


Countstar® Altair

**Designed for the Daily Use in cGMP
Production Environment**





Countstar® Altair Automated Cell Analyzer



The Countstar® Altair is designed based on the classic Trypan Blue exclusion principle, integrating the advanced “fix focus” optical imaging bench, the most advanced cell recognition technologies, and software algorithms. Enable to get the information of cell concentration, viability, aggregation rate, roundness, and diameter distribution by one run.

To meet the **cGMP regulation**, Countstar®Altair software, equipped with a powerful data management function, offers a 4-level user access control feature, e-signatures, and log files, that is in compliance with the FDA 21CFR Part11 regulations.

For use in cGxP, process development, and research.
Not approved as medical device to date.



Development of Bioprocessing

Development of Bioprocessing

No matter if working in the antibody or vaccine industry, a reliable and efficient monitoring and analysis of the production machines, the cell cultures, is crucial for optimizing yield and product quality as even small changes in the bioprocess parameters can influence the performance of cell cultures.



Pharmaceutical Industry

Pharmaceutical Industry

The procedure of monoclonal antibodies production includes animal immunization, cell fusion, selection of hybridomas, detection of antibodies, cloning of hybridoma cells, cryopreservation, and mass production of monoclonal antibodies. Countstar® Altair complies with the cGMP regulations and can accurately and effectively detect the state of cells and ensure the production of antibodies.



Quality Control

Quality Control

Stem cell therapy is one of the most promising medical therapies in the 21st century. From stem cell isolation, culture to reinfusion, cell concentration and cell viability must be monitored in the whole stem cell treatment process. Countstar® Altair provides a regularly compliant solution for quality control of stem cell therapy in preparation for effective detection of stem cell status.

Countstar® Altair Automated Cell Analyzer

Technology

- All-in-one Design, Integrated Computer
- Automatic, Fast and Easy to Use



Simple

Sensitive 10 inch Touchscreen Interface, allows the user to operate even with protective gloves.

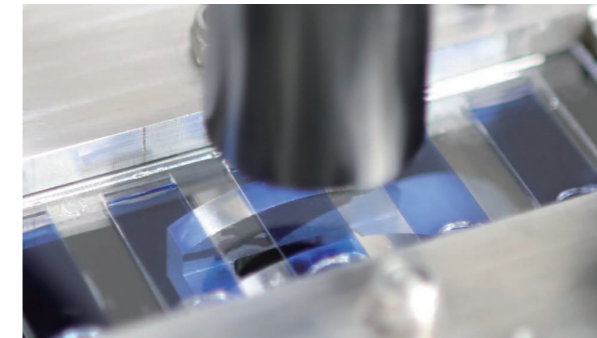
High Throughput

Analysis of up to 5 different samples in one single test sequence within 150 seconds.



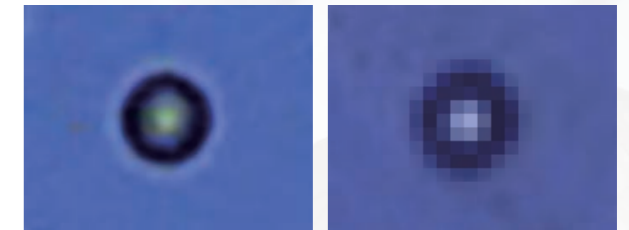
- Accurate and High Reproducibility Analysis Result

Unrivaled "Fixed focus" Patent



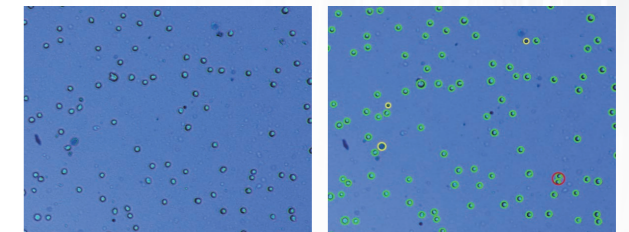
The Countstar® Altair contains an optical bench based on our "fixed focus" patent. There is no need for the user to focus under any circumstances: replacing the slide, changing the sample slot, different regions of interest selected. Results are highly reproducible and an interference by the operator is excluded.

