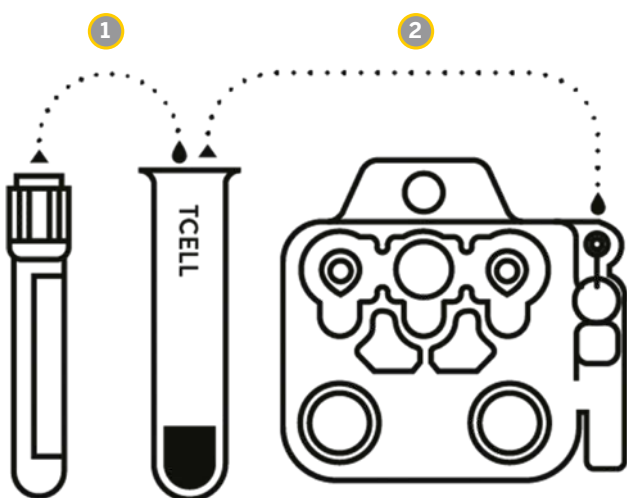
Accellix assays include a microfluidic cartridge and unitized dried down reagents allowing for automated sample preparation, increasing reproducibility and accuracy by reducing manual handling.

## KEY BENEFITS

- Sample preparation in a single-use, microfluidic cartridge.
- Room temperature stable dried down reagents.
- Compatible with various sample types and conditions.
- Wide sample concentration range
- Minimal sample volume
- No cross-contamination
- Reduces workflow time by automating manual steps



## SAMPLE ASSAY WORKFLOW



- 1 Pipette cells from sample tube into reagent tube
- 2 Pipette sample from reagent tube into assay cartridge

## AVAILABLE KITS

### CUSTOMIZED ASSAYS

Accellix will work with your team to engineer customized assays tailored to your unique targets.

### LYMPHOCYTE SUBSET ASSAYS

Accellix Lymphocyte Subset assays are used to enumerate T cell, Monocyte, B cell, and NK cell populations.

### T CELL SUBSET ASSAYS

Accellix T Cell Subset assays are used to enumerate common T Cell populations.

### STEM CELL ASSAYS

Accellix Stem Cell assays are used to enumerate hematopoietic progenitor cells.

# User Friendly Software



## PLUG-AND-PLAY USER INTERFACE

Touchscreen interface with customizable features

### ON-BOARD COMPUTER EXECUTES PROTOCOL

- Sample preparation.
- Data acquisition.
- Analysis.

### RESULTS DISPLAYED AND FILES GENERATED AT PROTOCOL CONCLUSION

- On-screen reports.
- Results summary pdf.
- Raw data fcs and csv files.

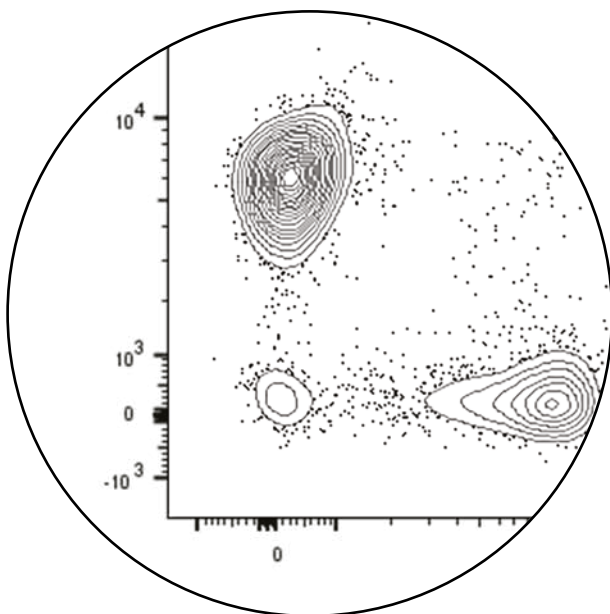
### ENSURES TRACEABILITY

- Compliant with 21 CFR part 11.
- Features include Login credentials, timed lockout and more.

