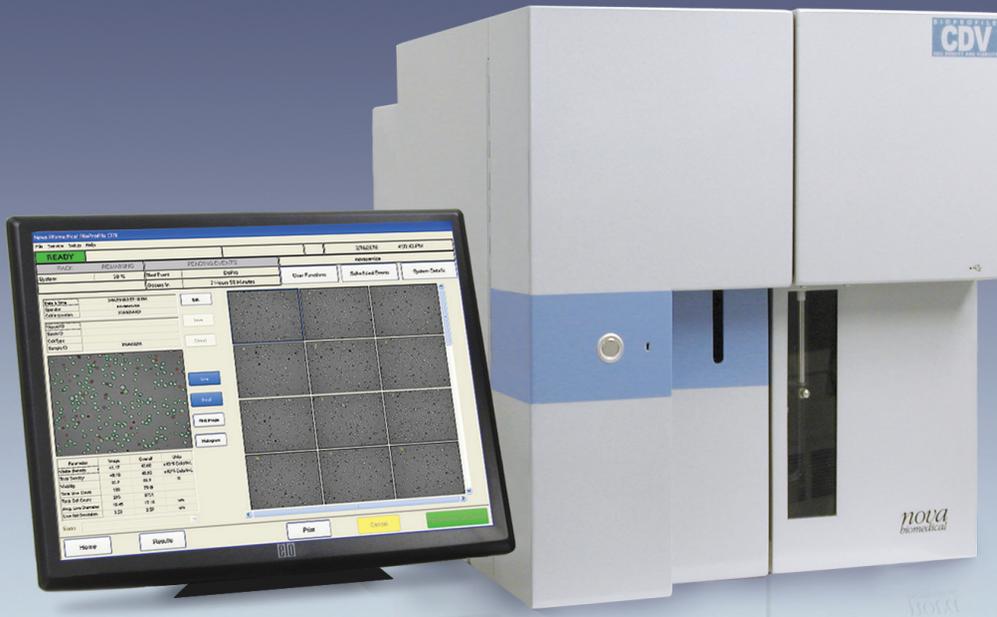


BioProfile®
CDV™

Advanced Technology Automated Cell Density/Viability Analyzer



Measures Cell Count, Cell Viability, Cell Size

**High Resolution Automated Trypan Blue
Exclusion Assay at the Cost of
Low Resolution Assays**

Fast Counts, Less than 2.5 Minutes

**Wide Measurement Range,
Up to 80 Million Cells per ml**

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Advanced Technology Automated Analyzer for Cell Density

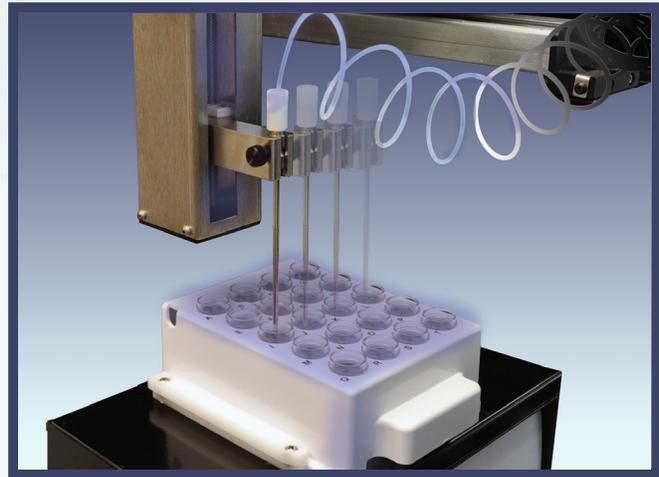
Cell density and cell viability are among the most critically needed measurements in biopharmaceutical cell culturing and production of recombinant proteins. Timely, accurate viable cell density measurements are critical in reducing cell culture excursions, maintaining cell culture health and optimizing cell culture yields. These measurements also provide vital information in many other areas of cell-based research such as therapeutic cloning, cancer research, and cell based toxicity studies.

BioProfile CDV incorporates advanced, state-of-the-art technology for rapid, high resolution measurement of cell density and cell viability at a moderate cost. Based on the widely recognized trypan blue exclusion method, BioProfile CDV combines advanced technology in robotics, optics and computer algorithms in a highly automated analyzer:



Advanced, High Speed Robotic Automation

BioProfile robotics automate the entire trypan blue method including sampling, mixing, staining, diluting and cell classification. BioProfile robotics are designed to be very precise and reproducible while maintaining structural integrity of fragile cell lines and homogeneity of cell mixtures. Operator technique deviations in manual pipetting of samples, trypan blue staining and cell counting are eliminated.



