

Description of processing of the subject of the performance of the public contract

We hereby declare, that the company EMD Group takes responsibility to supply CE/IVD version of 6-color (8 parameters) ACEA Biosciences Inc. **flow cytometer "NovoCyte D2060R"** to "The International Association for Aid to Children Suffering from Leukaemia" at the children's haematology ward in the Iashvili hospital, address: Department of Pediatric Hematology/Oncology, Ljubljana St. № 2 / 6, Tbilisi, Georgia. The contact person: Dr. Tamar Javakhadze.

Detailed specifications of the cytometer is given below:

- Six-colour flow cytometer
- Lasers: blue 488 nm and red 640 nm
- Without user setup of lasers
- User-replaceable filters
- Sensitivity to FITC less than 75 MESF (with a maximum tolerance of 10%)
- Sensitivity to PE less than 50 MESF (with a maximum tolerance of 10%)
- Cell Size: 0.2- 50 microns
- Sample aspiration volume: 10-5000 microlitres
- Precise volumetric counting (alternative to true count beads counting)
- An integrated and fully automated system for daily quality control of operations and measurements for monitoring all parameters of the apparatus (Automatic QC, compensation, cleaning, and report generation)
- PC with Windows (7-10), USB 3.0, DVD and monitor with min. 24-inch
- NovoExpress sophisticated software included
- Upgradeable to 15 colours (17 parameters in overall)
- Warranty for two years
- Starter pack for a smooth start of operation; Reagent Containers, Complimentary NovoCyte Flow Cytometer Starter Kit.
- Registered as CE/IVD (D versions) for six-colour analysis, as well as for an upgraded configuration

Delivery of the instrument will be done within 9 weeks period after signing a contract with the contracting authority. EMD Group will cover all costs for transport to the end user site, the delivery insurance, and will cover duties and any other charges imposed in connection with the import of the goods and taxes. We will pay any fees in connection with the delivery of the goods until they are handed over at the place of performance.

We will deliver all necessary components needed to install and put into operation the flow cytometer and will check its smooth operation, including its operation during a testing period (14 days). EMD group takes responsibility to collect and submit all documentation necessary for legal and smooth delivery of the flow cytometer.

We will provide a manual of operation for the 6-colour cytometer in English and Georgian and will provide them to the end user.

Considering speed of service and extended warranty period for the instrument requested by the contracting authority, the training will be split in two parts to derive the most efficient training experience:

1. Selected person from end-user site will be offered to travel headquarters of ACEA Biosciences in the US, where she/he will have an opportunity of several days extensive training in installation, performance, troubleshooting, technical as well as other pertinent aspects of the flow cytometer.
All travel costs (flight tickets), accommodation, health insurance etc. will be also covered by the EMD Group.
2. The trained person will install the instrument and provide two days training for appointed staff (at least 2 persons) back to the end user site, in Georgian.

EMD Group will provide supervision during the training in Georgia, also the company will take the responsibility that the equipment (flow cytometer “NovoCyte D2060R”) is installed correctly, according to manufacturer's recommendations.

This scheme is an alternative to installation and several hours training provided by regional trainer in English, which we think will not be efficient.

Content of the trainings, list of trainees, dates, record of attendance, photographic documentation and a report on training the medical personnel will be handed over to the contracting authority, and also to the end user.

After the delivery of the apparatus, its installation, training, and conclusion of the testing period, EMD Group will hand over to the contracting authority a final report on the performance of the delivery.

Warranty period for the supplied instrument will be 24 months; EMD Group takes responsibility to provide service for the cytometer free of charge, including all materials necessary for its full functioning as well as potential calibration/recalibration of the apparatus within 24 months warranty period.

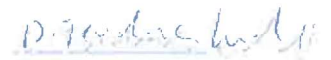
The reported fault of the flow cytometer (need for recalibration is also considered to be a fault) will be resolved at the location of installation of the device within 48 hours of the fault being reported, if the character of the fault needs involvement of regional service engineer, the maximum time for fixing the fault will be 1 month from reporting the issue.

Beyond 24 months, in the post-warranty period, the end user will be responsible for payment of any fees related to flow cytometer service/upgrade/repair. Cost of requested service/services will be calculated individually, based on reported issue.

