

**Countstar**  
Smart Cell Analysis



Countstar  
**Mira FL Plus**  
Fluorescence Cell Analyzer

# Countstar Mira FL Plus

Countstar Mira FL Plus fluorescence cell analyzer integrates AI-learning algorithms and patented fixed-focusing technology to realize accurate identification of cell characteristics. Through its intuitive interface and comprehensive suite of predefined applications, Mira FL Plus simplifies routine and advanced assays, including cell concentration and viability measurement using Trypan Blue or AO/PI staining method, and GFP/RFP transfection efficiency analysis. The operating system provides full audit trail and secure data management, meeting all FDA 21 CFR Part11 and GMP requirements.

## Intelligent, Easy to Use, Secure, and Compliant

- 1 Advanced imaging technology ensures clear, high-resolution images**
  - 8.3-MP cooled CMOS camera and high-performance optical lens provides high fluorescence sensitivity
  - Innovative "fixed focus" technology eliminates manual focusing
  - Enlarged field of view improves statistical accuracy
- 2 Powerful AI-learning image recognition algorithms ensure accurate results of both routine and complex image data**
- 3 Intuitive user interface with expandable applications simplifies routine assays and meets new challenges**
  - A comprehensive suite of pre-installed assay templates (BioApps) simplify routine operations, such as cell counting, Trypan Blue or AO/PI cell viability analysis, and GFP/RFP transfection efficiency analysis on common cell types.
  - Multi-dimensional data analyses are automatically performed for comprehensive review of experimental results.
  - New applications can be easily developed for challenging assays, allowing user to expand application scope into new frontiers.
- 4 Elegant and compact design saves lab space**
- 5 Mira FL Plus is fully compliant with the requirements of FDA 21 CFR Part11 and cGMP**

A complete 3Q verification scheme is available.



# CORE FEATURES

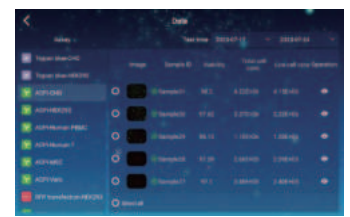


- All-in-one design
- Glove-sensitive 8 inch HD screen
- Compact (9.45 x 8.66 x 11.22 inches)

- Intuitive user interface
- Comprehensive suite of pre-installed BioApps for common cell types and assays
- Customizable BioApps



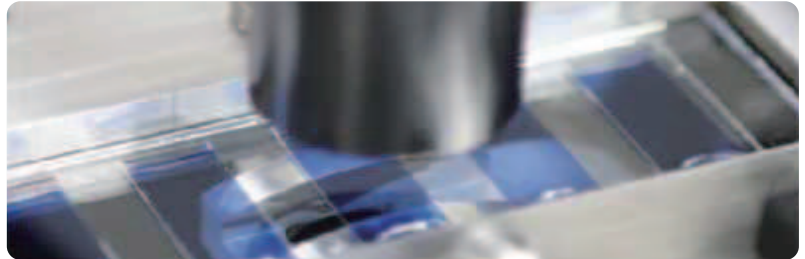
- Up to 5 samples in a single test cycle
- 20µL sample per analysis
- Automatic data analysis



# Advanced Imaging Technology Captures Clear, High-Resolution Images

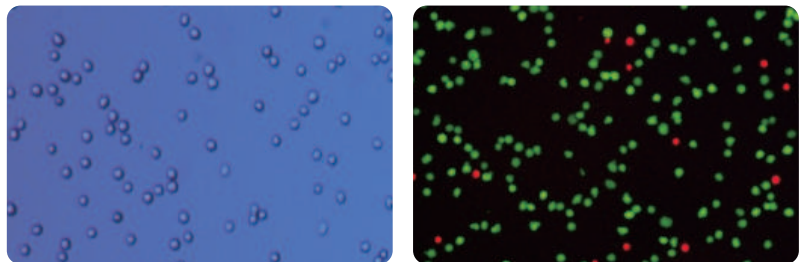
## ✦ Innovative fixed-focus technology

Eliminates experimental errors associated with manual focusing and insufficient auto-focusing.