Innovative Hemocytometer Counting Chamber Design

A unique hemocytometer counting chamber is designed to rapidly form a single, mono-layer of cells for precise optical focusing and uniform cell distribution within the counting chamber. Cells remain stationary within the counting chamber as the optics inspects multiple fields. This provides improved resolution compared to instruments that inspect a single field in a flow cell and have to move multiple sample aliquots through the flow cell for imaging.

and Cell Viability

State-of-the-Art, High Resolution Vision System

A high resolution vision system provides precise auto-focusing and improved image capture on a single, mono-layer of cells within the counting chamber. High quality images from up to 40 optical fields are captured in seconds. High resolution imaging allows all cells in the image field to be more accurately inspected and classified.



Advanced Computer Algorithms Provide Fast Image Processing and Classification

Advanced, high-speed computer algorithms rapidly process and classify digital cell images.

- 40 optical fields within the counting chamber can be processed and counted in as little as 2.5 minutes.
- Accuracy, reproducibility and statistical reliability of the cell count are improved through the ability to classify a large number of cells from multiple optical fields in minutes.

A screenshot of a software interface for cell counting. The main window displays a grayscale image of cells, with some cells highlighted in green and others in red. To the right of the image are four buttons: "Live", "Dead", "Print Image", and "Histogram". Below the image is a table with the following data:

| Parameter | Image | Overall | Units |
|--------------------|-------|---------|------------------------|
| Viable Density | 41.17 | 43.00 | $\times 10^5$ Cells/mL |
| Total Density | 49.18 | 49.93 | $\times 10^5$ Cells/mL |
| Viability | 83.7 | 86.1 | % |
| Total Live Count | 180 | 7519 | |
| Total Cell Count | 215 | 8731 | |
| Avg. Live Diameter | 18.45 | 17.16 | um |
| Live Std Deviation | 3.53 | 3.57 | um |

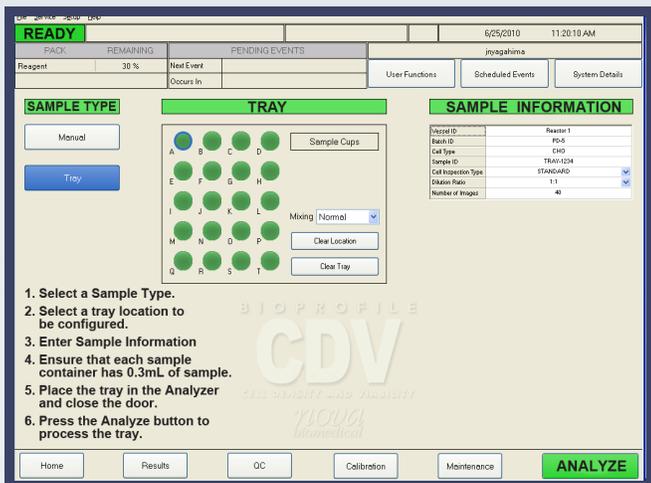
Flexible Applications

BioProfile CDV is applicable to mammalian cell viability and cell density studies in many applications:

- Cellular based therapies such as hematopoietic stem cell therapy
- Cancer research
- Cell base toxicity studies
- Drug discovery studies.
- Research or therapeutic cloning
- Cell proliferation studies

