

EVE™

Automatic cell counter



Counting with EVE, affordable automatic cell counting

Benchtop automatic cell counter, EVE!
No more manual counting!

EVE™

Automatic cell counter, with state-of-the-art optics provides image analysis for cell counting. The EVE™ is a benchtop size counter, designed to measure live, dead, and total counting, which gives us capability for viability with accuracy and precision.

Key features and benefits

Fine distinction of clumped cell

- An advanced analysis algorithm provides accurate results in clumped cell

Applicable for broad range of cell sizes and types

- From primary (tissue, blood) cell lines to stem cells

User friendly

- 7 inch LCD touch screen • Benchtop size • No maintenance needed

Data storage and analysis

- Stores 500 test results, transfers the data to PC using USB drive • Provided PC software will give you more in-depth analysis

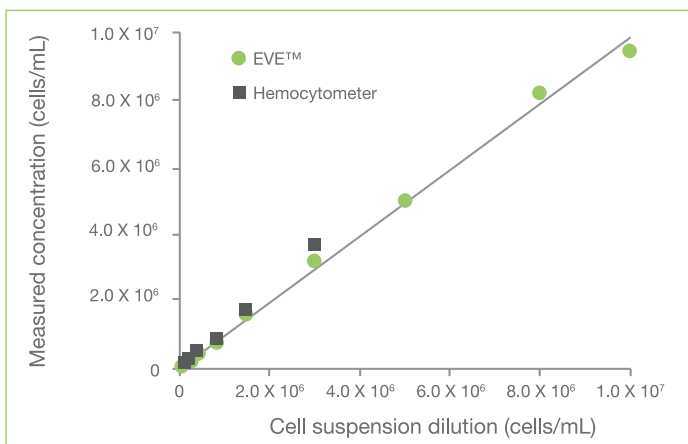
Cell size gating function

- Select range of cell size

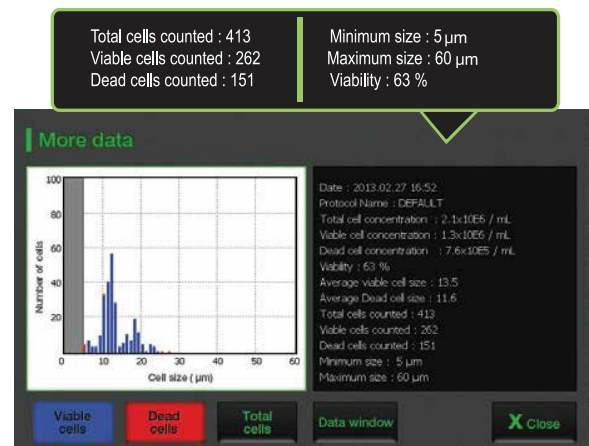
Convenient for use



Correlation of EVE™ and manual counting



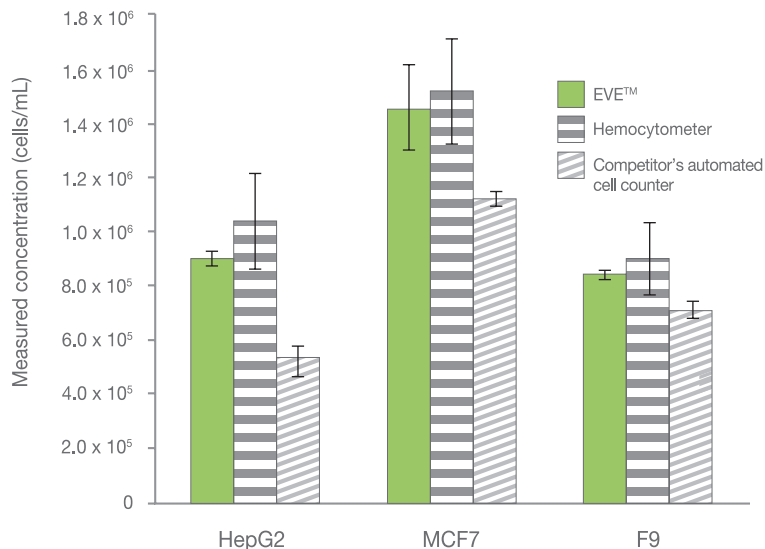
Measuring from the EVE™ extends further the high concentration range than hemocytometer readings



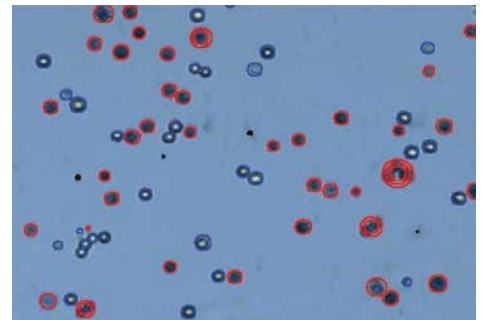
More data window to check the detail result and select the cell size gating

Faster! Accurate! Easy to use!

o Total cell counting result (Clumped cell)



The MCF7 breast cancer cell line can be clumpy. The EVE™ counting algorithm identifies and counts individual cells within these cell clumps for accurate analysis.



Clumped cells (HepG2, MCF7, F9) were counted with EVE™, a hemocytometer and the competitor's automated cell counter. In accuracy and precision, EVE™ is comparable to the hemocytometer for all cell lines. The competitor's cell counter was shown significantly less numbers in clumped cell. Cell counting results were obtained seven times repetition.

o Cell lines validated on EVE™

| Cell Type | Animal | Organ | Growth Properties |
|-----------|--------|-----------------|-------------------|
| HeLa | Human | Skin | Adherent |
| NIH-3T3 | Mouse | Embryo | Adherent |
| U-2 OS | Human | Bone | Adherent |
| Jurkat | Human | Blood | Suspension |
| KG-1 | Human | Blood | Suspension |
| HepG2 | Human | Liver | Adherent |
| Hep3B | Human | Liver | Adherent |
| LNCaP | Human | Prostate | Adherent |
| SH-SY5Y | Human | Brain | Adherent |
| SCN2.2 | Rat | Brain | Adherent |
| F9 | Mouse | Embryo | Adherent |
| MCF7 | Human | Breast | Adherent |
| A549 | Human | Lung | Adherent |
| GH3 | Rat | Pituitary gland | Adherent |

o Specifications

| Item | Description |
|--------------------------------------|--------------------------------------|
| Counting time | < 20seconds |
| Cell measurement range (cells/mL) | 1x10 ⁴ -1x10 ⁷ |
| Optimal measurement range (cells/mL) | 1x10 ⁵ -4x10 ⁶ |
| Cell size range | 5-60 µm |
| Sample volume | 10 µL |
| Staining Method | Trypan blue stain |
| Display | 7" LCD touch screen |
| Exporter formats | JPEG (image), CSV(raw data) |
| Data export | USB drive |
| Dimensions | 27cm(w)x20cm(d)x19cm(h) |
| Weight | 2.1 kg (4.6 lb) |

o Ordering information

| Cat No. | Description | Contents |
|----------|---|--|
| EVE-MC | EVE™ Automatic cell counter | Main device, Power supply, USB drive, EVE™ Cell counting slide (50 slides) |
| EVS-050 | EVE™ Cell counting slide | 50 slides (100 counts) |
| EVS-1000 | EVE™ Cell counting slide | 1,000 slides (2,000 counts) |
| EVS-5000 | EVE™ Cell counting slide | 5,000 slides (10,000 counts) |
| EBB-001 | Test beads Concentration (avg.) 1.0 x 10 ⁶ | 1 mL |

EVE™



[website](http://www.nanoentek.com) www.nanoentek.com
[e-mail](mailto:sales@nanoentek.com) sales@nanoentek.com

FOR RESEARCH USE ONLY.
This product is not approved for diagnostic or therapeutic use.