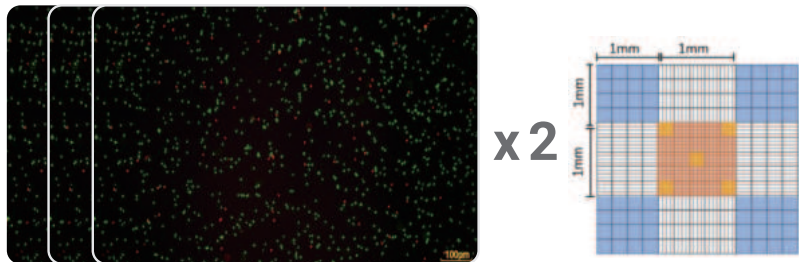
## ✦ High-definition optics

The 8.3-MP CMOS camera provides high optical resolution and sensitive fluorescence detection, captures detail-rich high-resolution images.

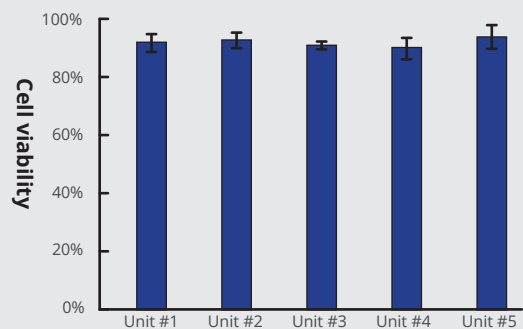
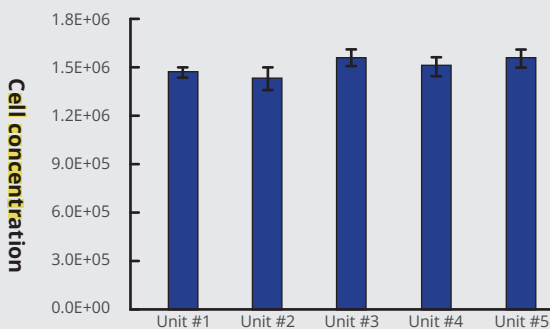


## ✦ Expanded field of view

The view field area is about twice that of a standard hemocytometer, increasing the number of cells detected and reducing counting error.



## Highly reproducible results across multiple units with CV < 5%

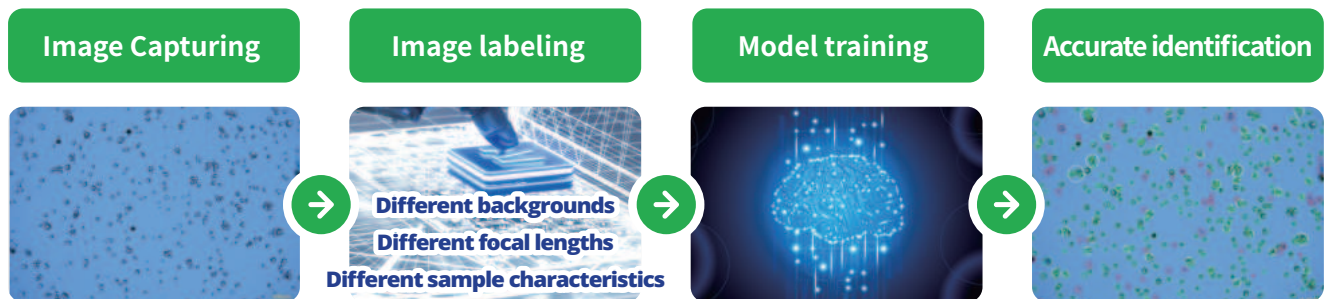


The same sample was analyzed on 5 Mira FL Plus instruments with 5 replicate analyses on each instrument. The CV values of measured cell concentrations and cell viability rates are <5% on each instrument and among the five units.



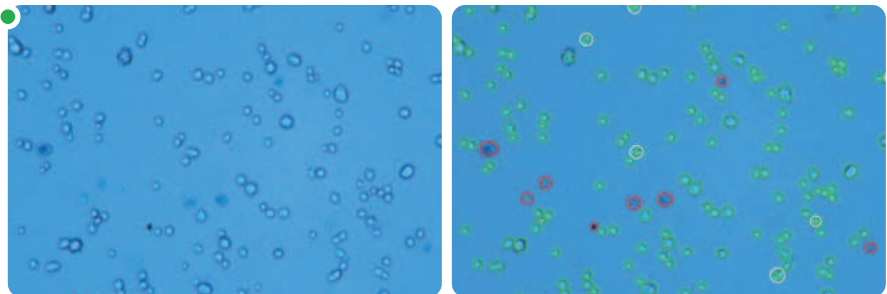
# AI-learning Algorithms for Accurate Image Processing

Countstar Mira FL Plus adopts artificial intelligence (AI) deep learning algorithms, uses multiple cell features to accurately analyze samples that are challenging for traditional cell analyzers. As shown in the figures below, cells with irregular shapes, aggregations or uneven sizes are accurately identified and analyzed, ensuring the generation of accurate results.