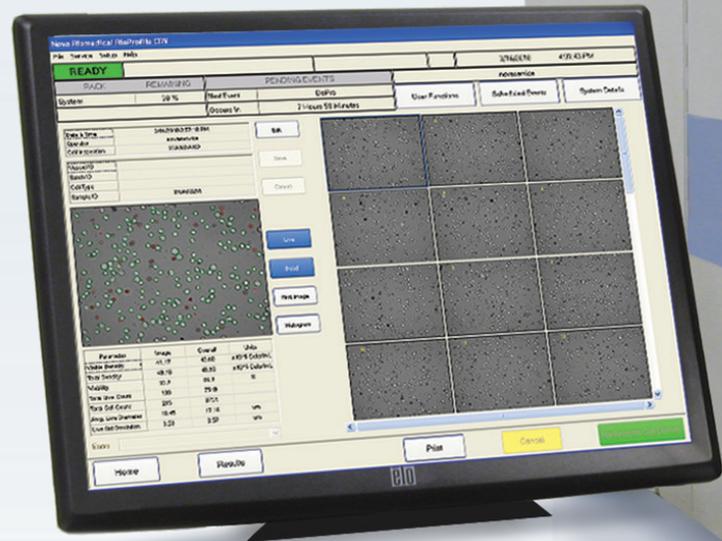
BioProfile® FLEX CDV™

Easy to Use, Labor-Saving Automation

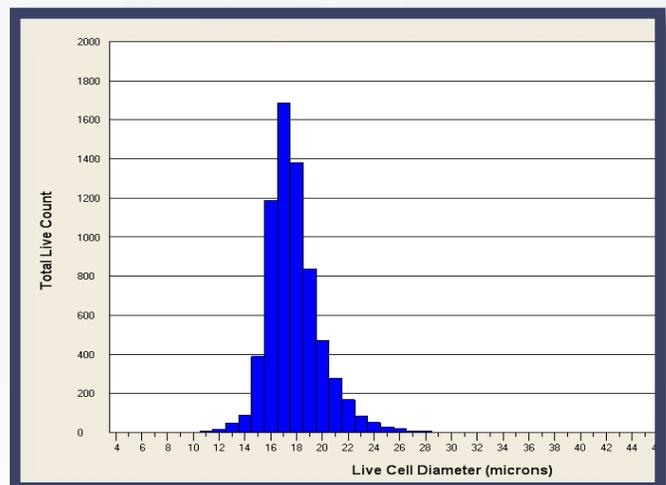
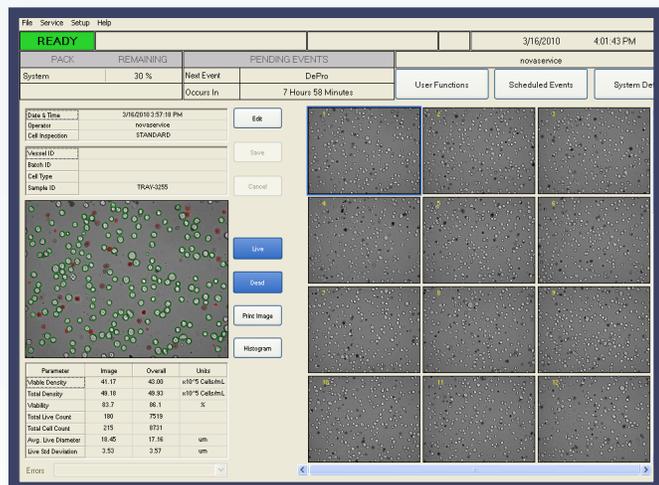


The intuitive, touchscreen interface is easy to use. No special operator skill is required.

BioProfile robotics automate the entire trypan blue exclusion method including sample aspiration, dilution, mixing, staining, cell classification and results archiving. This automation conserves labor for more skilled tasks. A 20-position sampler enables batch sampling and walk-away automation.



Accurate, Reproducible Cell Counts



BioProfile CDV counts up to 40 optical fields and thousands of cells for exceptional accuracy and reproducibility.

Histograms show distribution of live cell diameters.

- High resolution optics and an enlarged pixel area provide enhanced cell images for improved classification.
- Proprietary algorithms differentiate live cells from debris and other artifacts, and detect individual cells within aggregates.
- Enhanced mixing routines de-cluster aggregated cells.