5-Megapixel Color Imaging Technology



Countstar® Altair zoom in

Our Protected Image Recognition Algorithms

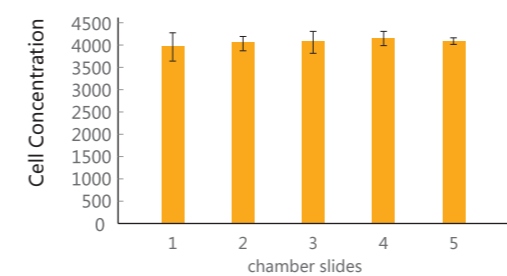


Extensive Observation Area

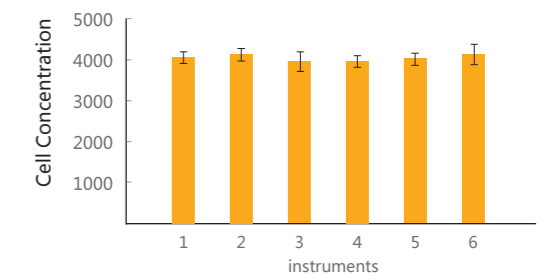
Leads to higher statistical accuracy in each single analysis. At a cell concentration of 1×10^6 cells / mL, the Countstar® Altair automatically analyses a total of 2610 cells in 3 field. In a comparable with a hemocytometer, in the 4 squares area normally only 400 cells are captured.