EMD Group LLC,

David Tevdorashvili, CEO

21.06.2017



NovoCyte[®] Flow Cytometer

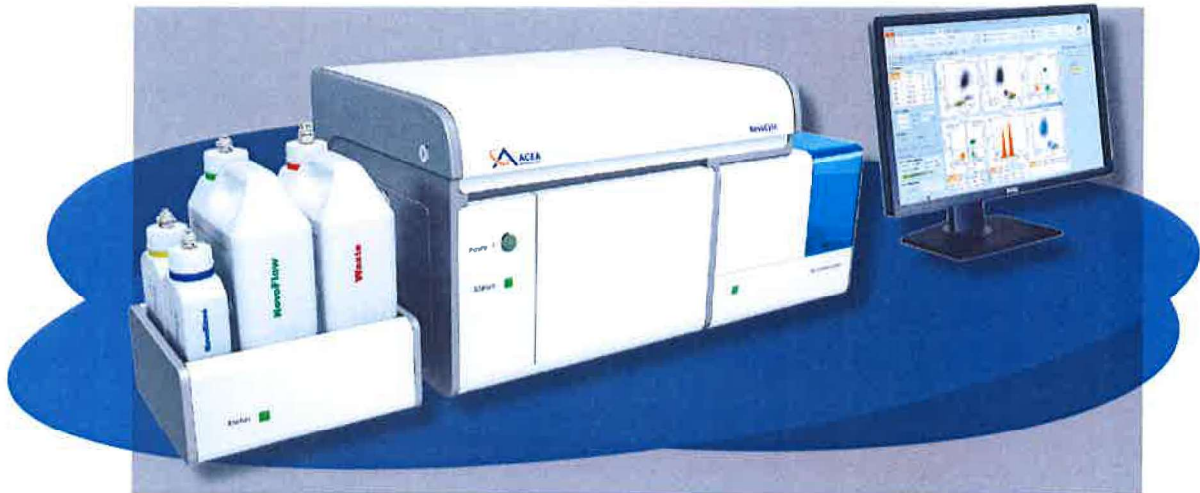


Technical Specifications

NOVOCYTE IS SIMPLY FOR EVERYONE

Research tools can be affordable and easy to use without sacrificing high performance over cost. Scientists can now address the full range of their current and future needs for multi-parameter flow cytometry analysis with the ACEA NovoCyte Flow Cytometer.

- **POWERFUL** - up to 17 parameter detection with enhanced sensitivity and resolution
- **INTUITIVE** - automated instrument maintenance functions and advanced data analysis capability for easy user interface.
- **CUSTOMIZABLE** - 1 to 3 laser options, exchangeable filters, multiple sampling options and flexible analysis formats.



Configurable Laser Systems

Standard Systems

Model Number	1000	2000R		2060R		3000			3005		
Lasers	488 nm	488 nm	640 nm	488 nm	640 nm	405 nm	488 nm	640 nm	405 nm	488 nm	640 nm
Detectors	445/45 nm					•			•		
	530/30 nm	•	•		•	•	•		•	•	
	572/28 nm	•	•		•	•	•		•	•	
	615/20 nm										
	660/20 nm								•	•	•
	675/30 nm	•	•	•	•	•	•	•	•		•
	725/40 nm									•	•
780/60 nm				•	•	•	•	•	•	•	•

Yellow Laser Systems

Model Number	2100YB		3000VYB			3000RYB		
Lasers	488 nm	561 nm	405 nm	561 nm	488 nm	640 nm	561 nm	488 nm
Detectors	445/45 nm		•					
	530/30 nm	•	•		•			•
	586/20 nm	•	•	•	•		•	•
	615/20 nm	•	•	•	•		•	•
	660/20 nm	•	•	•	•	•	•	•
	695/40 nm	•	•			•	•	•
780/60 nm		•	•	•	•	•	•	

NovoCyte® Specifications

Optics	Laser Configuration	Spatially separated beams with 10 x 80 µm elliptical spots
	Optical Alignment Procedure	Fixed, no operator alignment required
	Flow Cell	170 x 290 µm rectangular quartz flow cell
	Scatter Resolution	0.2 µm
	Cell Size	0.2 - 50 µm
	Fluorescence Threshold Sensitivity	FITC < 75 MESF; PE < 50 MESF; APC < 20 MESF
	Fluorescence Resolution	< 3% CV for CEN
	Filters	User Exchangeable
Fluidics	Sample Acquisition Rate	35,000 events/second
	Volumetric Absolute Count Precision	Syringe Pump: CV < 5%
	Sample Flow Rate	5-120 µL/min
	Sheath Flow Rate	6.5 mL/min
	Sample Aspiration Volume	10 µL - 5 mL
	Fluid Container Capacity	3 L sheath, 3 L waste, 500 mL cleaning, 500 mL decontamination
	Carryover	< 0.1%
Data Processing	Fluidics Maintenance	Automated startup, cleaning, decontamination and shutdown
	Parameters	Height and Area for FSC, SSC and all Fluorescence Channels, Width and Time
	Dynamic Range	24 bit; 7.2 decades logarithmic scale; no need for PMT voltage adjustment
	Compensation	Automatic compensation, manual compensation, visual compensation tools available for pre/post/live acquisitions
	Output Data Files	FCS 3.1, NovoExpress (.ncf), PDF reports, bitmap graphics, vector graphics, CSV
	Workstation	Dell OptiPlex 7040 SFF, 1 TB with 23.8" LCD monitor
Sampling	Computer Operating System	Microsoft Windows® 7 Professional (64 bit), Microsoft Office® 2016
	Software	ACEA NovoExpress®
	Manual Sample Loading	12 X 75mm tube, 1.5mL Eppendorf tube
Operating Conditions	Automatic Sample Loading	Optional - compatible with 12 x 75 mm tube, 1.5 & 2 mL tubes, "bullet" tubes in 96-pos. racks, 24-well, 48-well and 96-well microtiter plates
	Instrument Dimension (W X D X H)	23.6 x 17.7 x 15.4 in (60 x 45 x 39 cm)
	Instrument Weight	86 lb (39 kg)
	Power Requirements	100/115/230 VAC, 50-60 Hz
	Environment Requirements	Temperature: 15-32°C ; Relative Humidity: 80% maximum

*These specifications will be affected by the instrument used and the operating conditions.

Published by:

ACEA Biosciences, Inc.
6779 Mesa Ridge Road Ste. 100
San Diego, CA 92121
U.S.A.

www.aceabio.com

© 2017 ACEA Biosciences, Inc.
All rights reserved.

050170 - 20170417

For Research Use Only.

Not for use in diagnostic or therapeutic procedures.

Trademarks:

ACEA Biosciences, the ACEA logo, NovoCyte®, NovoExpress®, NovoSampler®, NovoFlow®, NovoRinse®, and NovoClean® are trademarks of ACEA Biosciences, Inc., in the United States and some other countries.

All other company and product names might be trademarks of the respective companies with which they are associated.