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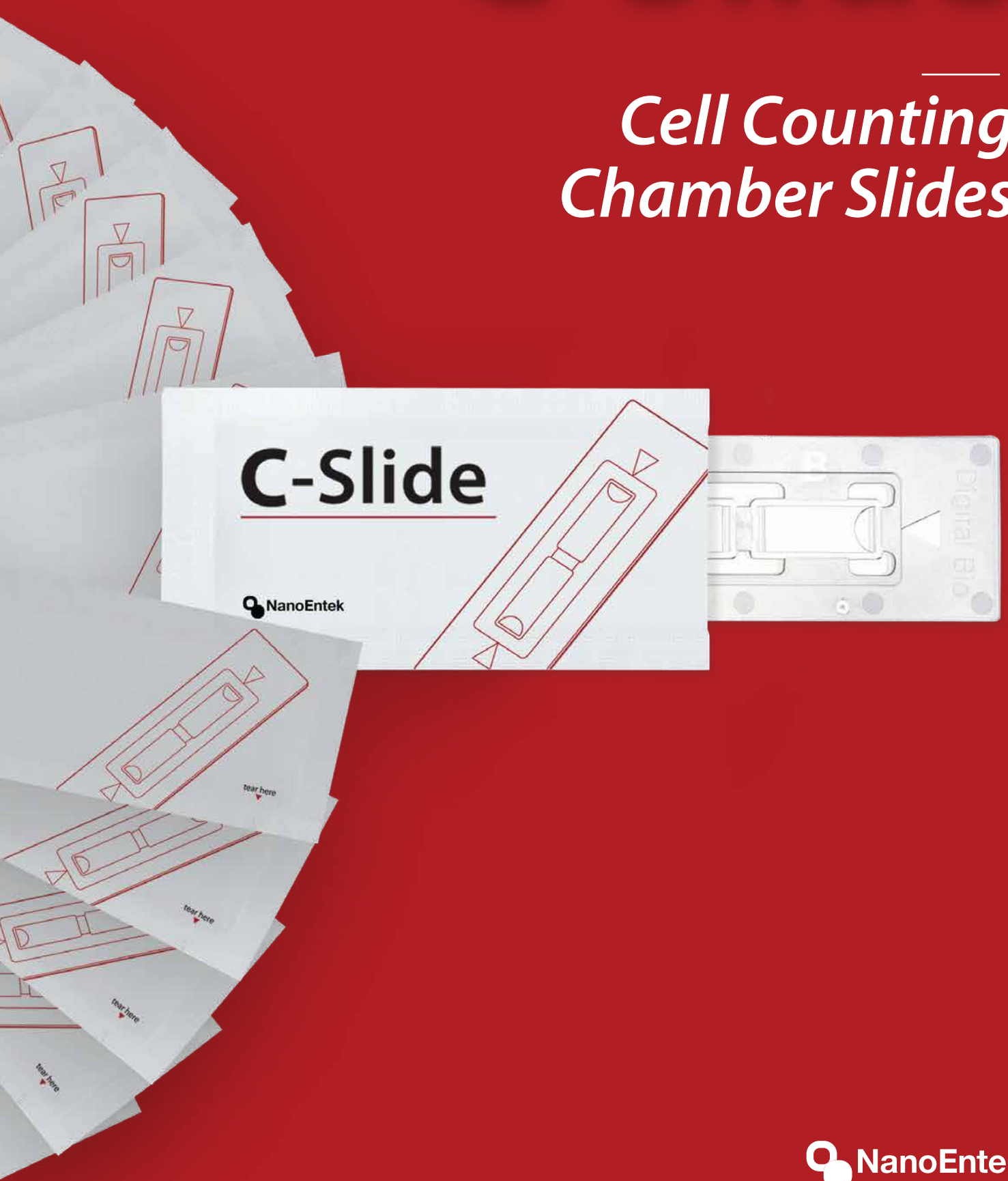
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CE

C-Slide

*Cell Counting
Chamber Slides*



C-Slide

Cell Counting Chamber Slide For Used With Automated Cell Counters

- No need for coverslips
- Disposable, eliminates the need for washing
- Reduce exposure to infectious samples and risk of contamination
- Guaranteed reproducibility and reliability
- Made of sturdy quartz grade optical plastic



Scan me



Specifications

Sample volume : 10 μ L

Staining method : Trypan blue stain

Dimension : 75 (L) x 25 (W) x 1.8 (H) mm

Ordering information

| Catalog Number | Product Name |
|----------------|--|
| CS-050 | C-Slide, Cell counting chamber slides 50 slides (100 tests) |



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NESCT-CS-001E (V.0.3)
FOR RESEARCH USE ONLY. Not for use in diagnostic procedures.

THE WORLD'S FASTEST AUTOMATED CELL COUNTER

LESS THAN 1 SEC!

EVE™ PLUS



EVE™ PLUS, Automated cell counter, with states-of-the-art optics provides image analysis for cell counting. The EVE™ PLUS is a benchtop size counter, designed to measure live, dead, and total counting, which gives us capability for viability with accuracy.

Key features and benefits

FAST

- Count less than 1 second

EASY

- Trypan blue staining method
- Auto focus, Manual focus
- Monitor to view the cell images
- Not required maintenance
- Small and compact (benchtop size)

ACCURATE

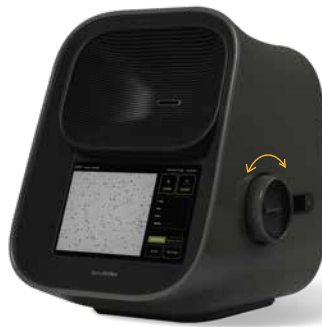
- Automated image analysis
- Count aggregated cell
- Cell size gating function (select range of cell size)
- Applicable for broad range of cell sizes and types

Convenient for use

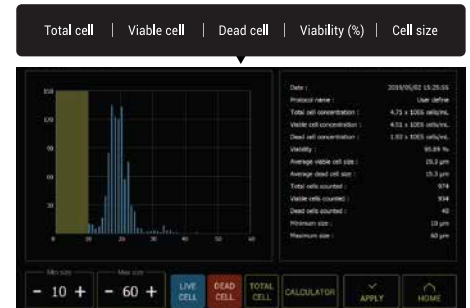
STEP 01. Load the sample



STEP 02. Adjust the focus

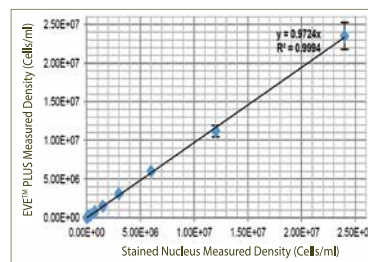
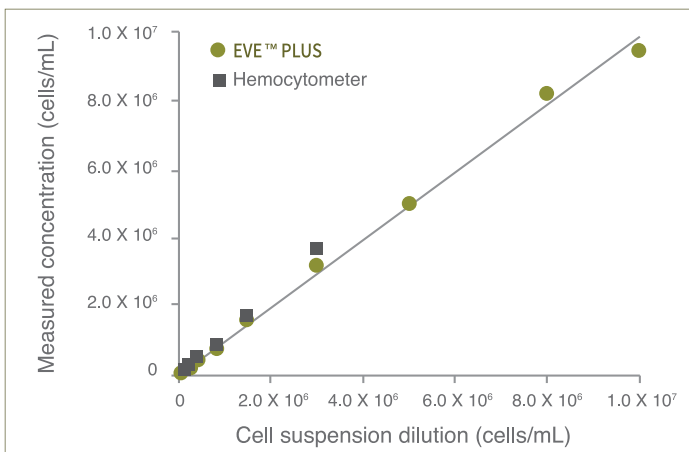


STEP 03. Get the results



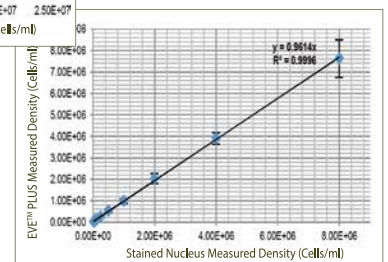
Results of Accuracy test

Measuring from the EVE™ PLUS extends further the high concentration range than hemocytometer readings