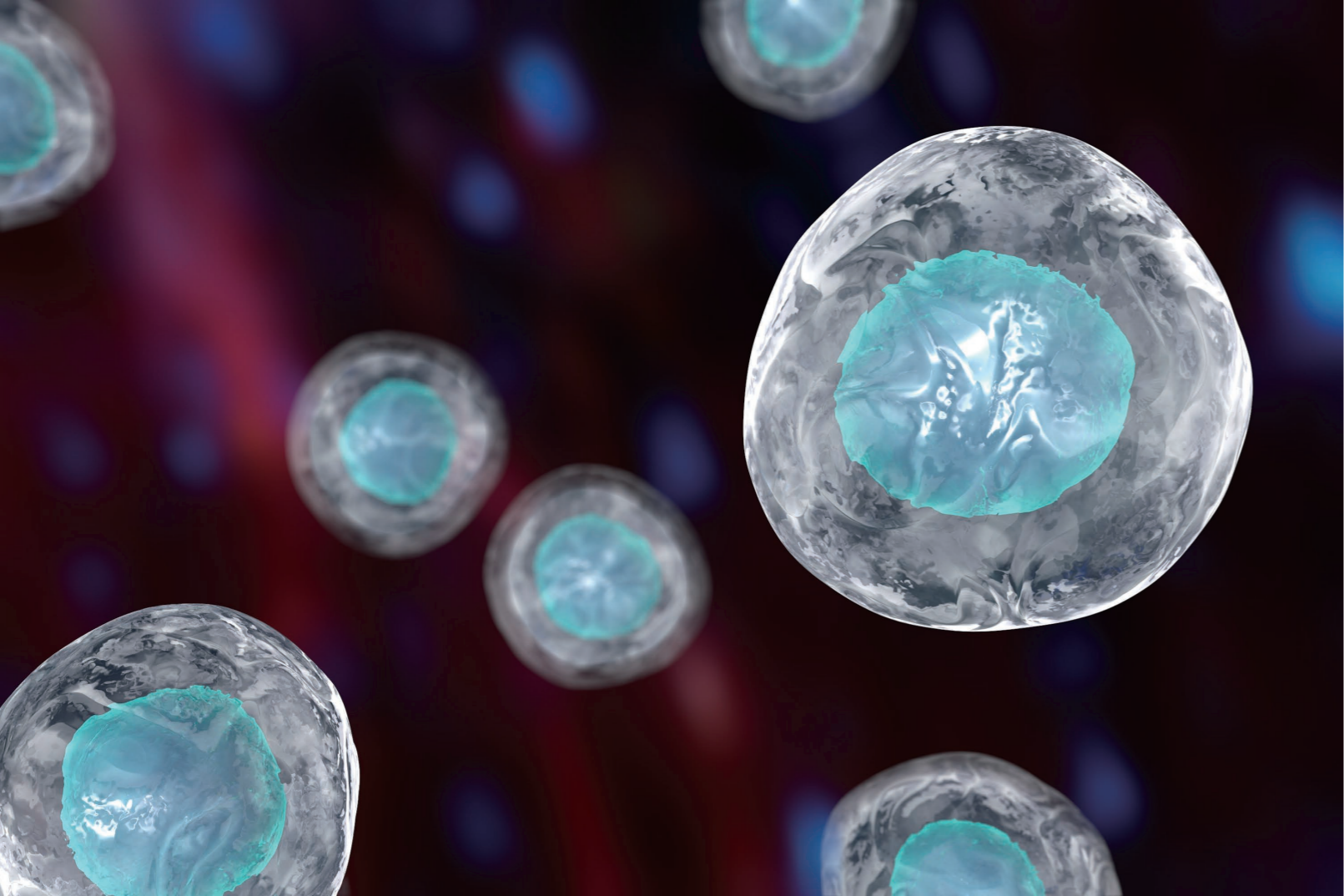
High Stability

Cell concentration stability test between 5 chamber slides CV<5%



Cell concentration stability test between 6 instruments CV<5%

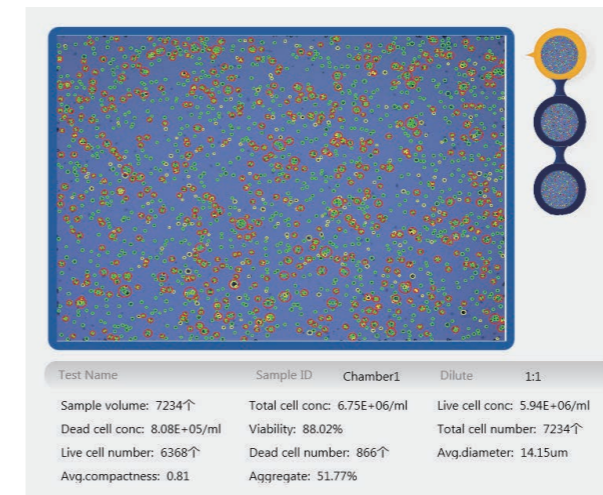




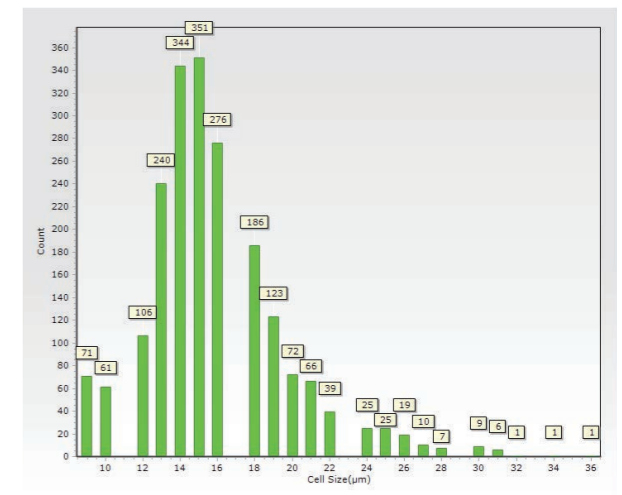
Countstar® Altair Automated Cell Analyzer

Technology

• Overview of All Sample Information



Overview of data



Diameter Distribution Histogram

• User-friendly, Easy-to-learn and Flexible Software

APP-like management, free to add experiment assay for different operators.



Product Parameters

Diameter range	3 μ m to 180 μ m
Concentration range	1 \times 10 ⁴ to 3 \times 10 ⁷ /ml
Objective magnificatio	2.5x
Imaging element	5-megapixel COMS camera
USB	1 \times USB3.0 1 \times USB2.0
Storage	500GB
RAM	4GB
Power supply	110–230 V/AC, 50/60Hz
Screen	10.4 inch touchscreen
Weight	13kg (28lb)
Size(W \times D \times H)	Machine: 254 \times 303 \times 453mm Package: 430 \times 370 \times 610mm
Operating temperature	+10 $^{\circ}$ C to +40 $^{\circ}$ C
Working humidity	20% to 80%

Countstar® Altair Automated Cell Analyzer

Data Management

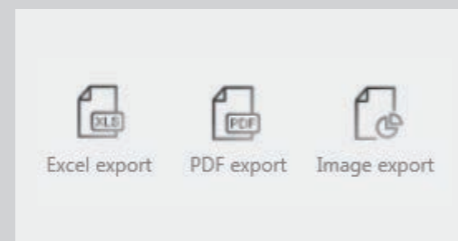
The Countstar® Altair database has a very intelligent and user-friendly design that gives users maximum flexibility and ensure the reliability the traceability of results.