Compatible Fluorochromes

NovoCyte® 3005 Channels

FL Channel	405nm					488nm					640nm			
	Pacific Blue™ Brilliant Violet 421	AmCyan Brilliant Violet 510	Pacific Orange™ Brilliant Violet 570	Qdot® 650 Brilliant Violet 655	Qdot® 705 Brilliant Violet 711	Qdot® 800 Brilliant Violet 785	FITC	PE	Cy5	PerCP eFlour70	PE-Cy7	APC	Alexa Fluor® 700	APC-Cy™7
445/45 nm	•						•							
530/30 nm		•												
572/28 nm			•					•						
660/20 nm				•					•			•		
725/40 nm					•					•			•	
780/60 nm						•								•

NovoCyte® 3000 Channels

FL Channel	405nm					488nm					640nm		
	Pacific Blue™ Brilliant Violet 421	AmCyan Brilliant Violet 510	Pacific Orange™ Brilliant Violet 570	Qdot® 605 Brilliant Violet 605	Qdot® 655 Brilliant Violet 650	Qdot® 800 Brilliant Violet 785	FITC eGFP	PE	PE-Texas Red	PerCP 7-AAD	PE-Cy7	APC	APC-Cy™7
445/45 nm	•						•						
530/30 nm		•											
572/28 nm			•					•					
615/20 nm				•					•				
675/30 nm					•					•			
780/60 nm						•							•

NovoCyte® 3000 RYB Channels

FL Channel	640nm			561nm				488nm					
	APC Alexa Fluor® 647	Alexa Fluor® 700	APC-Cy™7	PE	PE-Texas Red® mCherry	PE-Cy™5 mPlum	PE-Cy™5	PE-Cy™7	FITC eGFP	EYFP	Propidium Iodide	PerCP 7-AAD	PerCP-Cy™5.5
530/30 nm									•				
586/20 nm				•						•			
615/20 nm					•						•		
660/20 nm	•					•						•	
695/40 nm		•					•						•
780/60 nm			•					•					

NovoCyte® 3000 VYB Channels

FL Channel	405nm					561nm			488nm					
	Pacific Blue™ Brilliant Violet 421	AmCyan Brilliant Violet 510	Pacific Orange™ Brilliant Violet 570	Qdot® 605 Brilliant Violet 605	Qdot® 655 Brilliant Violet 650	Qdot® 800 Brilliant Violet 785	PE tdTomato	PE-Texas Red® mCherry	PE-Cy™5 mPlum	PE-Cy™7	FITC eGFP	EYFP	Propidium Iodide	PerCP 7-AAD
445/45 nm	•													
530/30 nm		•												
586/20 nm			•				•							
615/20 nm				•				•						
660/20 nm					•				•					
780/60 nm						•				•				•

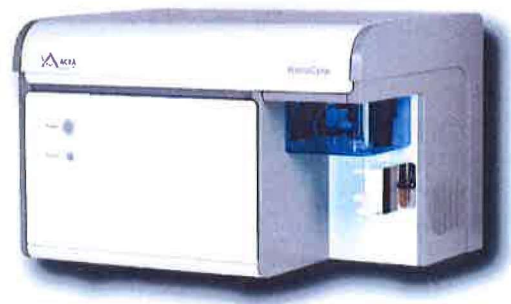
Experience the NovoCyte Advantage

Focus on advancing your research. Let the flow cytometer do the rest.

NovoCyte® Flow Cytometer High Performance Flow Cytometer for Everyone

The ACEA NovoCyte flow cytometer system is a high performance benchtop flow cytometer designed for all level of users and all types of laboratories. This budget-friendly instrument is capable of detecting up to 15 parameters with impressive sensitivity and resolution. The customizable laser and optical configuration of NovoCyte offers high degree of flexibility while providing complex cell analysis capabilities. The Novo-Express software enables intuitive and easy sample acquisition and analysis. It allows switching to analysis while still in the process of acquiring other samples. The NovoSampler Pro is an optional high throughput system that provides versatility in acquiring multiple sample formats such as single tubes, multiple tubes, 24-,48-, 96-well plates in a single, simple setup.

- **Powerful** - up to 15 parameter detection with enhanced sensitivity and resolution.
- **Intuitive** - complete acquisition and analysis software, providing high level of automation and advanced data analysis capability.
- **Customizable** - 1 to 3 laser options, exchangeable filters, multiple sampling options and flexible analysis formats.



INSTRUMENT FEATURES

Load-and-go, without the hassle

Optimized PMT Voltage & 24 Bit Detection Dynamic Range

Provides 10^7 dynamic range for signal detection and processing, offering a broader signal range than other flow cytometers.

Wide range of fluorescence and scattering signal intensities eliminates the need for complicated and laborious PMT voltage adjustment. Data acquisition is simply load-and-go.



Volumetric Fluidics System for Increased Accuracy & Easy Maintenance

Accurate pressure sensors monitor fluidic status in real-time, providing warning messages such as abnormal high pressures due to possible flow path obstruction. Automated fluidic functions maintain the instrument at an optimum status, allowing for reliable and accurate data acquisition.

Automated SIP (sample injection probe) washing following sample acquisition minimizes sample carry-over and increases capability to detect rare events.

High speed data acquisition of up to 35,000 events per second.



INSTRUMENT FEATURES

Customize and upgrade

Configurable Fluorescence Detection Channels for Enhanced Assay Flexibility



Customizable and upgradable selection of different wavelength lasers allows for personalized, versatile choices of fluorochromes for flow cytometry assays.

User interchangeable filters and dichroic mirrors broaden available fluorescence channels to expand users' detection options.