On-Board Storage and Recall of Images

| Recall Results | | | | | | | |
|----------------------|-----------|---------------|-----------------|-----------|--------------------|------------------|------------------|
| Date & Time | Sample ID | Total Density | Visible Density | Viability | Avg. Live Diameter | Total Live Count | Total Cell Count |
| 3/16/2010 4:13:38 PM | TRAV-3275 | 49.79 | 42.80 | 86.0 | 17.26 | 7464 | 8706 |
| 3/16/2010 4:13:01 PM | TRAV-3274 | 49.90 | 42.88 | 85.5 | 17.46 | 7463 | 8725 |
| 3/16/2010 4:12:28 PM | TRAV-3273 | 50.02 | 42.88 | 85.7 | 17.43 | 7488 | 8747 |
| 3/16/2010 4:11:52 PM | TRAV-3272 | 49.46 | 42.80 | 86.1 | 17.21 | 7449 | 8640 |
| 3/16/2010 4:11:17 PM | TRAV-3271 | 50.25 | 43.06 | 85.7 | 17.38 | 7530 | 8787 |
| 3/16/2010 4:10:41 PM | TRAV-3270 | 49.85 | 42.93 | 85.8 | 17.39 | 7463 | 8717 |
| 3/16/2010 4:10:05 PM | TRAV-3269 | 50.02 | 42.99 | 85.7 | 17.43 | 7488 | 8747 |
| 3/16/2010 4:09:29 PM | TRAV-3268 | 49.62 | 42.84 | 85.9 | 17.24 | 7456 | 8676 |
| 3/16/2010 4:08:53 PM | TRAV-3267 | 49.66 | 42.46 | 85.5 | 17.40 | 7424 | 8694 |
| 3/16/2010 4:08:18 PM | TRAV-3266 | 50.07 | 42.76 | 85.4 | 17.42 | 7477 | 8756 |
| 3/16/2010 4:07:42 PM | TRAV-3265 | 50.21 | 43.12 | 85.9 | 17.33 | 7541 | 8780 |
| 3/16/2010 4:07:06 PM | TRAV-3264 | 49.85 | 42.88 | 85.6 | 17.38 | 7463 | 8717 |
| 3/16/2010 4:06:30 PM | TRAV-3263 | 49.90 | 42.88 | 85.5 | 17.46 | 7463 | 8725 |
| 3/16/2010 4:05:54 PM | TRAV-3262 | 49.85 | 42.88 | 85.6 | 17.38 | 7463 | 8717 |
| 3/16/2010 4:05:18 PM | TRAV-3261 | 49.83 | 42.89 | 85.7 | 17.46 | 7465 | 8714 |
| 3/16/2010 4:04:42 PM | TRAV-3260 | 49.62 | 42.84 | 85.9 | 17.24 | 7456 | 8676 |
| 3/16/2010 4:04:06 PM | TRAV-3259 | 49.85 | 42.81 | 86.2 | 17.21 | 7466 | 8682 |
| 3/16/2010 4:03:30 PM | TRAV-3258 | 50.07 | 42.76 | 85.4 | 17.42 | 7477 | 8756 |
| 3/16/2010 4:02:55 PM | TRAV-3257 | 49.79 | 42.80 | 86.0 | 17.26 | 7464 | 8706 |
| 3/16/2010 4:02:19 PM | TRAV-3256 | 49.75 | 42.79 | 86.0 | 17.20 | 7482 | 8699 |
| 3/16/2010 3:57:18 PM | TRAV-3255 | 49.93 | 43.00 | 86.1 | 17.16 | 7519 | 8731 |
| 3/16/2010 3:56:43 PM | TRAV-3254 | 49.95 | 42.86 | 85.4 | 17.47 | 7459 | 8734 |
| 3/16/2010 3:56:07 PM | TRAV-3253 | 50.20 | 43.00 | 85.7 | 17.34 | 7520 | 8778 |

Images from the last 30 days can be stored and recalled from memory for re-analysis by new inspection criteria. After 30 days images are stored as jpeg files.

Low Cost of Operation



Reagent cartridges are easily replaced.

- BioProfile CDV reduces operating cost by using minimal reagent volumes.
- Ready to use, slide in reagent cartridges can analyze over 300 samples per cartridge, reducing the frequency of reagent replacement.

Fast, 2.5 Minute Cell Counts, Throughput Up to 25 Samples per Hour

BioProfile robotic automation, high-speed image capture and processing combine to provide the fastest cell counts and highest throughput.

Wide Measurement Range

- Selectable auto-dilution modes extend the BioProfile CDV measurement range to 80,000,000 cells/ml.
- The cell diameter detectable range is 4-70 microns.

Multiple Mammalian Cell Types

Variable inspection criteria allows multiple mammalian cell types such as CHO, hybridoma and NS0 cell lines to be accurately analyzed.

Comprehensive Customer Support

BioProfile CDV users are backed by an extensive array of support services from Nova and its authorized international distributors. BioProfile CDV customer support services include:

Installation

Installation, performed by Nova or an authorized dealer, consists of setting up the analyzer and verifying performance.