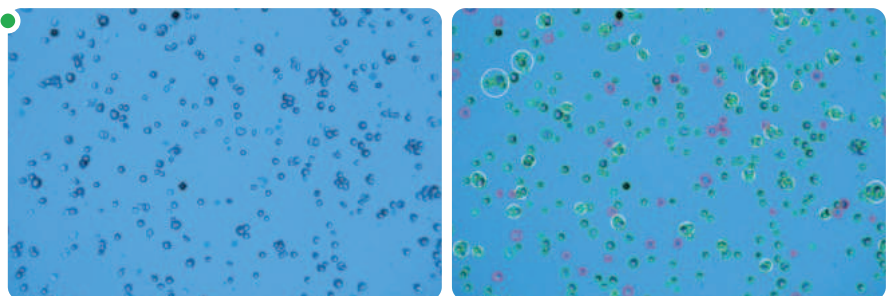
## Recognition of Mesenchymal Stem Cells with irregular morphology

- green circles indicate living cells
- red circles indicate dead cells
- white circles indicate aggregated cells



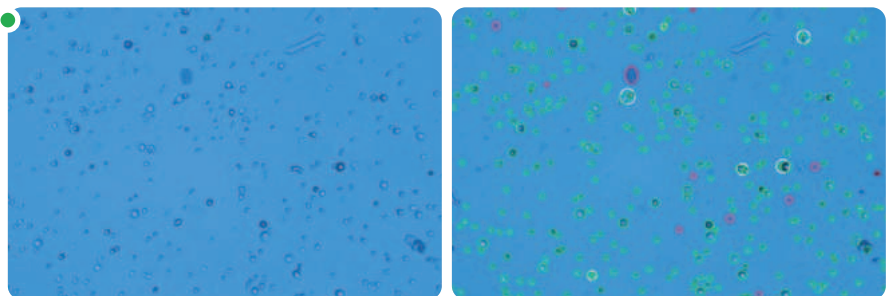
## RAW264.7 cells are small and tend to aggregate. Mira FL Plus can identify aggregated cells and accurately count individual cells.

- green circles indicate living cells
- red circles indicate dead cells
- white circles indicate aggregated cells



## Mira FL Plus can accurately identify freshly digested zebrafish embryonic cells that have uneven single cell sizes.

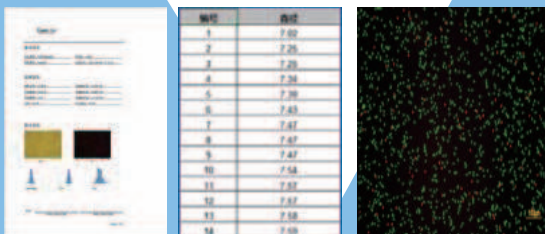
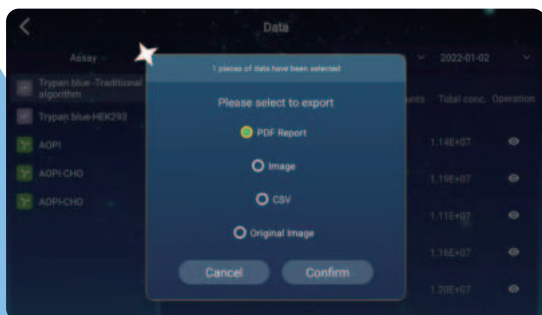
- green circles indicate living cells
- red circles indicate dead cells
- white circles indicate aggregated cells



# Comprehensive Multi-Dimensional Data Analysis Functions Simplify Result Evaluation

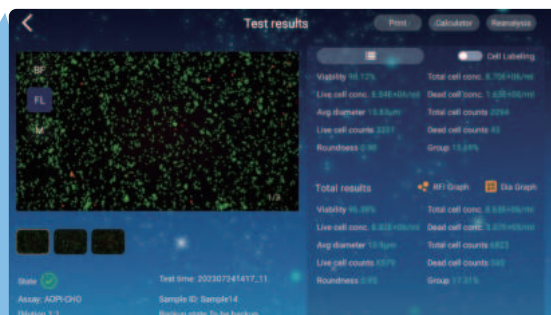
Countstar Mira FL Plus provides multiple data analysis tools beyond standard display of measured cell parameters such as cell concentration, viability, diameters, and aggregation. Diagrams, such as growth curve, diameter distribution, and fluorescence distribution, are automatically generated to help users quickly obtain deeper insight into their samples. Detailed reports with JPEG images can be generated in PDF or excel format.