13 Fluorescence Channel Detection: Flexibility Using Multiple Laser Options (405nm, 488nm, 561nm, 640nm)

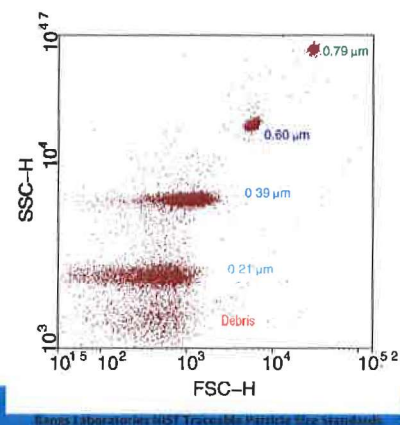
Instrument is customizable to meet detection needs with blue, red, violet and yellow lasers.

System can be upgraded as analytical requirements increase – no need to purchase another instrument.

State-of-the-art solid-state lasers provide high quality and extremely stable optical illumination.

High Sensitivity & High Resolution Detection

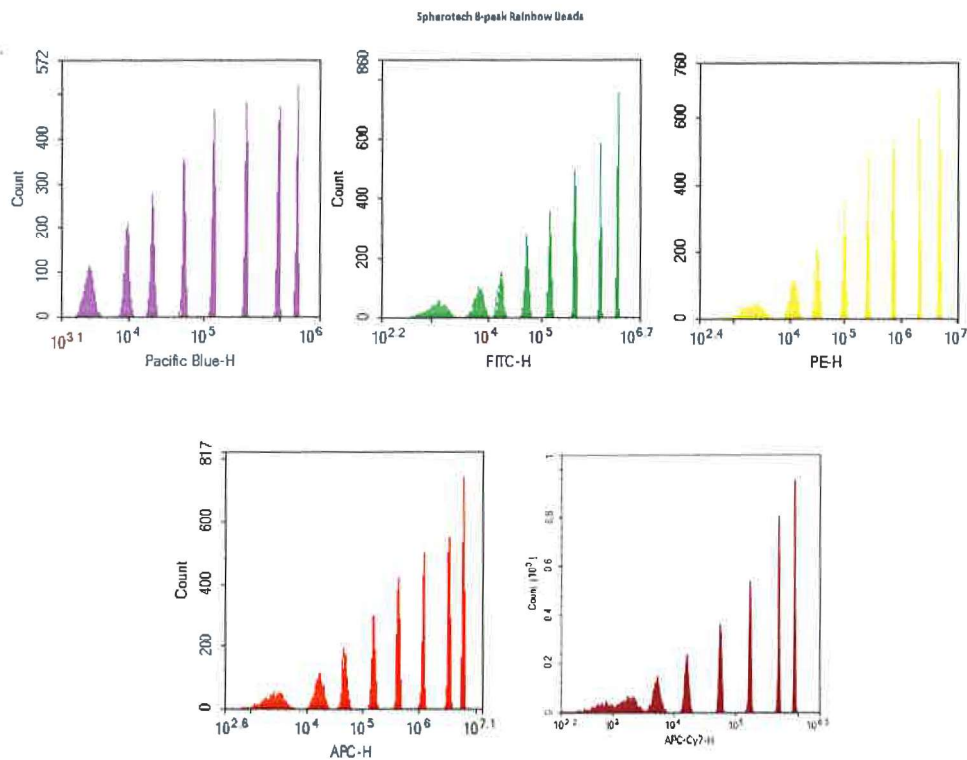
Highly efficient light collection ensures reliable detection of sub-micron particles and dim signals. Using innovative optical design for light collection and high quality PMTs, fluorescence signals are efficiently detected with an exceptionally high signal-to-noise ratio, ensuring a high detection sensitivity for dim markers and small particles.



INSTRUMENT FEATURES

High Fluorescence Signal Resolution Improves Detection Accuracy

Advanced optical and fluidic system design, premier quality components, and innovative signal processing algorithms collectively ensure accurate extraction of detection parameters with consistently low variation.



Novel Optical Design & Enhanced Signal Detection

Patent pending independent beam shaping optics and light collection system maximizes signal detection efficiency, increasing sensitivity and resolution for each fluorescence channel.

Fixed optical alignment removes need for daily setup and adjustment of optical system, saving time and minimizing testing effort.

Designed to meet your needs, the Spherotech 8-pink Rainbow Beads are the most accurate and consistent result of the instrument for testing.



INSTRUMENT FEATURES

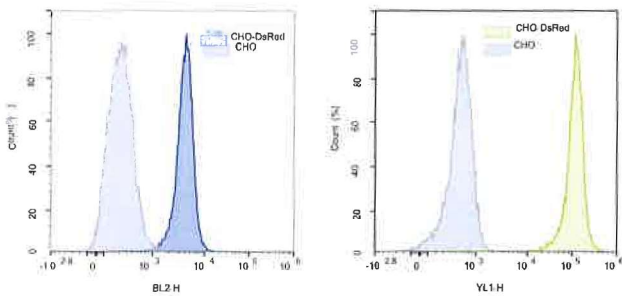
Enhanced excitation using 561nm laser

With the ever increasing availability of antibodies, fluorescent proteins, and fluorescent dyes, the number of applications continues to expand the field of flow cytometry and there is an increased need to efficiently detect these markers. We have incorporated multiple laser configurations within the NovoCyte flow cytometer to accommodate the varying needs of researchers. One such excitation laser that is very useful in the detection of fluorescent proteins and PE or PE tandem fluorochromes is the yellow-green 561nm laser. Using the 561nm laser for excitation allows us a higher stain index compared to 488nm laser excitation.