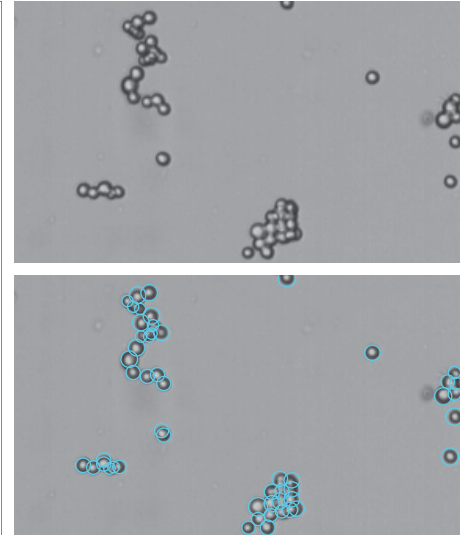
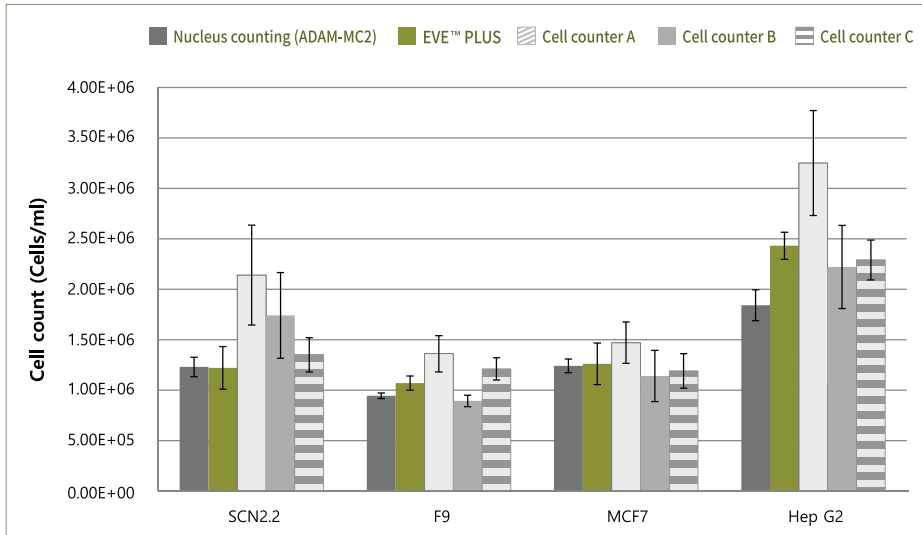
◀ Single cell

Clumped cell ▶



The World's Fastest Automated Cell Counter

Results of Correlation test (Clumped cell)



Clumped cells were counted with EVE™ PLUS, nucleus counting, and the automated cell counters A, B, C. NanoEnTek's ADAM-MC2 device was used for nucleus counting. It is accurate in clumped cells by counting the stained nuclei through the PI staining method. EVE™ PLUS is comparable to the nucleus counting for all cell lines with accuracy and precision. The other automated cell counters A, B, and C were shown inaccurate numbers in the clumped cell. EVE™ PLUS identifies and counts the individual cells within the clumpy cells for accurate analysis.

Cell lines validated on EVE™ PLUS

| Cell Type | Animal | Organ | Growth Properties |
|-----------|--------|-----------------|-------------------|
| HeLa | Human | Skin | Adherent |
| NIH-3T3 | Mouse | Embryo | Adherent |
| U-2 OS | Human | Bone | Adherent |
| Jurkat | Human | Blood | Suspension |
| KG-1 | Human | Blood | Suspension |
| HepG2 | Human | Liver | Adherent |
| Hep3B | Human | Liver | Adherent |
| LNCaP | Human | Prostate | Adherent |
| SH-SY5Y | Human | Brain | Adherent |
| SCN2.2 | Rat | Brain | Adherent |
| F9 | Mouse | Embryo | Adherent |
| MCF7 | Human | Breast | Adherent |
| A549 | Human | Lung | Adherent |
| GH3 | Rat | Pituitary gland | Adherent |

Specifications

| Item | Description |
|-----------------------------------|---|
| Counting time | <1 sec (Manual focus) <10 sec (Auto focus) |
| Cell measurement range (cells/mL) | 1 x10 ⁴ - 2x10 ⁷ |
| Cell size range | 5 - 60 μm |
| Sample volume | 10μL |
| Staining Method | Trypan blue stain |
| Display | Tablet PC |
| Exporter formats | JPEG(image), CSV(raw data), PDF |
| Data export | USB drive, Wifi |
| Dimensions | 27.4(w) x 23.3(d) x 27.4(h) cm |
| Weight | 4 kg |
| Technical support | provide remote assistance |

Ordering information

| Cat. No. | Description | Contents |
|----------|---|--|
| EVE-MC2 | EVE™ PLUS, Automated cell counter | Main device, Power supply, USB Wifi dongle, EVE™ Cell counting slide (50 slides) |
| EVS-050 | EVE™ Cell counting slide | 50 slides (100 counts) |
| EVS-1000 | EVE™ Cell counting slide | 1,000 slides (2,000 counts) |
| EBB-001 | Test beads Concentration (avg.) 1.0 x 10 ⁶ | 1mL |

EVE™ PLUS



FOR RESEARCH USE ONLY.
This product is not approved for diagnostic or therapeutic use.

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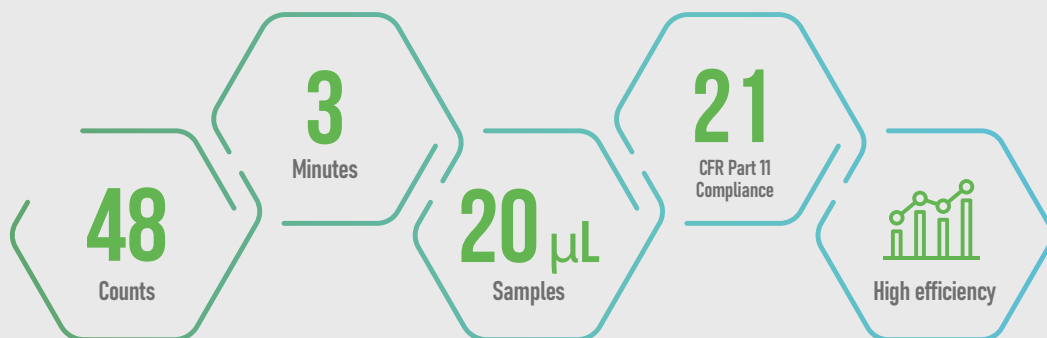
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A HIGH-THROUGHPUT AUTOMATED CELL COUNTER

EVE™ HT

AN IDEAL CELL COUNTER YOU CAN TRUST



EVE™ HT

A HIGH-THROUGHPUT AUTOMATED CELL COUNTER

Consistent results are essential

EVE™ HT is a high-throughput automated cell counter that can count 48 samples in just 3 minutes. EVE™ HT provides a perfect solution for cell line development and a large scale cell production.

Simple yet Sophisticated Cell Counter

EVE™ HT offer you a better cell counting method.

48 channels

Up to 48 samples at a time

EVE™ HT counting plate with 48 channels allows you to test up to 48 samples simultaneously.

3 minutes

Results in no time

EVE™ HT only takes 3 minutes to test one plate with 48 samples.

20 µL volume

Considering your valuable samples

Only 20 µL of sample volume is required for cell counts and viability.

High efficiency

Run different cell lines with one plate

A highly efficient disposable counting plate allows for different cell lines analysis using the same plate and provides multi test results.