## Multiple export formats



PDF, Excel Table, JPEG Picture

## Comprehensive data analysis tools



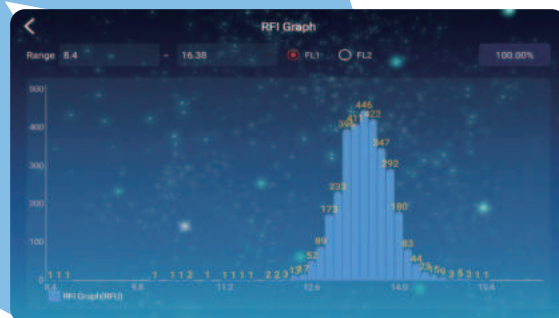
Clear display of data analysis results from multiple view fields



Growth curve



Diameter distribution histogram



Fluorescence distribution histogram



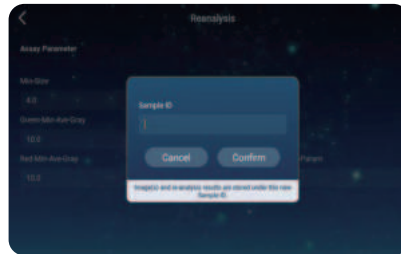
# cGxP Compliant Data Management

## Intelligent and Flexible Database Management Ensures Data Integrity and Security



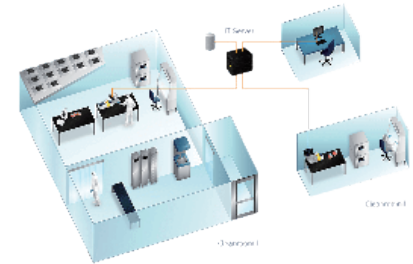
### Application-based Database Management

Test results are grouped by BioApp and ordered by time and Sample ID for easy retrieval.



### User Editing Management

Multiple user privileges can be defined to control data access and data editing privileges. Electronic signatures are required to edit or delete data. An audit trail is maintained to record all activities.



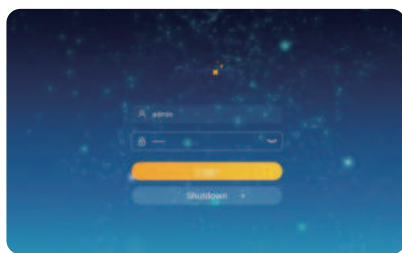
### Data Backup Strategies

Images and analysis results acquired on Mira FL Plus can be printed for hard copies through a network printer or backed up to an internal server in real time through local network, making your data "fool proof".

Local data backup can be performed either manually or automatically at scheduled time or during normal shutdown operations.

## Compliant Operation based on FDA and EMA guidelines

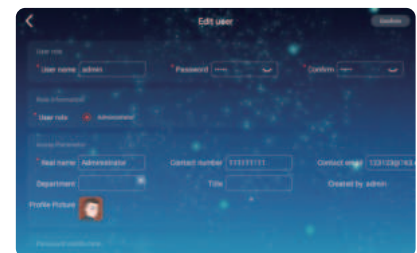
Mira FL Plus meets regulatory requirements of FDA 21 CFR Part11. The data management system provides password-controlled access with multiple user privileges and full audit trail record, ensuring data security and integrity. Complete 3Q service is customizable and performed by ALIT professional validation team.



Password-protected User Login System



Multiple Levels of User Privileges with Detailed Definitions



Electronic Signature and Audit Logs

A series of standard particle suspensions and comprehensive documents are provided to meet the needs of modern pharmaceutical production processes. A validation plan is available to meet IQ\OQ\PQ specifications.