DsRed Excitation

488nm laser

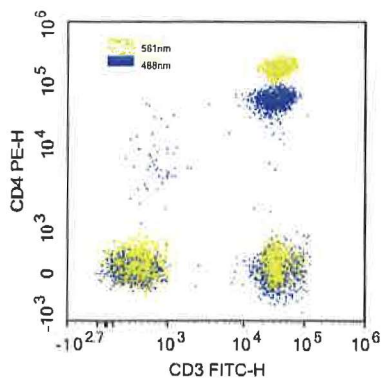
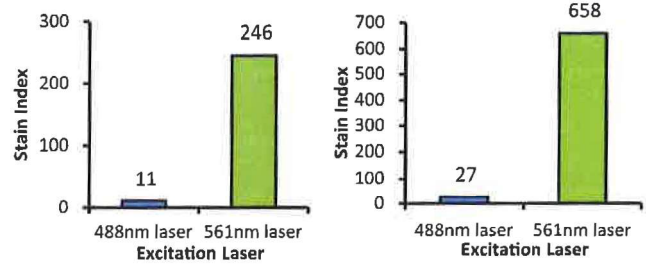
561nm laser



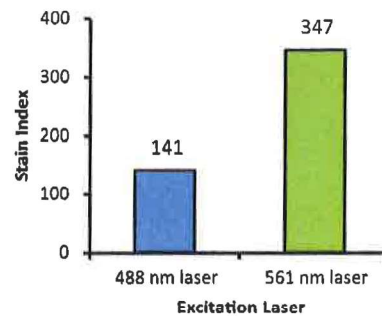
Stain Index - Fluorescent Proteins

Stain Index - DsRed

Stain index - mCherry



Stain Index - Human CD4 PE



The figures above represent the stain index of two fluorescent proteins and a PE conjugated antibody, excited by the 488nm and 561nm lasers on the NovoCyte flow cytometer. Stain index is represented by the area under the curve representing the population of cells that are positive for the marker of interest.



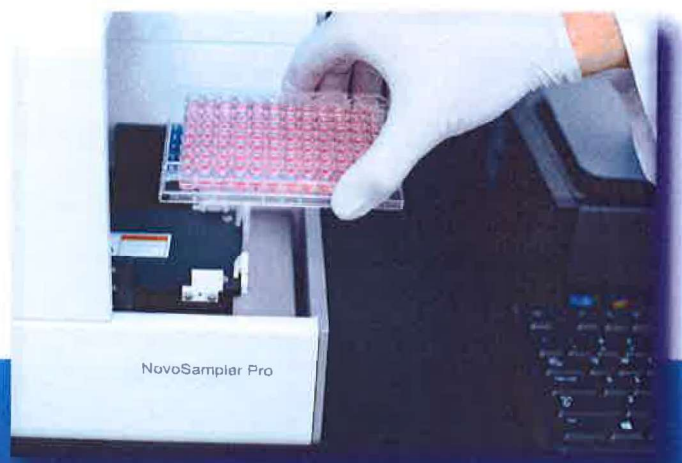
AUTOMATION CAPABILITIES

High Throughput capability with NovoSampler Pro



ACEA's NovoSampler Pro is an automatic sample loading system that fulfills the requirements on high-throughput and automated sample acquisition. The NovoSampler Pro seamlessly integrates with the NovoCyte flow cytometer, making it very easy to operate, delivering high-speed analysis and processing performance.

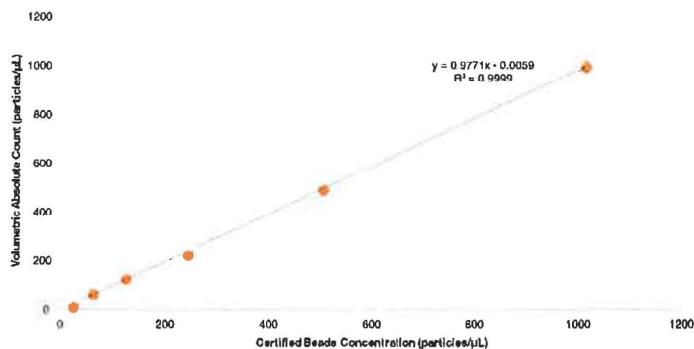
- Walk-away automation and increased productivity
- Maintains homogeneity and integrity of biological samples
- Simple installation, easy operation, and superior performance
- Programmable vortex-mixing mechanism
- Compatible with various sample formats:
 - 96 well plate (U, V, flat bottom)
 - 48 well plate
 - 24 well plate
 - 24 tube rack
 - Customized plates, tubes, racks



AUTOMATION CAPABILITIES

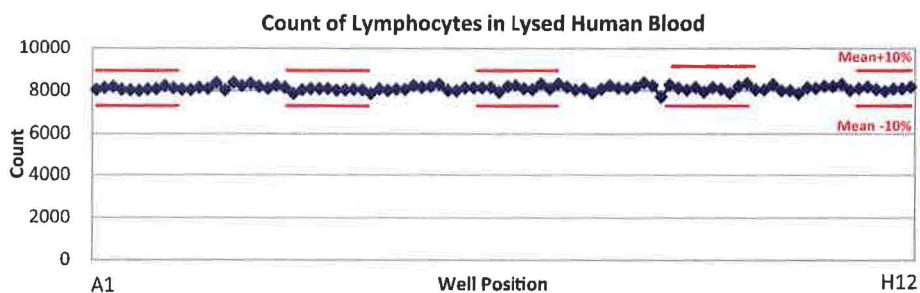
Volume-Based Direct Absolute Counting, No Additional Counting Beads Required

With a high accuracy syringe pump controlling the injected sample volume and minimal cell loss in the fluidics, the NovoCyte flow cytometer achieves accurate direct cell counting without the need for expensive counting beads.



The NovoSampler Pro ensures thorough sample mixing with default parameter settings and customized options for high performance acquisition. Users can adjust the vortexing speed, duration, and acceleration to optimize mixing efficiency depending on sample type.