Validation Assistance

Installation staff can perform additional reference analyzer correlation studies for new installations. Nova or its authorized agent will perform all tests and provide complete documentation to verify compliance to regulatory standards. In addition to Installation Qualification and Operation Qualification (IQ/OQ) support, we can assist with performance qualification (PQ) protocol development and implementation.

Timely Delivery of Reagents and Supplies

Nova and its authorized distributors have a history of providing timely access to reagents and supplies, so that you have the supplies you need, when you need them.

Cell Analysis Customization

Our Application Specialists can customize the setup of the BioProfile CDV analyzer to your specific process. With backgrounds in cell culture and digital imaging, our applications professionals can advise users on the optimal settings for your application.

Field Support

On those occasions when onsite service is required, we have local (in-country) trained staff ready to provide support as needed.

Specifications

Principle of Operation:

BioProfile CDV utilizes the industry standard Trypan Blue Exclusion Assay. The cell sample is allowed to settle on a proprietary flowcell that is incrementally moved past the microscope objective (10x). The high powered Vision System, using proprietary detection algorithms, processes the result.

Measured Parameters:

Total Cell Density
Viable Cell Density
% Viability
Live Cell Diameter
Live Cell Standard Deviation/Histogram

Detectable Cell Density Ranges (utilizing selectable on-board dilution)

Dilution Ratio: 1:1
Density Range 100,000–20,000,000 cells/mL

Dilution Ratio: 1:2
Up to 40,000,000 cells/mL

Dilution Ratio: 1:4
Up to 80,000,000 cells/mL

Detectable Cell Diameter Range:

4 – 70 microns

Viability:

0 – 100%

Sample Volume:

less than 300 uL of aspirated volume

Sampling Options:

Individual via syringe/cup
Automated batch using 20-position sampling tray

Analysis Times:

Less than 2.5 minutes
for manually introduced samples

Less than 3.0 minutes
for tray samples

Dimensions:

16"W x 18.5"H x 20"D
(40.6cm W x 47.0cm H x 50.8cm D)

Weight:

Less than 50 pounds (22.7 Kg)

Reagent Pack Description:

2 Pack System with integral waste bag, on-board system diluent, and deproteinization solution.
300+ Samples/pack

Operating Temperature Range:

15-40°C (59-104°F)

User Interaction

17" Touch Screen
Keyboard
Mouse
Printer Support (USB or Network printer)
Barcode Reader
Simple, intuitive User Interface

Data Transfer/Communication:

USB Thumb Drive
Ethernet (RJ45 Connector)

Safety Certifications:

TUV, IEC 61010-1:2001

Quality Systems Certification:

TUV: ISO 9001:2000

FDA Registered, OPC Compliant, PAT Compatible, 21 CFR Part 11 Compliant

21CFR Part 11 Compliant

FDA-regulated Good Laboratory Practice (GLP) and current Good Manufacturing Practice (cGMP) sites that utilize computers for instrument control, data acquisition, data transfer and archiving must follow 21CFR Part 11 requirements for electronic records and signatures.

BioProfile CDV provides comprehensive features to assist with meeting these requirements:

- Limited Access: Administrative password configuration tools limit access to BioProfile CDV electronic records through password privilege levels. Automatic log-off and password de-activation features are also available to prevent unauthorized access.
- Electronic Record Retention and Retrieval: All data are securely and confidentially retained through password access control in both human readable and electronic form.
- Audit Trails: Time stamped audit trails record the date and time of operator entries of actions that create, modify, or delete electronic records. Records are maintained in original and audited form.

Other BioProfile Products

BioProfile FLEX

BioProfile FLEX is an automated, modular, multi-test analyzer for fast, comprehensive cell culture analysis. BioProfile measures up to 16 key cell culture attributes from a small 1 ml sample. Results are available in 2-8 minutes, depending on tests selected. The modular design of BioProfile FLEX can be customized with one to four analytical modules.

- Chemistry/Electrolyte/Gas Module
- Cell Density, Cell Viability, Cell Diameter Module
- IgG Module
- Osmolality Module (Integrated Advanced Instruments Model 2020)



BioProfile FLEX with On-Line Autosampler

BioProfile On-Line Autosampler connects BioProfile FLEX to as many as ten bioreactors for online automated sampling. Scheduling of sampling is user programmable. Individual syringe or cup samples can also be analyzed during periods when on-line autosampling is not scheduled.