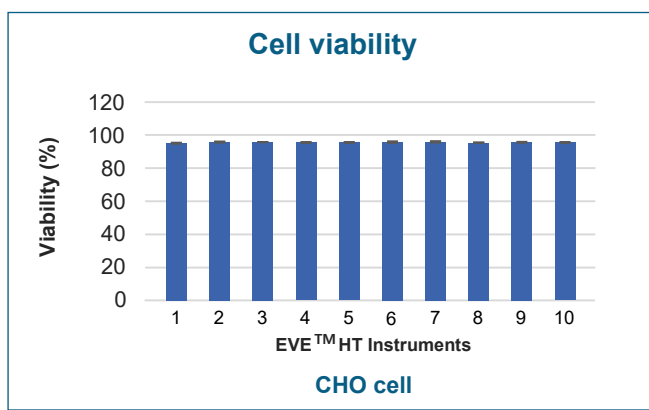
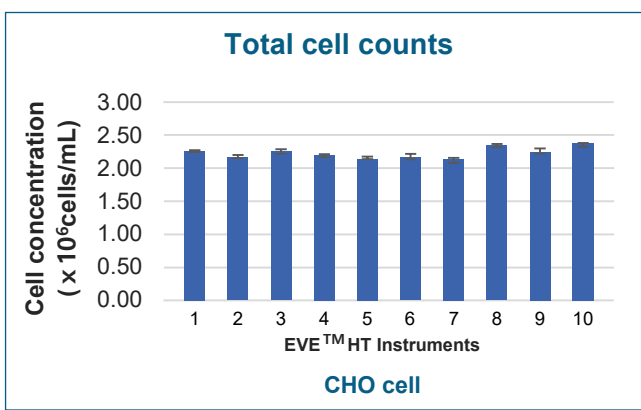


Disposable EVE™ HT assay plate

Manufactured with high precision, EVE™ HT plate provides time-saving workflow that is easy to use.

High multi-instrument precision for CHO cells

Multiple experiment data for total count and viability using ten EVE™ HT showed high device-to-device comparability.

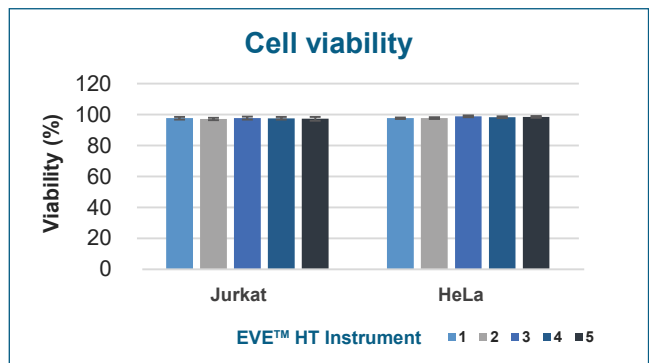
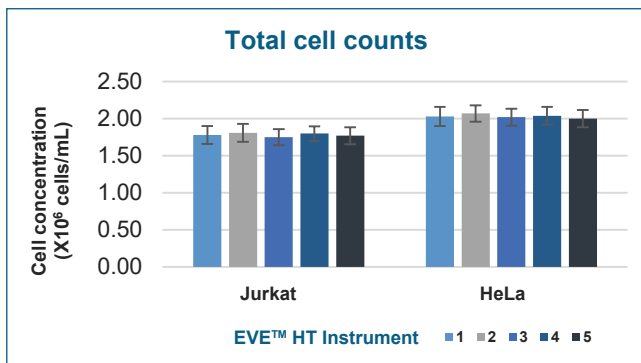


| EVE™ HT precision | Cell total count (CV) | |
|--------------------------|-----------------------|------|
| | Average | CV |
| Well to well | 2.18 × 10E6 | 4.3% |
| Plate to plate | 2.30 × 10E6 | 3.5% |
| Instrument to instrument | 2.31 × 10E6 | 0.5% |
| System-wide precision | 2.27 × 10E6 | 7.0% |

| EVE™ HT precision | Viability (CV) | |
|--------------------------|----------------|------|
| | Average | CV |
| Well to well | 97% | 0.9% |
| Plate to plate | 97% | 0.3% |
| Instrument to instrument | 96% | 0.4% |
| System-wide precision | 97% | 0.9% |

Low instrument-to-instrument variability

With five EVE™ HT, consistent results have been demonstrated across different instruments.

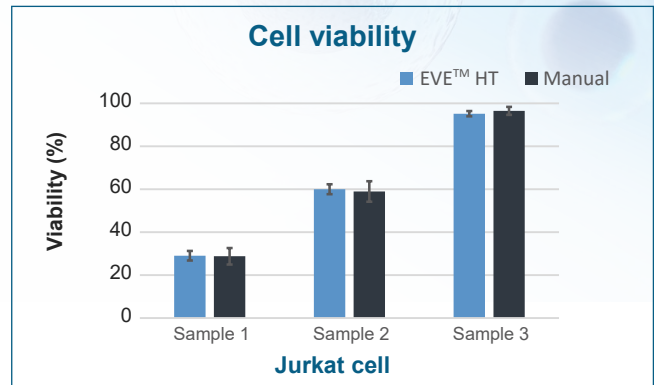
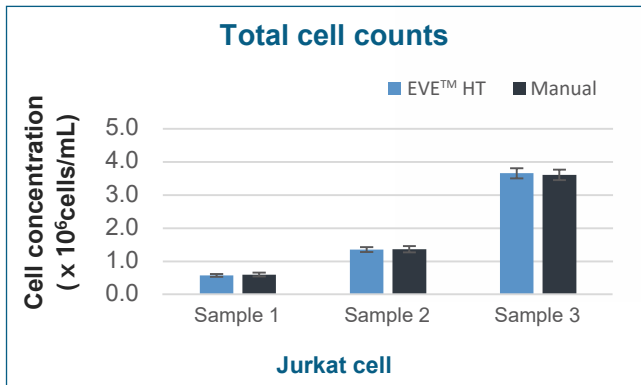


| EVE™ HT precision | Cell total count (CV) | |
|--------------------------|-----------------------|------|
| | Jurkat | HeLa |
| Well to well | 4.9% | 4.8% |
| Plate to plate | 2.4% | 1.2% |
| Instrument to instrument | 1.6% | 1.1% |
| System-wide precision | 6.3% | 5.9% |

| EVE™ HT precision | Viability (CV) | |
|--------------------------|----------------|------|
| | Jurkat | HeLa |
| Well to well | 0.7% | 0.6% |
| Plate to plate | 0.2% | 0.1% |
| Instrument to instrument | 0.4% | 0.5% |
| System-wide precision | 1.0% | 0.7% |

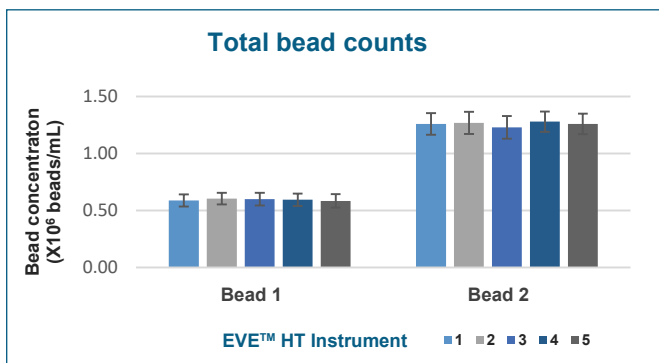
Comparison between EVE™ HT and manual counting

Compared to traditional hemocytometer, EVE™ HT provides highly compatible results in varying concentrations and viabilities.