We observe consistent counts for AccuCount Fluorescence Particles (not shown), Jurkat cells (not shown), and lysed PBMCs with CVs of 1.9%, 3.1% and 1.5% using 96-well plates on the NovoSampler Pro.

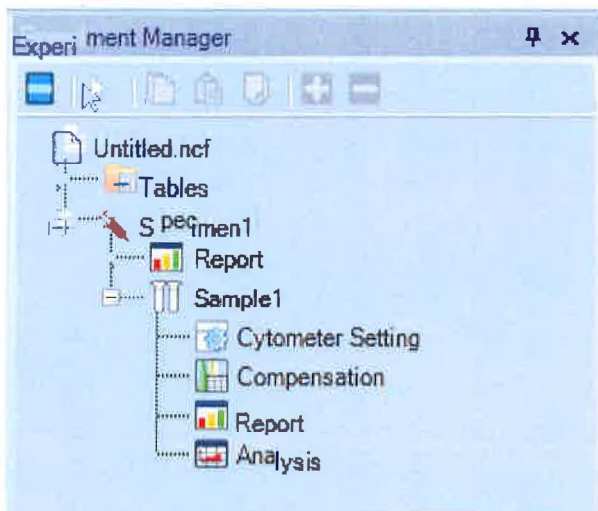


Normal human peripheral blood samples stained with CD45 / CD3 / CD4 / CD8 cocktail were loaded onto a 96-well plate, and process with a loading settings of: 1200rpm, 15s, stop condition of 30uL, high flow rate.



SOFTWARE

The Novo Express Experience: Simple and Easy

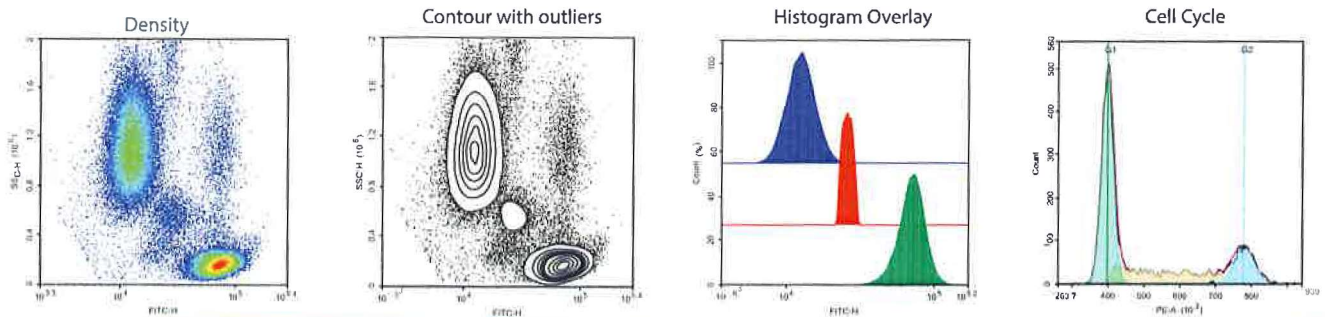


Experiment Analysis Design

Experiment Manager provides a schematic view of the sample analysis being performed. This allows for access to cytometer settings, compensation matrix, report generation and data analysis. Multiple samples can be analyzed with the same settings by a simple drag-and-drop template function.

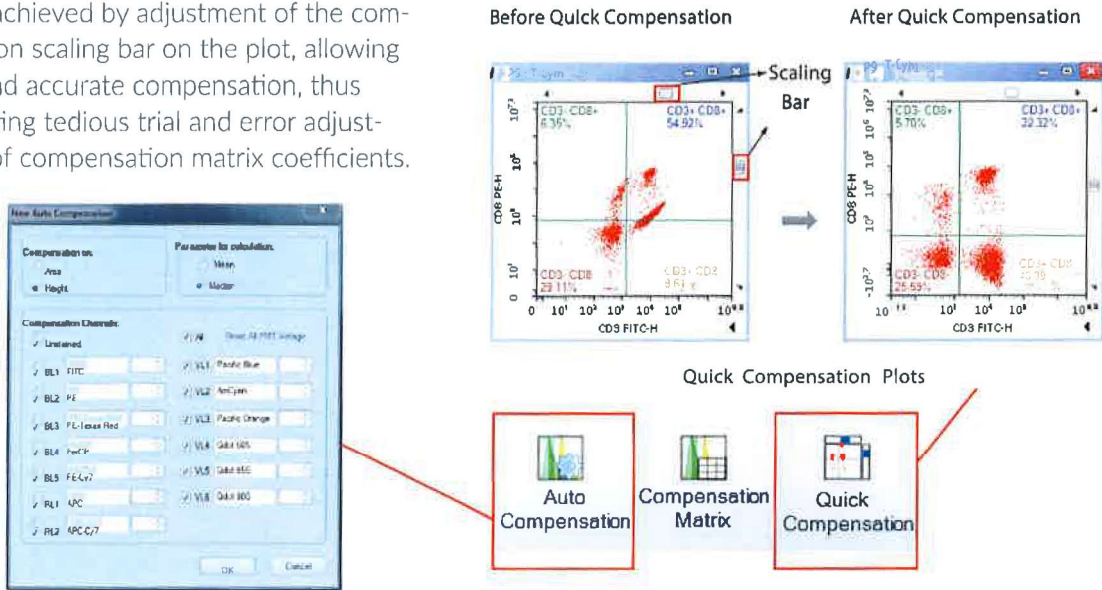
Automated & Versatile Data Analysis Functions

Powerful NovoExpress software allows efficient data acquisition, data analysis and report generation. NovoExpress software provides flexible analysis templates and plotting tools, offering enhanced data analysis efficiency.