Data Storage



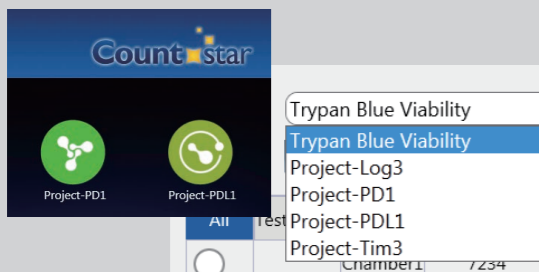
Countstar® Altair has 500GB of memory that allow you to store more than 160,000 samples of data.

Data Output



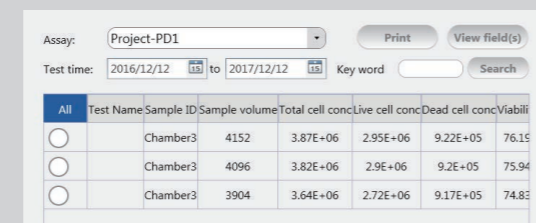
Flexible data output formats, including PDF, EXCEL, JPEG with USB2.0 & 3.0 external ports.

Multi-project Data Management



Data can be classified base on experiment assay/project by adding a new experiment program. New test result will automatically save to database under the defined assay/project, so that can help you easily organize the data and quickly access to the data you need.

Data Searching

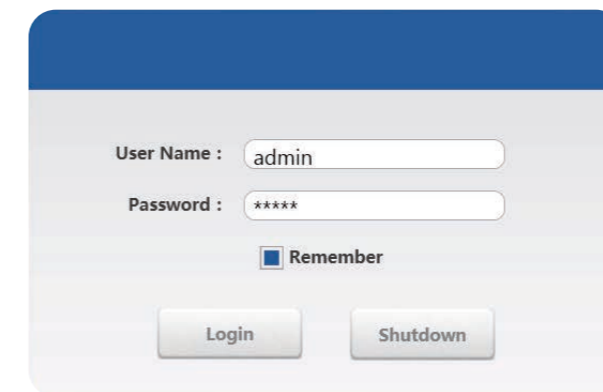


Data can be searched by assay/project name, date, and keywords. And the retrieved data enable to be viewed, printed and exported.

Countstar® Altair Automated Cell Analyzer

FDA 21 CFR Part11

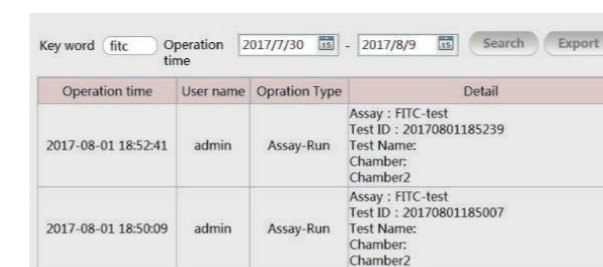
To meet the requirements of cGMP regulated environments, the software of the countstar® Altair is complied with FDA 21 CFR part 11.