High instrument-to-instrument consistency

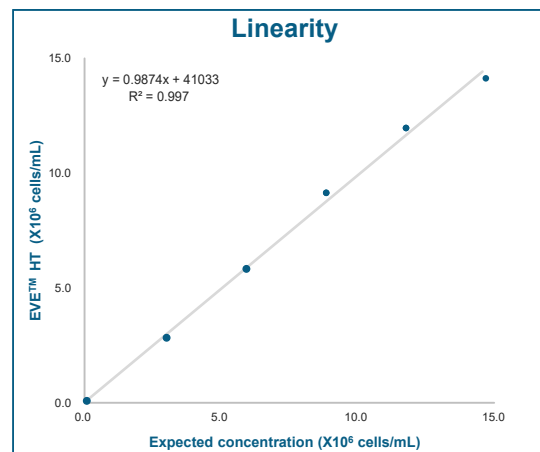
Beads solution stained with trypan blue was loaded into a total of 96 wells of two counting plates for analysis where each plate consists of 48 wells. The same sample was analyzed for comparison using a different instrument. As a result, high device-to-device comparability was shown.



| EVE™ HT precision | Bead total conc. (CV) | |
|--------------------------|------------------------------|------------------------------|
| | 5 x 10 ⁵ beads/mL | 1 x 10 ⁶ beads/mL |
| Well to well | 8.1% | 6.4% |
| Plate to plate | 0.4% | 0.8% |
| Instrument to instrument | 1.5% | 1.2% |
| System-wide precision | 9.2% | 7.6% |

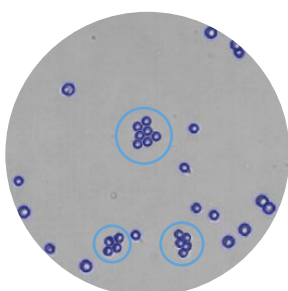
High linearity with expected concentration

Manual counting using hemocytometer was used to compare low and high concentration within optimal range for EVE™ HT linearity test. A high linearity was shown as a result.



Advanced counting – Declustering algorithm

Counting clumped and irregular-shaped cells with declustering algorithm is now available on EVE™ HT.

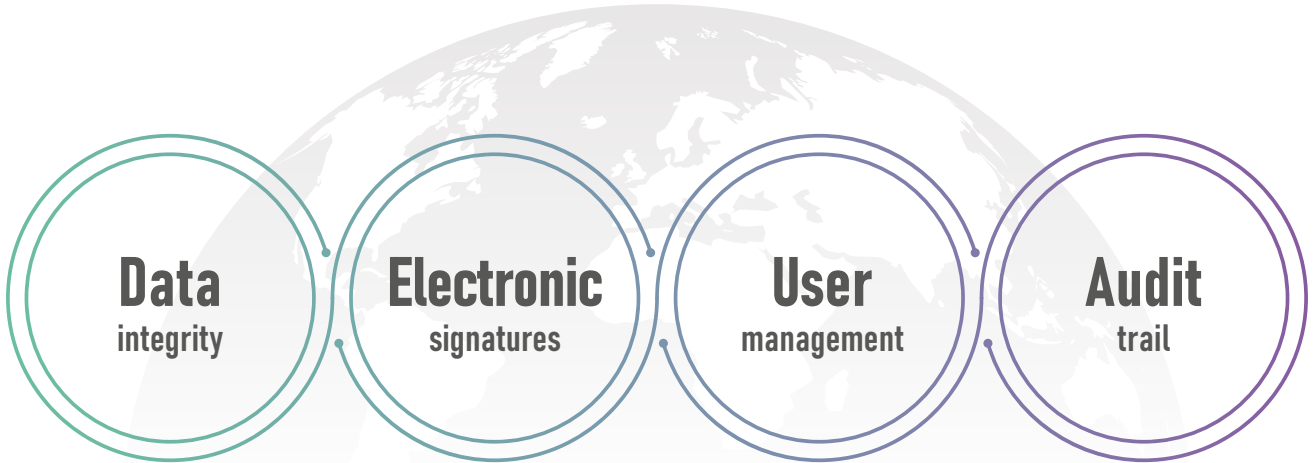


» With EVE™ HT, you can

- Individually count cells when they are aggregated
- Count each cell based on size and shape
- Exclude debris from results

21 CFR Part 11 Compliance

EVE™ HT offers an optional feature to safeguard data integrity required by 21 CFR Part 11. With this feature, not only a company can easily manage users and only give authority to specific users to manage data, but also allows EVE™ HT to save every user activity and create an audit trail.



| Date Time | User | Log |
|----------------------|------------|---|
| 20220713 09:53:17 AM | | [System] Software is Initializing |
| 20220713 09:53:26 AM | | [User] A user(admin_nano) attempts to log in. |
| 20220713 09:53:26 AM | admin_nano | [User] A user(admin_nano) logs in successfully. |
| 20220713 09:53:43 PM | | [System] Software is Initializing |
| 20220713 09:53:46 PM | | [User] A user(admin_nano) attempts to log in. |
| 20220713 09:53:50 PM | | [User] A user(admin_nano) attempts to log in. |
| 20220713 09:53:53 PM | | [User] A user(admin_nano) attempts to log in. |
| 20220713 09:53:53 PM | admin_nano | [User] A user(admin_nano) logs in successfully. |
| 20220713 09:54:28 PM | admin_nano | [E] [E] a Change the information in the [0] Name of the channel [A01] of the project[2022.07.04.10.45]. |
| 20220713 09:54:28 PM | admin_nano | [E] [E] a Change the information in the [1] Name of the channel [A01] of the project[2022.07.04.10.45]. |
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| 20220713 09:54:28 PM | admin_nano | [E] [E] a Change the information in the [1] Name of the channel [A04] of the project[2022.07.04.10.45]. |

| User Name | Access Level |
|-----------|--------------|
| admin | Admin |
| User1 | User |
| User2 | User |
| User3 | User |
| User4 | User |
| User5 | User |
| User6 | User |

User Name: User1
 Current Password:
 New Password:
 Confirm Password:
 User Access Level: User
 Digital Signature:

EVE™ HT
Test report

Sign. Signature

admin_nano
 2023-02-15 09:28:02

| | |
|--------------------|---------------------|
| Project name: | Cell test 5 |
| Project type: | Cell |
| Date & time: | 2023/02/08 16:22:08 |
| Cell type: | HELA |
| Group Name: | HELA |
| Well Name: | A01 |
| Sample Name: | HELA(01) |
| Total Conc.: | 1.20E+006 Cells/mL |
| Live Conc.: | 1.08E+006 Cells/mL |
| Dead Conc.: | 1.45E+005 Cells/mL |
| Viability: | 87.87 % |
| Average cell size: | 10.89 µm |
| Min size: | 5.00 µm |
| Max size: | 80.00 µm |
| Dilution factor: | 1.00 |
| Sensitivity level: | 2 |
| Correction factor: | 7 |
| Viability level: | 7 |

Size Graph

Ver. 1.0.0.55
002
P20230215_092802



Ordering Information

| Cat. No. | Product |
|----------------|--|
| EVE-HT | A High-throughput automated counter, EVE™ HT |
| EVH-020 | EVE™ HT Counting kit <ul style="list-style-type: none"> · Counting plate (48 channels) · Mixing well plate (96 wells) · Trypan blue stain 0.4% · Reservoir |

| Cat. No. | Product |
|-----------------|--|
| EHPQ-001 | EVE™ HT QC plate - Low level (Optional) |
| EHPQ-002 | EVE™ HT QC plate - Middle level (Optional) |
| EHPQ-003 | EVE™ HT QC plate - High level (Optional) |
| EHPP-001 | EVE™ HT Preparation plate (Optional) |

Specification

| Item | Product |
|----------------------------|--|
| Channels (optics) | Bright field |
| Staining method | Trypan blue |
| Counting Speed | 3 minutes (48 samples) |
| Loading sample vol. | 20 µL / channel |
| Measurement range | 1 x 10 ⁴ ~ 1 x 10 ⁷ cells/mL |

| Item | Product |
|-------------------------|--------------------------------|
| Cell size range | 5 ~ 80 µm |
| 21 CFR Part 11 | Available |
| Operation System | Windows 10 Enterprise LTSC |
| Dimensions | 588 x 461 x 458 mm (W x L x H) |
| Weight | 58 kg |

NanoEntek, Inc.

