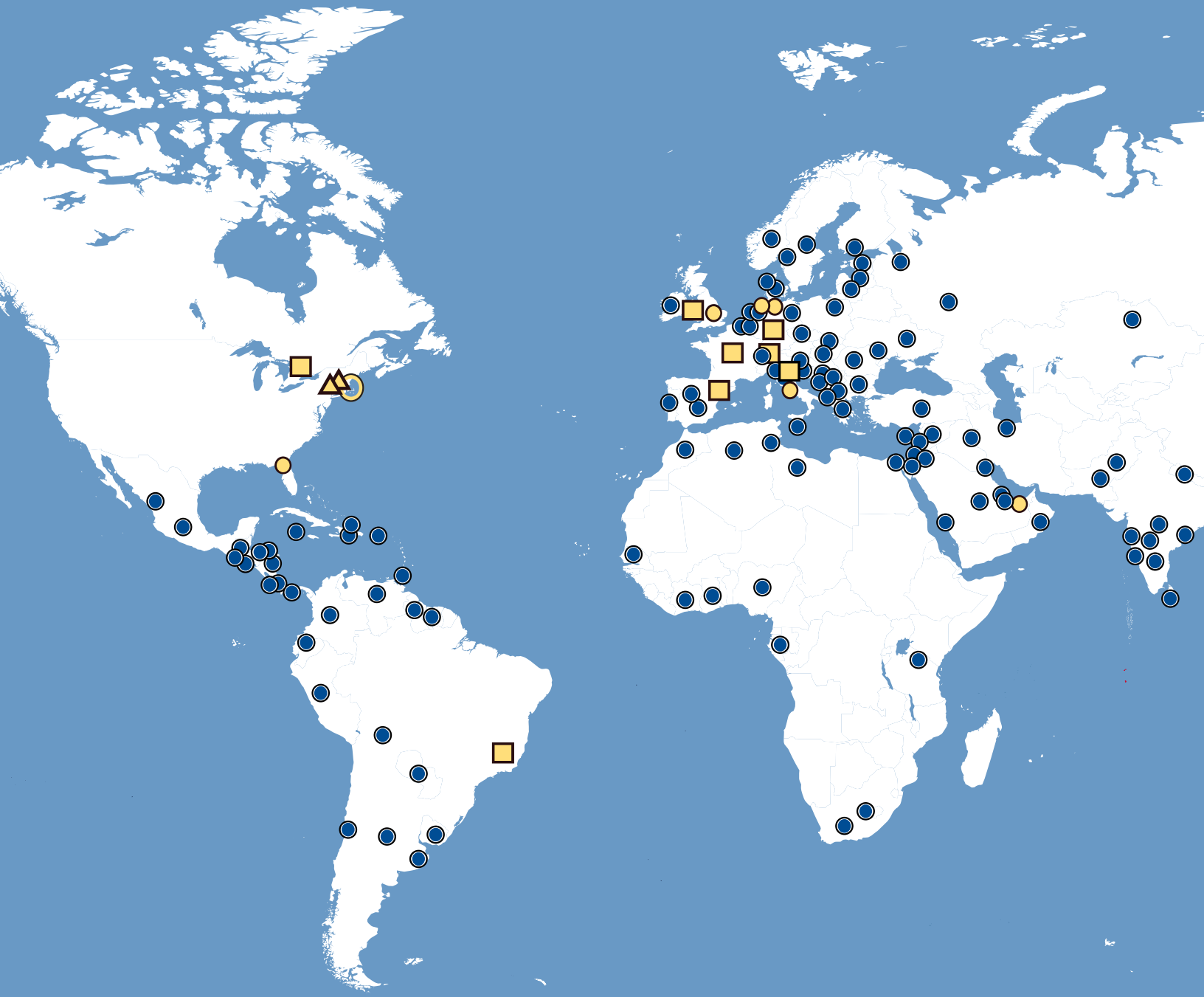
nova® biomedical

A World Leader

in Critical Care and Point-of-Care Testing

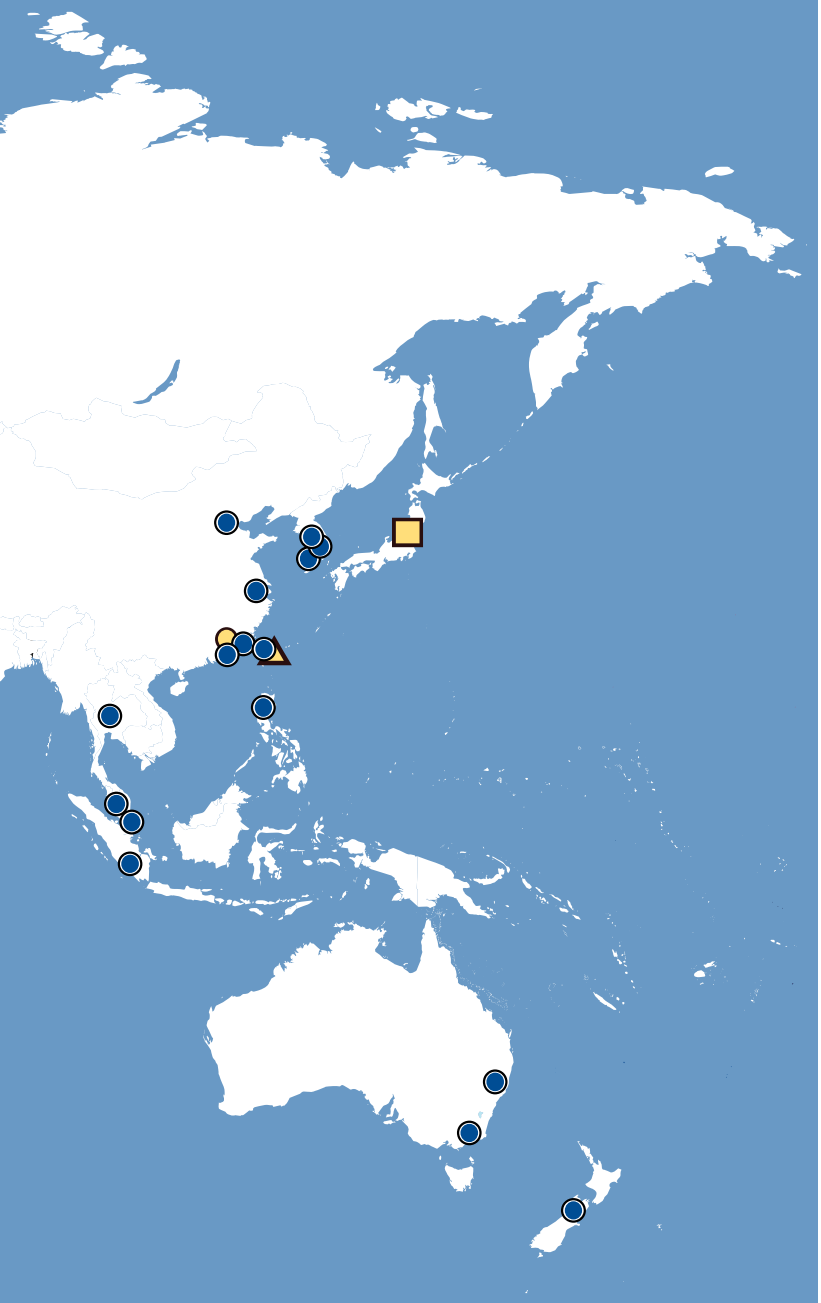


Nova Biomedical Headquarters
United States - Waltham, MA

Manufacturing Sites
United States - Waltham, MA
Billerica, MA
Taiwan - Taipei

Sales Subsidiaries
Brazil - Belo Horizonte
Canada - Mississauga, Ontario
France - Les Ulis, Courtaboeuf
Germany - Mörfelden-Walldorf
Italy - Lainate, Milan
Japan - Minato-ku, Tokyo
Spain - Barcelona
Switzerland - Zurich
United Kingdom - Runcorn, Cheshire

International Dealers
110 Dealers Worldwide



International Sales Support Offices
Africa - Hamburg, Germany
Asia Pacific - Hong Kong, China
Central & South America - Miami, FL, USA
Southern Europe - London, United Kingdom
Middle East - Dubai, UAE
Russia - Hamburg, Germany
Northern Europe - Siena, Italy

Nova Biomedical is One of the World's Fastest Growing In Vitro Diagnostics Companies

Nova Biomedical is the largest privately held in vitro diagnostics (IVD) company in the United States and the third largest in the world, employing over 1,300 people. Our eight percent compound annual growth rate over nearly a decade is triple the average IVD market growth, making Nova one of the fastest growing IVD companies in the world.