BioProfile 400, BioProfile 100 Plus, Basic 4, Basic 2, BioProfile 300A and 300B Fermentation Analyzers

Nova's BioProfile analyzers include four models of fully automated cell culture analyzers with test menus of two to ten tests, including chemistry, gases and electrolytes. Each model offers automatic calibration, one-button operation, and 40 position batch processing capability.



BioProfile 300A and 300B offer glucose, lactate, acetate, ammonium, pH, sodium, potassium and a choice of either phosphate or glycerol. These systems offer measurement ranges specifically suited to bacterial fermentations.

BioProfile pHox

BioProfile pHox is designed to measure acid/base and respiratory parameters from mammalian cell culture and bacterial fermentations. This compact, easy-to-use analyzer provides rapid, accurate results throughout a wide range of pH, PCO₂ and PO₂ levels encountered in cell cultures and fermentations.



BioProfile System Selection Guide

| | Glc | Lac | Glu | Gln | NH ₄ | pH | PCO ₂ | PO ₂ | Na | K | Ca | OSM | CD | CV | CDi | IgG | Ace | PO ₄ | Gly |
|----------------------------|-----|-----|-----|-----|-----------------|----|------------------|-----------------|----|---|----|-----|----|----|-----|-----|-----|-----------------|-----|
| BioProfile FLEX | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | | |
| BioProfile 400 | X | X | X | X | X | X | X | X | X | X | | | | | | | | | |
| BioProfile 100 Plus | X | X | X | X | X | X | | | X | X | | | | | | | | | |
| BioProfile Basic 4 | X | X | X | X | | | | | | | | | | | | | | | |
| BioProfile Basic 2 | X | X | | | | | | | | | | | | | | | | | |
| BioProfile 300A | X | X | | | X | X | | | | | | | | | | | X | X | |
| BioProfile 300B | X | X | | | X | X | | | | | | | | | | | X | | X |
| BioProfile pHox | | | | | | X | X | X | | | | | | | | | | | |

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NOVA BIOMEDICAL HEADQUARTERS: 200 Prospect Street, Waltham, MA 02454-9141 U.S.A. TEL: (781) 894-0800 (800) 458-5813 FAX: (781) 894-5915 Int'l FAX: (781) 899-0417
NOVA BIOMEDICAL AUSTRIA/EASTERN EUROPE/MIDDLE EAST: Laxenburger Strasse 33/6, A-1100 Vienna, Austria TEL: (43) 1-603 09 700 FAX: (43) 1-603 09 702 e-mail: office@novabio.at
NOVA BIOMEDICAL CANADA, LTD: 17 - 2900 Argenta Road, Mississauga, Ontario L5N 7X9 Canada TEL: (905) 567-7700 (800) 263-5999 FAX: (905) 567-5496 e-mail: info@novabio.ca
NOVA BIOMEDICAL FRANCE: Parc Technopolis - Bât. Sigma 3 Avenue du Canada 91940 Les Ulis Courtaboeuf, France TEL: (33) 1-64 86 11 74 FAX: (33) 1-64 46 24 03 e-mail: novabio@infonie.fr
NOVA BIOMEDICAL GmbH: Messenhäuser Str.42, 63322 Rödermark, Germany TEL: (49) 6074-8448-0 FAX: (49) 6074-844833 e-mail: info@novabiomedical.de
NOVA BIOMEDICAL INDIA: 307, Apra Plaza II, Plot No.14, Sector - 10, Dwarka, New Delhi - 110 075 India TEL: +91-11-25085653 +91-11-25075653 FAX: +91-11-25085630 e-mail: novabio@nde.vsnl.net.in
NOVA BIOMEDICAL K.K.: B-3F Omori Bellport, 26-Minami Oi 6-chome, Shinagawa-ku, Tokyo 140-0013, Japan TEL: (03) 5471-5461 FAX: (03) 5471-5474 e-mail: info@novabiomedical.co.jp
NOVA BIOMEDICAL U.K.: C3-5 Evans Business Centre, Deeside Industrial Park, Deeside, Flintshire CH5 2JZ United Kingdom TEL: 44 1244 287087 FAX: 44 1244 287080 e-mail: office@novabiomedical.co.uk

IN THE U.S.A., call toll-free 800-458-5813 **IN CANADA,** call toll-free 800-263-5999
Internet address: www.novabiomedical.com
e-mail: info@novabiomedical.com