Pre & Post Acquisition Compensation

In addition to automated compensation, instantaneous compensation results can be simply achieved by adjustment of the compensation scaling bar on the plot, allowing rapid and accurate compensation, thus eliminating tedious trial and error adjustments of compensation matrix coefficients.



Automatic fluidic monitoring and maintenance

Adding to the user-friendliness of the NovoCyte system is the automatic fluidic monitoring station and easy to use maintenance icons. There is no need to manually check whether the cleaning or sheath fluids are low or the waste container is full, these levels are automatically monitored and the system will notify the user when action is required. Similarly, routine fluidic cleaning and maintenance procedures can be accessed within the NovoExpress software with a simple click of the icon.



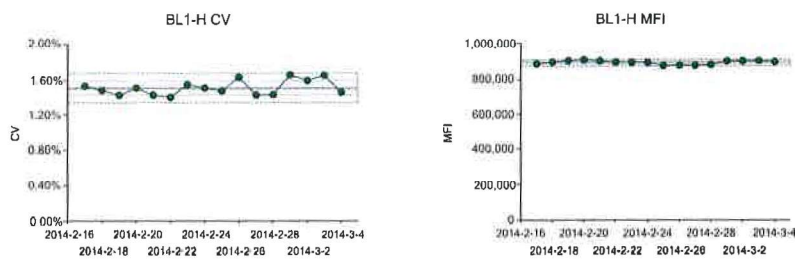
Fluidic maintenance toolbar



DAILY CONVENIENCE

QC test & QC reports

Embedded within the NovoExpress software is the automatic quality control evaluation. By running one drop of QC particles, every user can determine proper instrument performance and track this performance over time using the automatically generated QC reports. Each time the QC test is run, QC reports are automatically generated and saved for future reference. This ensures proper performance monitoring on not only a day to day basis, but also over long-term use.



Low Carryover between samples

Flow cytometry allows for the sequential processing and quantitative analysis of many samples. Limiting sample carryover is important not only when acquiring multiple samples, but also during the analysis of rare events as carryover from previous samples can substantially effect the quantitation of rare event detection. Therefore, it is important for a flow cytometer to limit sample carryover without manual intervention. Here we show the low sample carryover on the NovoCyte flow cytometer.

ACEA NovoSampler Pro carryover is less than 0.1%

Sample	Count	Sample	Count	Sample	Count
ACBP 1-1	102,841	ACBP 2-1	100,370	ACBP 3-1	103,205
ACBP 1-2	99,320	ACBP 2-2	101,635	ACBP 3-2	104,101
ACBP 1-3	99,993	ACBP 2-3	103,289	ACBP 3-3	104,237
PBS 1-1	24	PBS 2-1	17	PBS 3-1	16
PBS 1-2	2	PBS 2-2	5	PBS 3-2	5
PBS 1-3	3	PBS 2-3	3	PBS 3-3	4
Carryover*	0.021%	Carryover*	0.014%	Carryover*	0.012%

The carryover of 3 automatic mixing groups were 0.021%, 0.014% and 0.012%.

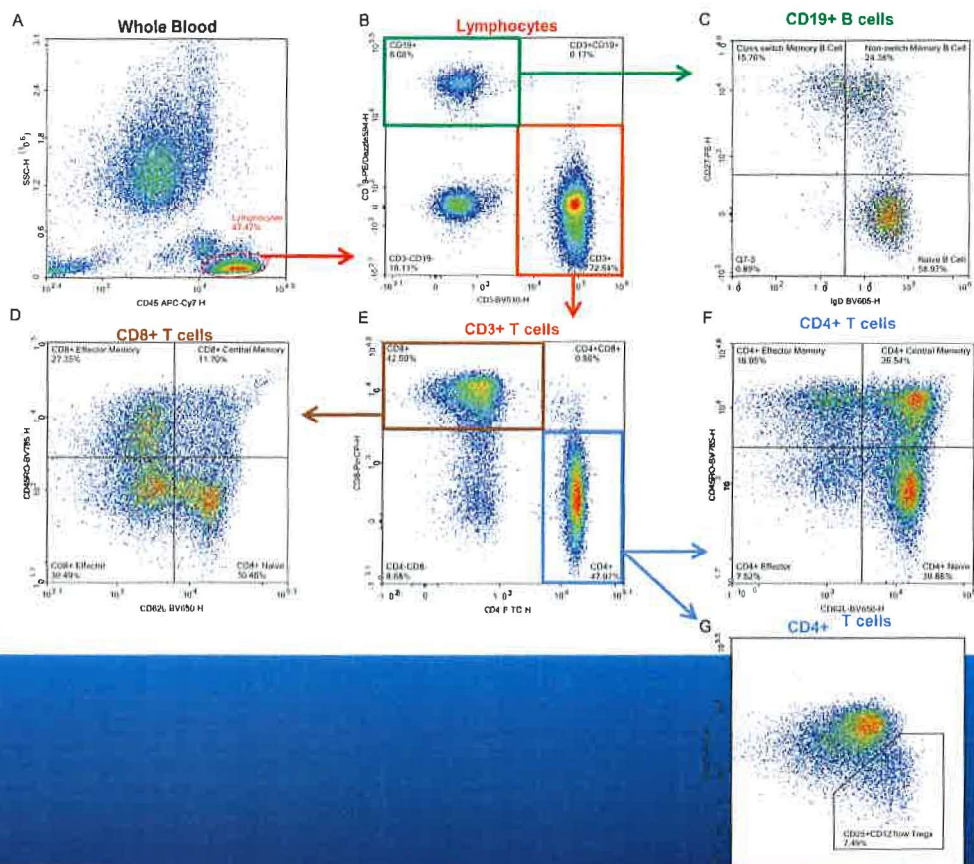
*Carryover assay methods: For samples, we prepared 30 samples of fluorescently labeled particles (ACBP 50-10) and 30 wells of PBS at 15001 per well. The samples were loaded using NovoSampler Pro, and the carryover was calculated using the following formula: $\frac{\text{Carryover Count}}{\text{Sample Count}} \times 100\%$. The results are shown in the table above. The carryover of 3 automatic mixing groups were 0.021%, 0.014% and 0.012%.