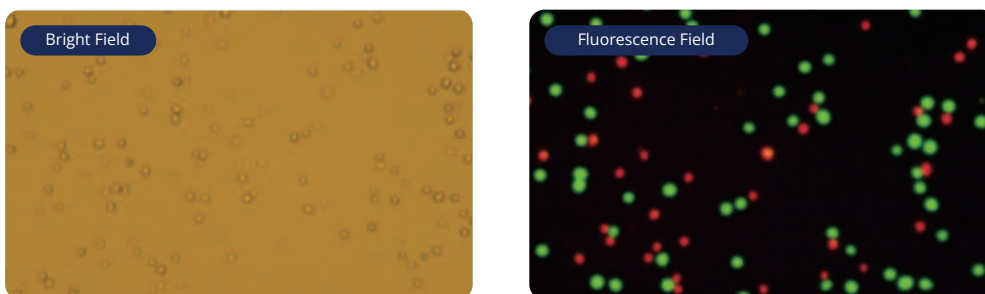


# APPLICATIONS

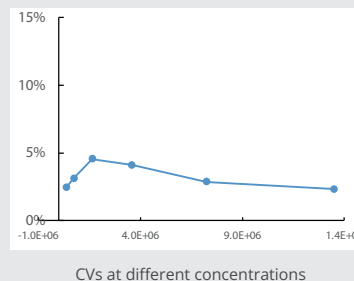
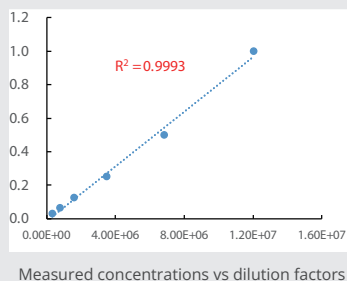
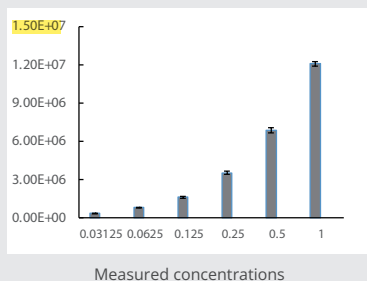
## AO/PI Dual Fluorescence Cell Density & Viability

The AO/PI dual fluorescence staining method provides more accurate results of cell density and viability than the traditional Trypan Blue and MTT methods. Acridine Orange (AO) and Propidium iodide (PI) are DNA binding dyes with different membrane permeability. AO is capable of permeating through an intact nuclear membrane, binding to the DNA of all cells in a sample and emitting green fluorescence at 525nm max when excited at 480nm. PI can only permeate through compromised cell membrane of dying or dead cells and emit red fluorescence at 615nm when excited at 525nm. When a dead cell with both AO and PI dyes in the nucleus is excited at 480nm, the emitting light of the AO dye is completely absorbed by the PI dye which then emits red fluorescence light at 615nm, ensuring single light emission. Additionally, it ensures that only nuclei containing cells will get stained in whole blood samples, allowing a fast and one-step cell titer and viability analysis of PMBCs even in the presence of erythrocytes.

### AO/PI dual fluorescence analysis of PBMC cells



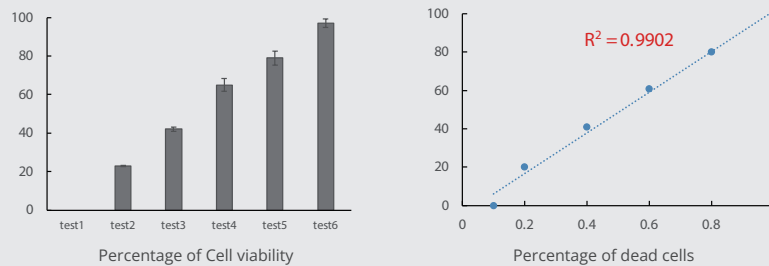
**Concentration gradient:** A total of 6 PBMC cell samples were prepared through serial dilution. Bright field images, green and red fluorescent images were acquired with 5 replicates for each sample. High reproducibility was observed with CV<5% across all concentrations (left and right panels). Excellent linearity was obtained with  $R^2$  of 0.9993, shown in the cell concentration vs dilution factor diagram (center panel).







**Viability gradient:** Dead PBMC cells, prepared with boiling water, were mixed with untreated cells with ~100% viability at ratios of 5:0, 4:1, 3:2, 2:3, 1:4, 0:5. Bright field images, green and red fluorescent images were acquired with 5 replicates for each sample using the AO/PI PBMC BioApp. The numbers of viable and dead cells obtained from the fluorescent images were used to calculate percent of viability. As shown in the histogram (left) and linearity plot (right), excellent accuracy, reproducibility and linearity were obtained.