### LIMS CONNECTIVITY



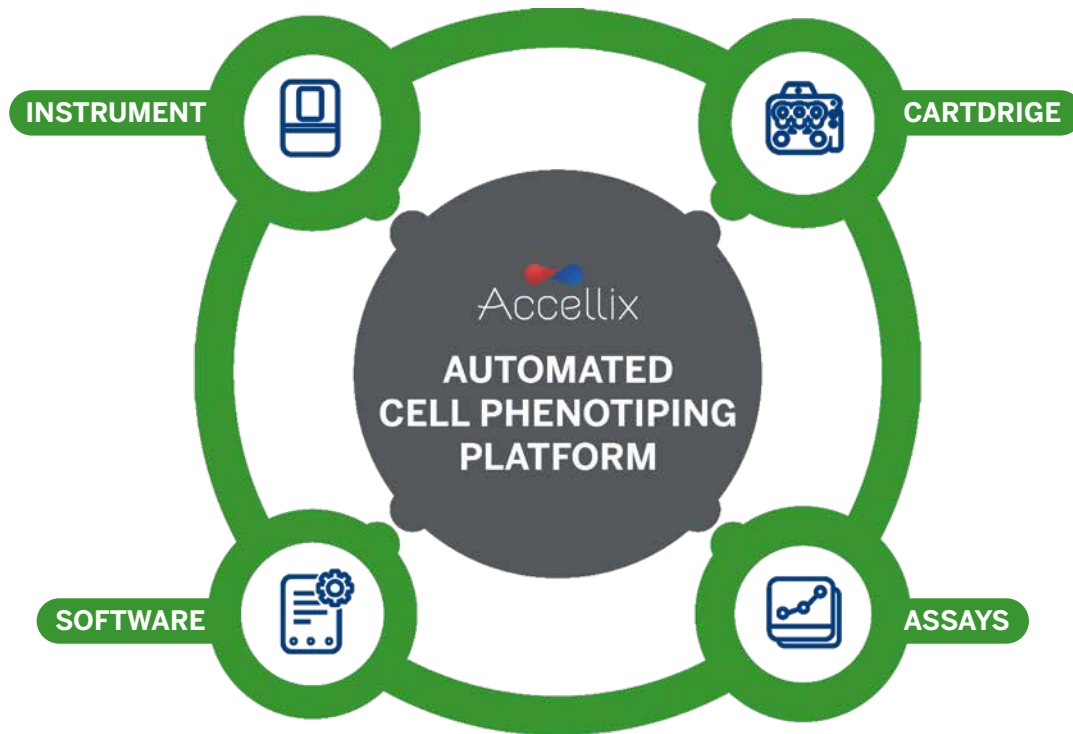
Name	Value
Classification type	General
Viable CD45+ / CD45+ [%]	33.70
CD3+ / Viable CD45+ [%]	67.81
CD4+ CD8- / Viable CD45+ [%]	43.37
CD4- CD8+ / Viable CD45+ [%]	20.80
CD4- CD8- / Viable CD45+ [%]	3.10
CD4+ CD8+ / Viable CD45+ [%]	0.40
CD45+ [cells/mL]	3736654
Viable CD45+ [cells/mL]	1257895
Viable CD3+ [cells/mL]	851128
Viable CD4+ CD8- [cells/mL]	545489
Viable CD4- CD8+ [cells/mL]	261654
Viable CD4- CD8- [cells/mL]	38722
Viable CD4+ CD8+ [cells/mL]	5263
Total Beads Count	1330
uL Sample Run	5.3



## ALGORITHM-BASED AUTOANALYSIS

- Fully automated data analysis and auto classification process tailored to customer's needs.
- Increase reproducibility and eliminate subjectivity.
- Free up critical staff to perform other tasks.

# Cell Therapy Quality Control is critical. It doesn't have to be difficult.



## CELL PHENOTYPING ON DEMAND

Stringent process controls are needed to monitor critical parameters throughout the cell therapy manufacturing process. These laborious tests are challenging to scale.

The Accellix Automated Cell Phenotyping Platform eliminates these limitations and automates your entire QC workflow from sample preparation to data analysis, generating rapid cell phenotyping results directly in the manufacturing suite.

## SOME CHALLENGES IN CELL THERAPY QC INCLUDE:

- Complex sample and reagent preparation
- Limited numbers of highly skilled technicians
- Costly maintenance
- Highly variable manual analysis
- Large footprint in a dedicated QC space



# Accellix Automated Cell Phenotyping Platform

## CAPABILITIES

### STANDARD & CUSTOMIZED KITS

- 6-color assay panels
- T Cell Subset panels
- TBNK (T/B/NK cells & monocytes) panels
- N-1/N-2 test kits (liquid conjugated antibodies added by user)
- Stem Cell panels
- Custom drug release assays
- Custom characterization assays

### SAMPLE TYPES & CONDITIONS

- Whole blood, apheresis, purified cells
- Differential RBC lysis or non-lyse
- Sample concentration range of 1-50+ million cells/mL
- Sample volume: 10-25 uL
- Adjustable sample dilution and acquisition time in cartridge

### INSTRUMENT

- Dimensions: 37x23x51 cm
- Weight: 13.5 kg
- Electrical requirements: 100-230 V AC, 50/60Hz
- Operating environment: Ambient temperature

### OPTICS

- Excitation laser: 488nm laser diode
- Fluorescence detector: High-performance SiPM (silicon photomultiplier) array
- Fluorescence detection range: 510-800 nm

### SOFTWARE

- Accellix custom software runs on an embedded PC
- Output: On-screen reportables; results summary PDF, raw data FCS and CSV files
- 21 CFR part 11 compliant

## THE ACCELLIX MISSION

To provide quick and accurate flow cytometry results in a compact and easy-to-use platform designed for use on the manufacturing floor and at the point-of-need.

The Accellix platform enables its partners in the field of cell therapy to meet their critical quality control requirements as they advance life-changing therapies benefiting patients worldwide.

The Accellix team is an interdisciplinary group with deep experience in all aspects of the platform. Accellix is headquartered in San Jose CA, USA, with additional offices in Jerusalem, Israel and a growing network spanning several continents to serve our EMEA and APAC customers.

Accellix is the legal manufacturer of the Accellix solution (instrument, cartridges and software). bioMérieux and Accellix have a strategic partnership for co-distribution.