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website www.nanoentek.com

e-mail sales@nanoentek.com

Blog www.blog-nanoentek.com

Count with confidence, Count with EVE HT FL!



EVETM HT FL

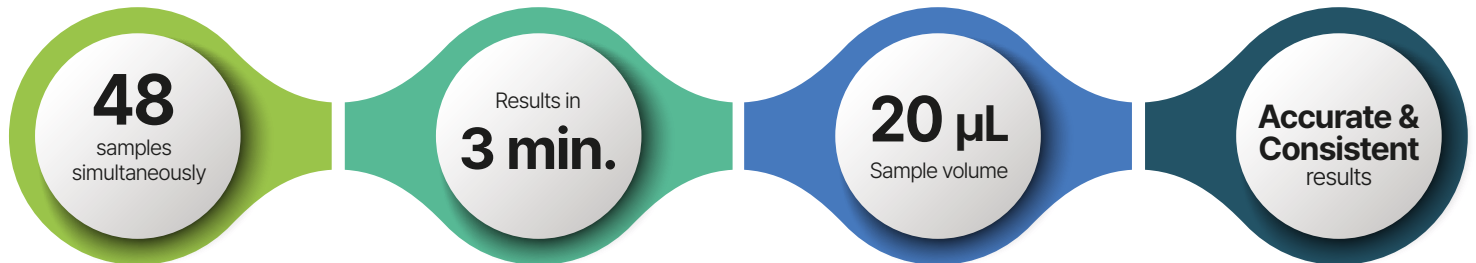
High-throughput Fluorescence Cell Counter

- Primary Cells
- PBMCs
- Stem Cells
- Cell Lines

Introduction

EVE™ HT FL is a high-throughput automated fluorescence cell counter equipped with **bright field** and **dual fluorescence channels (AO/DAPI)**. In just **3 minutes**, up to **48 samples** can be counted and analyzed. EVE™ HT FL delivers precise and accurate results, making it the best option for both cell lines and primary cell counting in a variety of applications.

Features

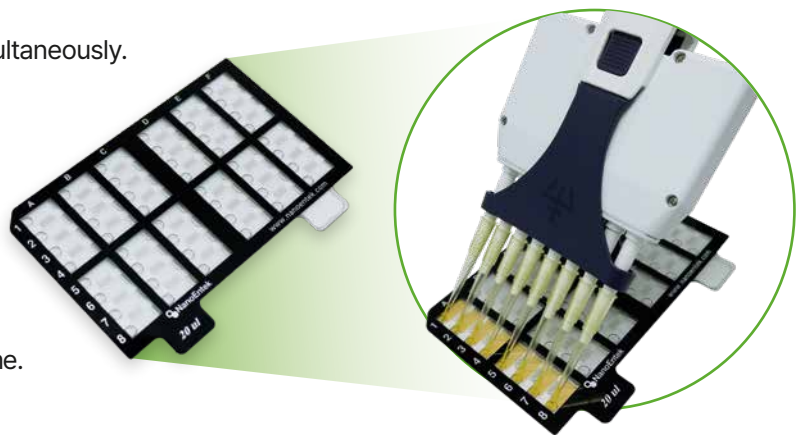


Level Up Your Productivity

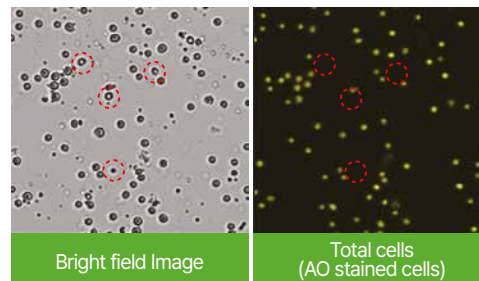
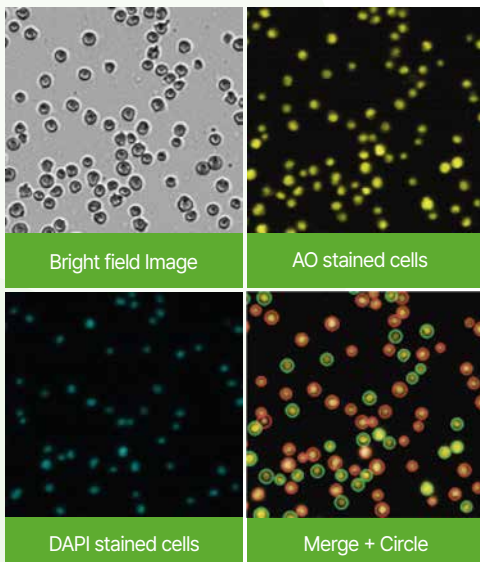
In just **3 minutes**, up to **48 samples** can be counted simultaneously. Don't wait! Count your samples in 3 minutes. Leading to substantial time saving by eliminating the need for frequent reloading and waiting periods.

Small Sample Volume

EVE™ HT FL only needs **20 µL** of your valuable samples. Save your cells for more measurements or better outcome.



Dual fluorescence for accurate measurements of primary cells or PBMCs



Counting PBMCs ONLY!

PBMCs are often mixed with RBCs or platelets. Use EVE HT FL to count only nucleated cells such as PBMCs. Fluorescence based counting is more accurate than traditional Trypan Blue based counting.

Diverse Cell Counting Applications

Primary Cells

PBMCs

Cell Lines

Stem Cells

Hepatocytes

Leukocytes

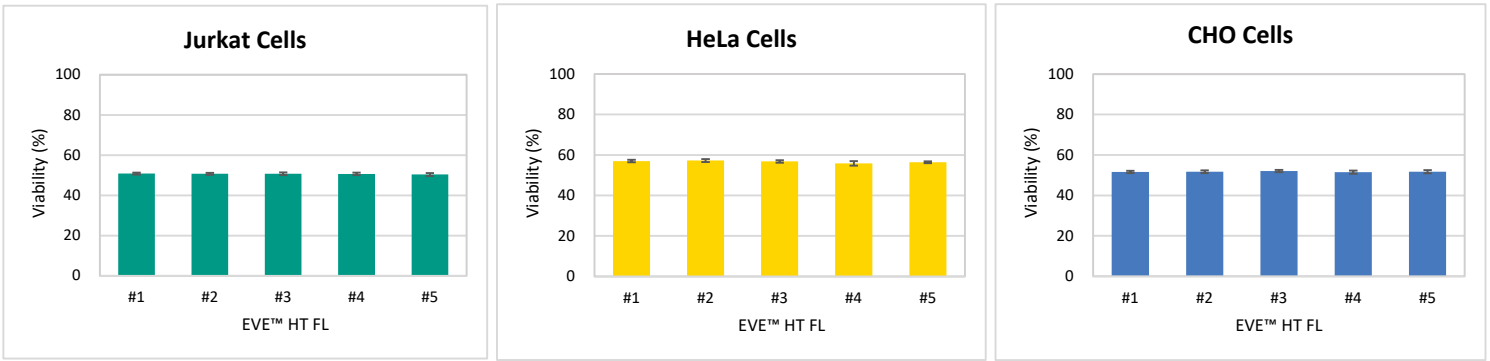
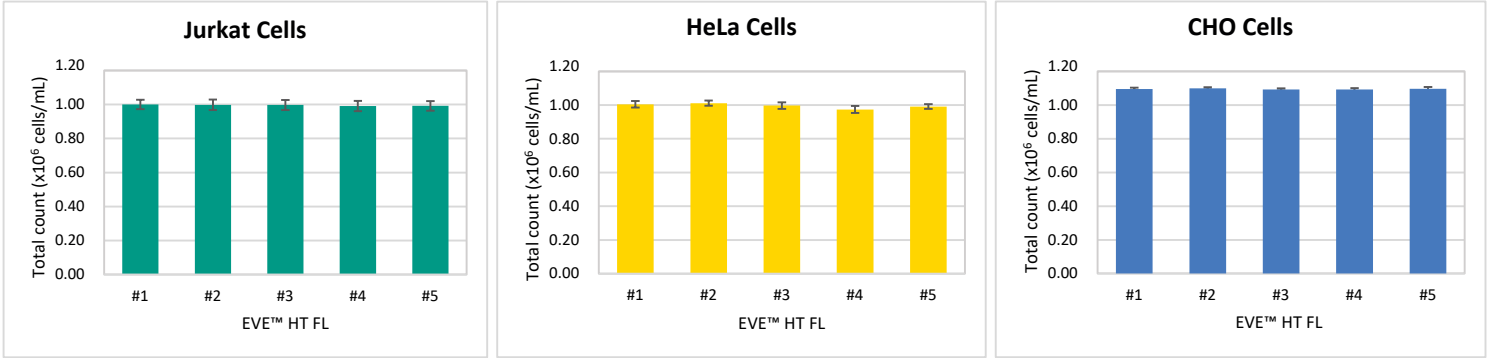
Splenocytes