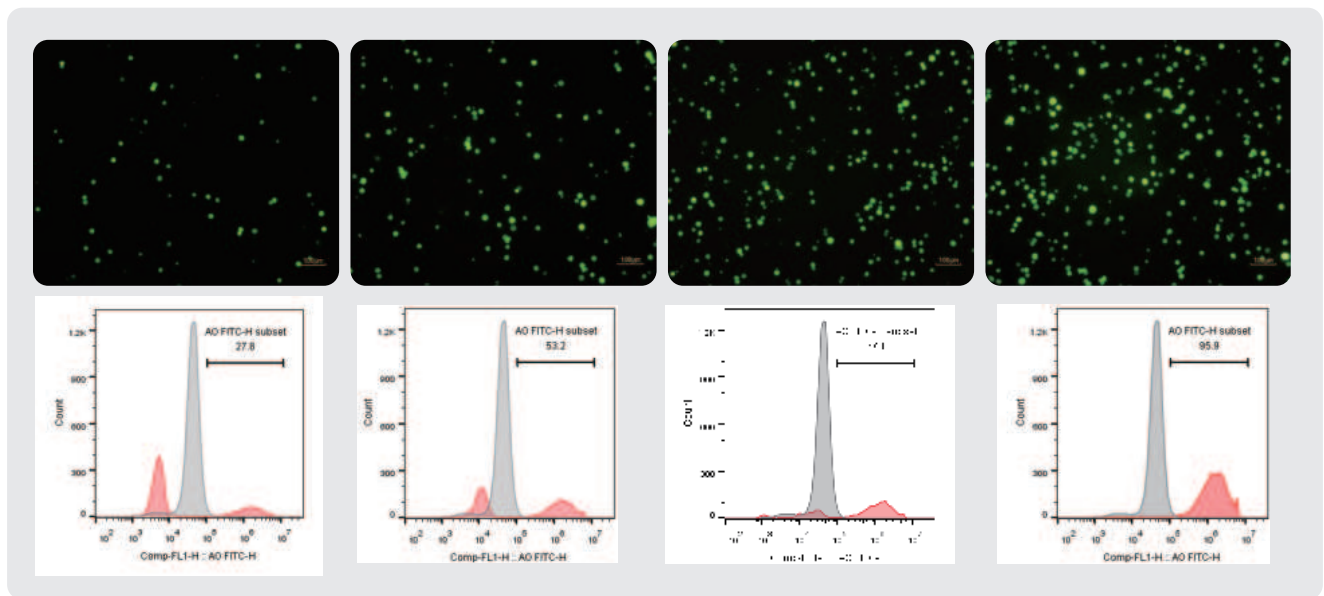


# GFP/RFP Transfection Efficiency Analysis

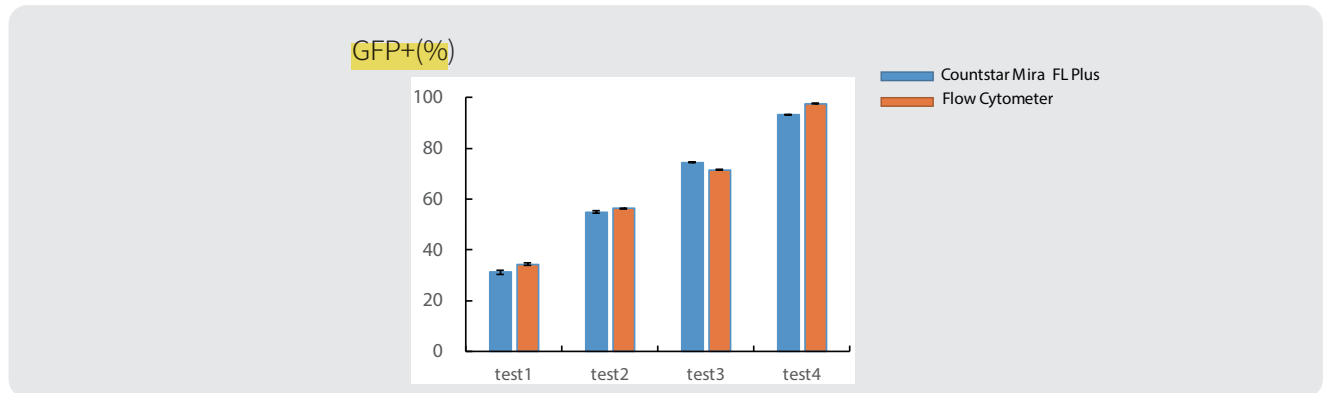
Transfection efficiency is a key factor in cell line development, viral vector development and production. Accurate and efficient quantitative analysis of the co-transfected fluorescent marker is essential in monitoring transfection efficiency, particularly in viral vector-based gene therapy. Mira FL Plus cell analyzer generates accurate transfection efficiency results that are comparable to those of flow cytometers, also provides detailed analyses of various cell characteristics through AI-powered image processing of both bright field and fluorescent images, greatly simplifying the assay to accelerate process development of cell and gene **therapies**.