Outstanding Performance in Broad Applications

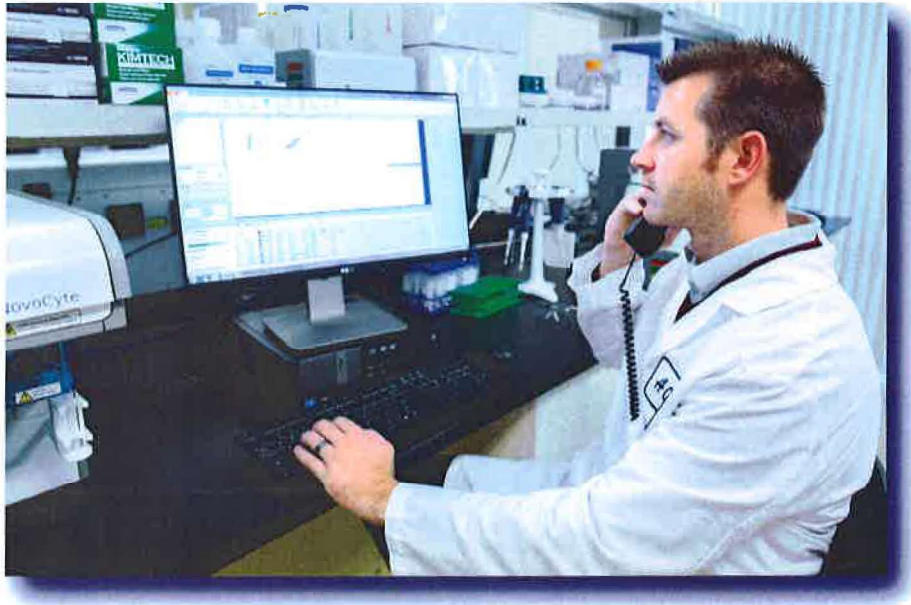
Immunophenotypic analysis of human blood leukocyte subsets using a 13-color antibody panel

Identification and analysis of specific sub-populations of cells is one of the many essential uses of flow cytometry, especially in terms of its ability to multiplex and identify several markers in one sample. As such, immunophenotyping of blood samples is one of the more popular uses of multi-color flow cytometry. In certain applications, using multiple markers simultaneously for immunophenotyping is more powerful and efficient than using multiple samples with fewer markers. However, to accomplish this task, what is needed is a powerful flow cytometer that has the ability to both detect and analyze the plethora of colors that is utilized in such an experiment. Here we demonstrate immunophenotypic analysis of a human blood sample utilizing 13 fluorescent markers on the NovoCyte 3000. In this staining, subsets of T cells, B cells, were identified and analyzed using the NovoExpress acquisition and analysis software. The data clearly demonstrate that using the NovoCyte benchtop flow cytometer allows for performance of high-quality, complex flow cytometry with a 13-color antibody panel.



SERVICE AND SUPPORT

ACEA Biosciences is fully committed to providing high performance products as well as reliable service and support to customers.



ACEA NovoCyte Flow Cytometer Service and Warranty

In order to ensure customer's long term success with the NovoCyte line of flow cytometers, ACEA is standing by with a technical service and support team, who will provide the knowledge and experience needed for operational excellence of the system.

Preventive Maintenance and Extended Service Warranty

It is always a good idea to ensure optimal performance of the ACEA NovoCyte flow cytometer even beyond the original manufacturing warranty period. ACEA offers a variety of service contracts for your peace of mind. Preventive maintenance and extended warranty and service agreements can be offered for periods of up to 7 years. The services and support provided for Extended Warranties are identical to the one-year warranty.

Technical Application Support and Training

ACEA's technical application support scientists are at your immediate reach to provide applications and instrumentation technical or troubleshooting assistance. Highly capable ACEA support team members can provide 24/7 remote support or on-site support to ensure smooth laboratory operation. For more information, visit www.acea-bio.com.





6779 Mesa Ridge Road
Suite #100
San Diego, CA 92121

TELEPHONE
858 724 - 0928

FACSIMILE
858 724 - 0927

WEBSITE
www.aceabio.com

June 20, 2017

ACEA Biosciences Statement on NovoCyte® IVD Configuration Name and Catalog Assignment

ACEA Biosciences differentiates the fully validated IVD NovoCyte systems for use as CE-IVD classified devices from RUO classified devices by adding a letter D as a prefix to the model number configuration and a suffix to the catalog number. The configuration of the CE-IVD devices are similar to the RUO devices, however the designated 'D' configurations assure that devices to have been validated using appropriate QA guidelines for CE-IVD use.

ACEA Biosciences establishes that it will support its IVD configured systems to ensure quality and high performance in IVD applications.

Information provided by:

A handwritten signature in blue ink, appearing to read 'René Nuñez', is written over a horizontal line.

René Nuñez
Associate Director of Marketing – Flow Cytometry

ACEA Biosciences, Inc.
6779 Mesa Ridge Rd. #100, San Diego, CA 92121
D: 858-724-0928 x 3083, F: 858-724-0927
rnunez@aceabio.com
www.aceabio.com