Adipocytes

Accurate and Precise Results

Instrument-to-instrument Variability with Cell Lines

5 EVE™ HT FL instruments were put to the test using three different cell line samples (Jurkat, HeLa, and CHO) to compare their differences. The results below show very low instrument-to-instrument variability.

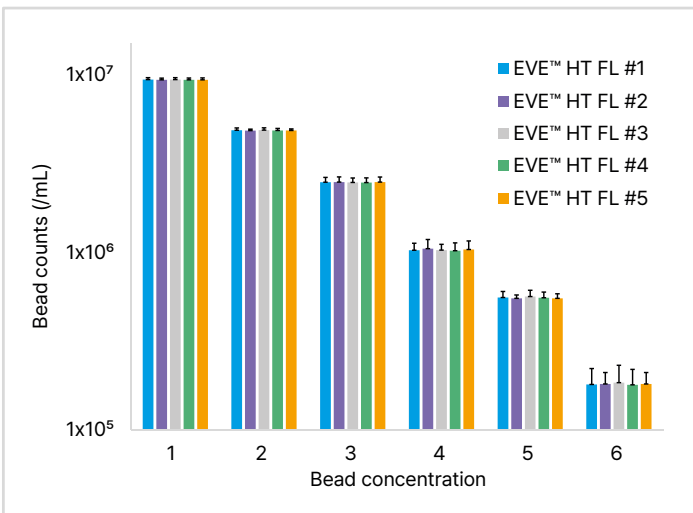


| Cell Line | Comparison | Total count (CV) | Viability (CV) |
|-----------|--------------------------|------------------|----------------|
| Jurkat | Instrument to instrument | 0.44% | 0.21% |
| | Plate to plate | 2.77% | 0.99% |
| | Whole result | 5.70% | 4.38% |
| HeLa | Instrument to instrument | 1.14% | 0.91% |
| | Plate to plate | 1.45% | 0.85% |
| | Whole result | 5.29% | 3.73% |
| CHO | Instrument to instrument | 0.24% | 0.37% |
| | Plate to plate | 0.58% | 1.07% |
| | Whole result | 5.33% | 4.28% |

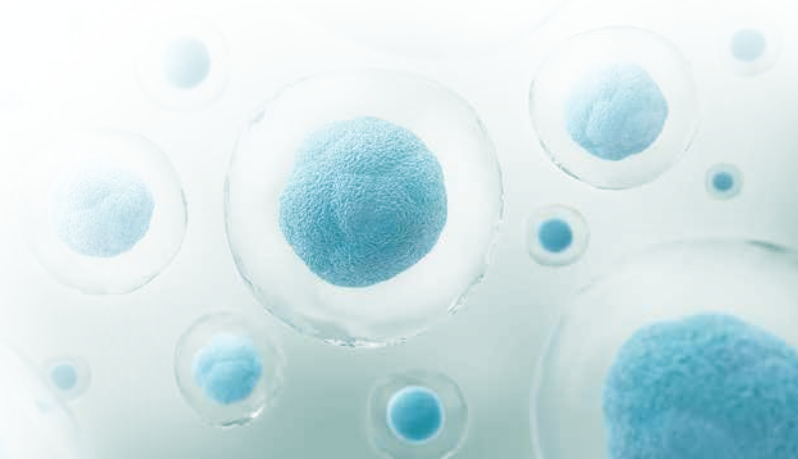
*Whole result: CV value was calculated by combining a total of 400 results measured 16 times each on 5 instruments and 5 plates.

Instrument-to-instrument Variability with Beads

5 EVE™ HT FL were used to measure fluorescent reference beads (for AO channel) at 6 different concentrations. The results below show very little instrument-to-instrument variability.

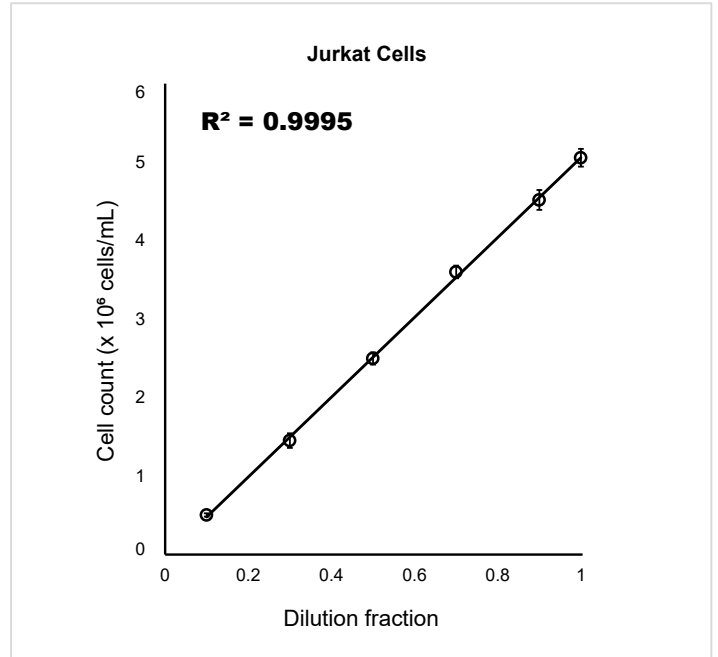
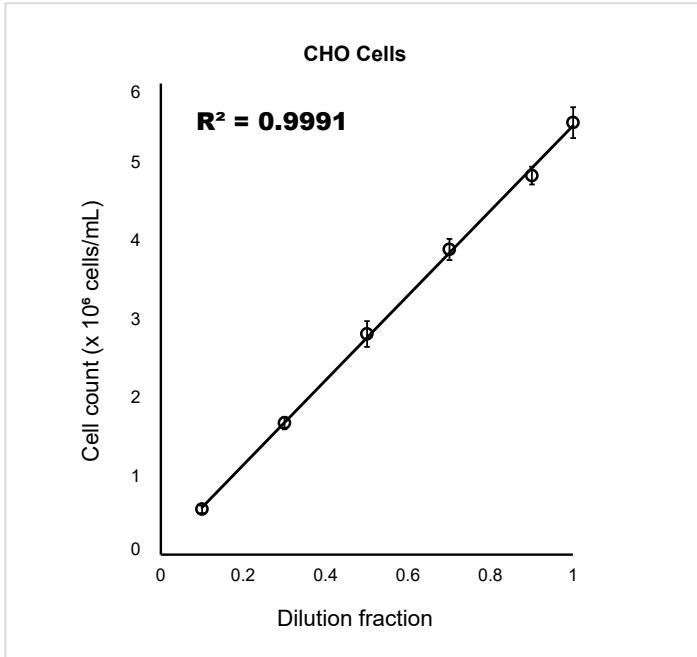


| | Bead 1 | Bead 2 | Bead 3 | Bead 4 | Bead 5 | Bead 6 |
|-------------------------------|--------|--------|--------|--------|--------|--------|
| Instrument to instrument (CV) | 0.17 % | 0.28 % | 0.28 % | 1.02 % | 0.98 % | 1.04 % |