the graph below should include title, larger font for Axes and axes label. the %GFP positive cells number should be clearly annotated.

## Accurate transfection efficiency analysis, visible proof of single cell transfection status



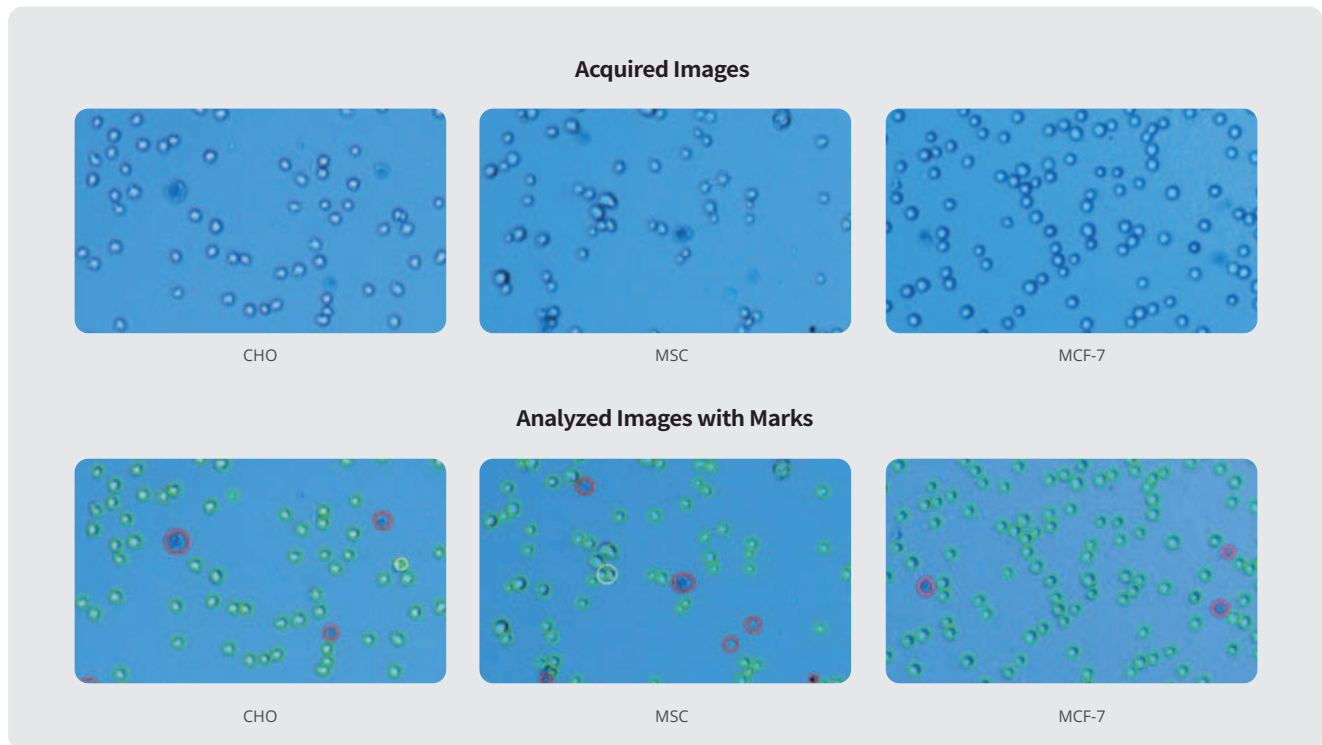
HEK293 cells transfected with GFP at different efficiency were analyzed both on Mira FL Plus and a CytoFlex flow cytometer. Fluorescent images obtained on Mira FL Plus show increasing transfection levels from left to right. The transfection efficiency values calculated through AI-powered image processing on Mira FL Plus are consistent with those measured on a CytoFlex flow cytometer (shown below).