User Login System



4-level Access User Management



E-Signature and E-Record

Countstar® Altair Automated Cell Analyzer

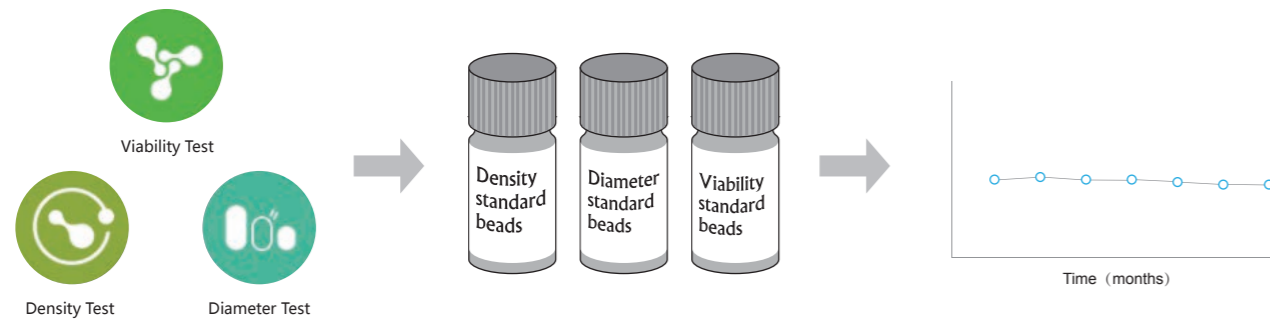
Standard Particles and IQ/OQ/PQ Service



To meet the requirements of cGMP regulated environments ALIT Life Science provides the verification documents to validate the Countstar® Altair in production processes.

The QA department of ALIT Life Science has established a comprehensive infrastructure to meet all the requirements for the a validation of their analyzer, from the instrument design process up to a final factory acceptance test, to guarantee a successful verification (IQ, OQ, PQ).

Instrument Stability Test(IST)



ALIT Life Science has established a comprehensive validation plan that test and monitor the stability and accuracy of the result of Countstar Altair to guarantee the data is reliable in the daily use.

ALIT Life Science has deigned a examination program(Instrument Stability Test, IST) to make sure that performance of instruments meet the requirements of cGMP regulatated environments. IST will examine and calibrate the instrument once in a period of time to prove that the result measured by this instrument remain accurate and stable after years of use.

Density Standard Beads

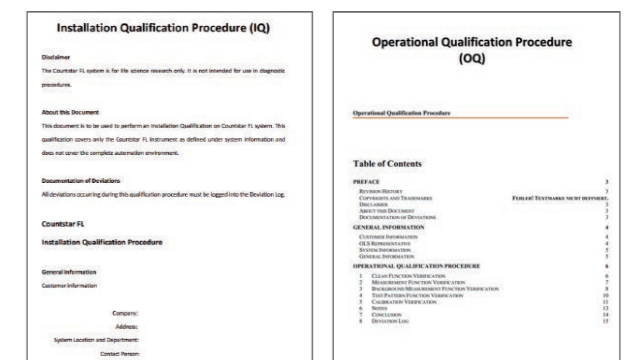
- Use to calibration of concentration to ensure data quality.
- Ensure accuracy and stability of measurement.
- Comparable results between different Countstar® Altair instruments and samples.
- 3 different standard of Density Standard Beads are available: 5x10⁵/ml、 2x10⁶/ml、 5x10⁶/ml.

Viability Standard Beads

- Use to calibration of viability to ensure data quality.
- Ensure accuracy and stability of measurement.
- Comparable results between different Countstar® Altair instruments and samples.
- 4 different standard of Viability Standard Beads are available: 25%、 50%、 75%、 100%.

Diameter Standard Beads

- Use to calibration of diameter to ensure data quality.
- Ensure accuracy and stability of measurement.
- Comparable results between different Countstar Mars instruments and samples.
- 2 different standard of Diameter Standard Beads are available: 8 μm and 20 μm.



Order Information

Instrument

Product Name	Brand	Cat. No.
Countstar® Altair Cell Analyzer	Countstar	1169

Consumables

Product Name	Brand	Volume	Cat. No.
Chamber Slides	Countstar	50 slides/box	12-005-50

Kit

Product Name	Density	Volume	Cat. No.
Trypan Blue Solution	0.2%	20ml	19-0001

Density Standard Particle

Product Name	Density	Cat. No.
Density Standard Beads 1	5x10 ⁵ /ml	B0111
Density Standard Beads 2	2x10 ⁶ /ml	B0121
Density Standard Beads 3	5x10 ⁶ /ml	B0131

Viability Standard Particle

Product Name	Viability	Cat. No.
Viability Standard Beads 1	25%	B0311
Viability Standard Beads 2	50%	B0321
Viability Standard Beads 3	75%	B0331
Viability Standard Beads 4	100%	B0341

Diameter Standard Particle

Product Name	Diameter	Cat. No.
Diameter Standard Beads 1	8µm	B0211
Diameter Standard Beads 2	20µm	B0221

ALIT Life Science Co., Limited

Web: www.countstar.com

E-mail: info@countstar.com