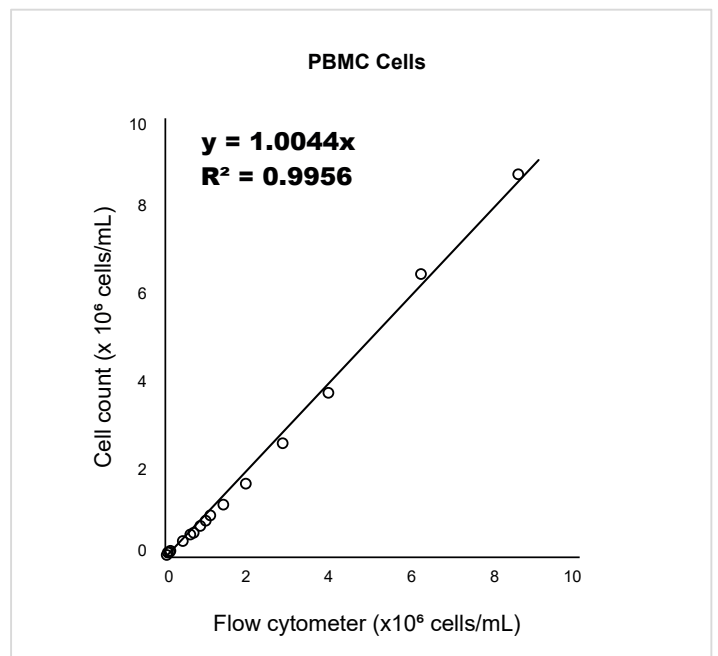
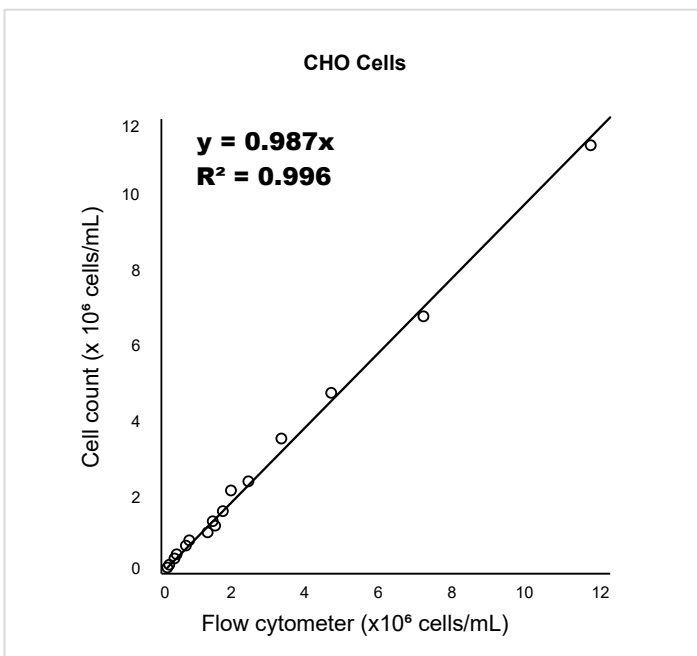
Excellent Linearity Across Wide Range

Following ISO standard for cell counting, we evaluated linearity of EVE™ HT FL using 2 cell lines (CHO cells and Jurkat cells). The following results demonstrate outstanding linearity.



High Correlation Between EVE™ HT FL and a Flow Cytometer

Cell samples were measured using EVE™ HT FL and a flow cytometer. For both CHO cells and PBMCs, total cell counts measured by EVE™ HT FL were highly correlated with those measured by a flow cytometer.



21 CFR Part 11 Compliance READY

EVE™ HT FL is ready for 21 CFR part 11 compliance for cGMP facilities.

Electronic Records

Audit Trails

Electronic Signatures

User Management

Audit Trail

Electronic Signatures

| User Name | Access Level | Lock | Creation date |
|------------|--------------|------|---------------|
| admin | Admin | | 2025.01.15 |
| supervisor | Supervisor | | 2025.01.21 |
| user | User | | 2025.01.21 |
| user2 | User | | 2025.02.20 |

User Management

Data Analysis Report

Results can be easily saved as a PDF report and your data can be easily shared with anyone. Also, more detailed results and raw images can be exported in Excel and JPG files to help you run more extensive data analysis or prepare presentations.

EVE™ HTFL Test report

Customizable Setting for Cell Counting

Users can customize image analysis parameters which can be saved and easily imported for next measurements. This feature allows users to find best sets of parameters that help identify only those cells of their interest and minimize the effects of non-cell debris or unwanted subtypes of cells.

Set parameters for each channel



Scan me

Ordering Information

| Cat. No | Product | Contents |
|-------------------------------|---|--|
| Device and Accessories | | |
| EVE HT FL | High-Throughput Fluorescence Cell counter | Main device, Desktop, Monitor, Multi pipette |
| EHPP-001 | Preparation Plate | Preparation Plate, 1 plate |
| Kit and Consumables | | |
| EVFL-020 | EVE HT FL Counting Kit | 960 tests / kit Counting plate (48 channels × 20 plates) Mixing well plate (96 wells × 10 plates) Reservoir (5 pcs × 4 packs) |
| EVAD-960 | AO/DAPI Staining Solution | 20 mL × 2 bottles Acridine orange (AO) & 4',6-diamidino-2-phenylindole (DAPI) stain |
| EVTB-960 | Trypan Blue Stain | 20 mL × 2 bottles Trypan blue stain (0.4 %) |
| EVEB-960 | Erythrosin B Stain | 20 mL × 2 bottles Erythrosin B stain (0.05 %) |
| QC Plate and Beads | | |
| EHGQ-001 | EVE HT FL QC Plate Fluorescence | Low level, 1 plate |
| EHGQ-002 | EVE HT FL QC Plate Fluorescence | Middle level, 1 plate |
| EHGQ-003 | EVE HT FL QC Plate Fluorescence | High level, 1 plate |
| EHBQ-001 | EVE HT FL QC Plate Bright | Low level, 1 plate |
| EHBQ-002 | EVE HT FL QC Plate Bright | Middle level, 1 plate |
| EHBQ-003 | EVE HT FL QC Plate Bright | High level, 1 plate |
| EFB-001 | EVE HT FL Test Beads | 1 mL x 1 tube |
| EHB-001 | EVE HT BR Test Beads | 1 mL x 1 tube |
| Software | | |
| EVE HT FL 21 CFR Part 11 | EVE HT FL 21 CFR Part 11 software | 21 CFR Part 11 software |

Specifications

| | | | |
|-----------------|--|---------------------------|---|
| Analysis Time | 3 - 20 minutes for 48 samples | Loading Sample Volume | 20 µL per channel |
| Measuring Range | Detectable range: $1 \times 10^4 - 2 \times 10^7$ cells/mL Optimal range: $1 \times 10^5 - 1 \times 10^7$ cells/mL | Operation System | Windows 10 |
| Cell Size Range | Detectable size: 1 - 85 µm (Fluorescence mode) 5 - 85 µm (Brightfield mode) Optimal size: 5 - 80 µm (Fluorescence mode) 10 - 80 µm (Brightfield mode) | Power | 100 - 240V, 50/60Hz |
| Channel | Dual fluorescence channels (AO & DAPI) Brightfield channel | Dimensions | 586 × 461 × 458 mm (W×D×H) |
| | | Weight | 61 kg |
| | | Staining Solution | AO/DAPI mixed solution Trypan blue stain Erythrosin B stain |
| | | 21 CFR Part 11 Compliance | Available (Optional) |



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FOR RESEARCH USE ONLY.
This product is not approved for diagnostic or therapeutic use.

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