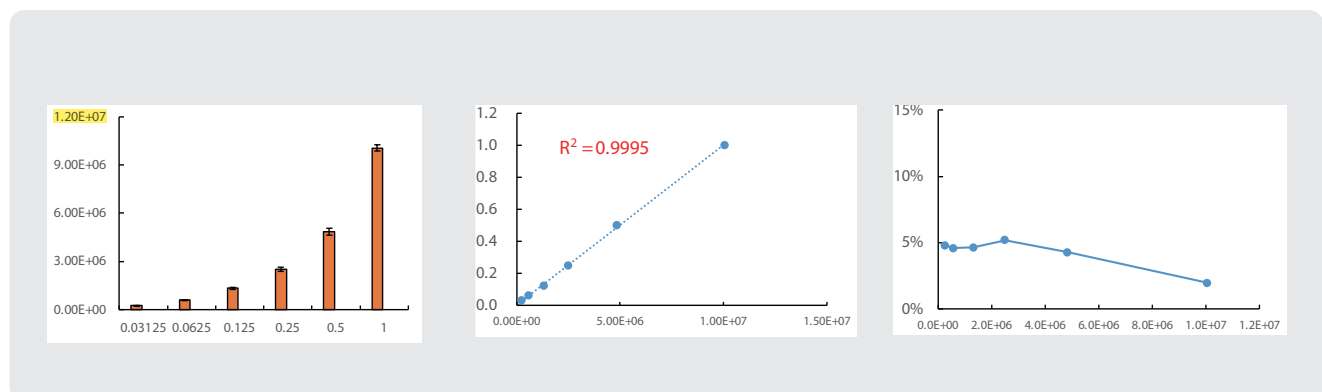
# Trypan Blue Cell Titer and Viability Analysis

The complexity of this assay increases when samples contain **different cell types or cells with various morphologies**. The AI-learning image processing algorithms on the Mira FL Plus can precisely detect all cells, even if the cells are aggregated or in unusual shapes.

## Bright field analysis of CHO, MSC and MCF-7 cells after Trypan Blue **staining**



**Gradient dilution experiment results of CHO cells:** A total of six CHO cell samples were prepared through serial dilution. After staining with 0.2% Trypan Blue staining reagent, bright field images were acquired with 5 replicates for each sample. High reproducibility was observed with CV<5% across all concentrations (left and right panels). Excellent linearity was obtained with  $R^2$  of 0.9995, shown in the cell concentration vs dilution factor diagram (center panel)



# Product Specification

<b>Cell diameter range</b>	1-180µm (optimal 8-60µm)
<b>Concentration range</b>	$1 \times 10^4$ - $3 \times 10^7$ cells/mL
<b>Optimal concentration range</b>	$5 \times 10^5$ - $1 \times 10^7$ cells/mL
<b>Optical magnification</b>	5X
<b>Imaging element</b>	8.3 MP cooled CMOS color camera
<b>Single field analysis area</b>	2.8mm <sup>2</sup>
<b>Image resolution</b>	1920 × 1080
<b>Fluorescence channel</b>	Ex:465-485nm Em:535/40nm, 600LP
<b>USB Interface</b>	2 × USB2.0
<b>Storage capacity</b>	128GB
<b>Power input</b>	110-230V/AC, 50/60Hz
<b>Screen size</b>	8 inches
<b>Product weight</b>	8.82lbs (4kg)
<b>Product size (W × D × H)</b>	9.45 x 8.66 x 11.22 inches (240 × 220 × 285mm)

# Product Ordering Information

	Product Description	Product Name	Product No.
<b>Device</b>	Automatic Cell Fluorescence Analyzer	Countstar Mira FL Plus	IN050202(USA) / IN050203(EUR)
<b>Consumables</b>	Countstar chamber slides (50 tablets/box)		CO010101
	AO/PI staining kit (5mL or 25mL)		RE010212 / RE010213
	0.2% Trypan Blue staining kit (20mL)		RE010112

## ALIT LifeTech Inc.

Countstar series product is for research purposes only and is not approved for diagnostic operation.