Nova's size and rapid growth are the result of customers throughout the world responding to the exceptional quality and value of Nova's technology, products, and customer service. Our strong corporate commitment to these three areas has made Nova a world leader in critical care and point-of-care (POC) testing.

A Global Company

Nova has sales and service operations in 100 countries, through subsidiaries or distributors. Nova's wholly-owned subsidiaries are located in Brazil, Canada, France, Germany, Italy, Japan, Spain, Switzerland, the United Kingdom, and the U.S., with distributors in 95 additional countries. Nova's subsidiaries and distributors provide product information, demonstrations, local inventory, and complete technical support. Whether you are located in North America, Europe, Russia, the Middle East, Africa, Asia, the Pacific Islands, Latin America, or the Indian Subcontinent, Nova can support your critical care and POC testing needs.

Nova's global manufacturing operations take place in facilities are located in Waltham and Billerica, Massachusetts, U.S., and Taipei, Taiwan. These facilities occupy a total of 40,000 square meters (430,000 square feet) of manufacturing space.

nova® biomedical

A Leader i

in Technology for Medical S

A Technology Leader

Nova Biomedical is the world leader in whole blood biosensor development. Beginning with the world's first whole blood biosensors for sodium, potassium, and ionised calcium in 1979, Nova was the first to develop over 20 whole blood biosensors. Some biosensors are not available from any other manufacturer. Our StatStrip glucose biosensor technology, which measures and corrects for interferences, has achieved worldwide scientific acclaim for its breakthrough improvement in accuracy. Over 200 published scientific studies have proven the laboratory-equivalent accuracy of StatStrip in POC settings such as intensive care, neonatal intensive care, surgery, and burn care. It is the only glucose biosensor proven to have no clinical interferences and accurate enough to have been cleared by the U.S. Food and Drug Administration (FDA) for use with critically ill patients.

In addition to whole blood biosensor technology that utilises electrochemistry, we have developed analyzers with whole blood immunoassays, whole blood photometry, and digital imaging.

Maintaining leadership in any technology industry requires a long-term perspective and commitment to research and development. Nova Biomedical has consistently invested more than 10 percent of sales into research and development—double the industry average. Nova employs over 125 scientists and engineers in research and development, including 25 doctoral level scientists. Our investment in research and development provides continuous product improvement and new advanced technology for our customers.

Directed by Medical Science

Nova's advanced technology is directed by our involvement with the clinical and medical communities. Through our Medical and Scientific Affairs department, we work with clinicians throughout the world to find areas of clinical need that can be improved through the application of our measurement technologies. We also encourage studies of our products in patient populations that stress the limits of analytical performance. Over 200 papers have been published in peer-reviewed journals over the last eight years that validate the excellent performance of our products in medical areas such as sepsis and septic shock, foetal distress, acute kidney injury, severe burn, neonatology, oncology, and cardiac surgery.

Measurement Technologies

Potentiometry (whole blood or plasma)

Ace	pH electrode with acetate permeable membrane
iCa	Calcium ionophore in polyvinyl chloride (PVC)
Cl	Chloride anion ionophore in PVC
K	Valinomycin in PVC
Li	Lithium ionophore in PVC
iMg	Magnesium ionophore in PVC
Na	Sodium ion selective glass membrane or sodium ionophore in PVC
NH_4^+	Ammonium ion selective electrode (ISE) ionophore
***P*CO_2**	pH electrode with CO_2 gas permeable membrane
pH	Hydrogen ion selective glass membrane
TCa	Calcium electrode with acidified sample
TCO_2	pH electrode, CO_2 membrane, acidified sample
Urea	Urease enzyme membrane with ammonium ISE

Amperometry (whole blood/plasma, or cell culture media)

Chol	Cholesterol oxidase immobilised enzyme, mediator
Creat	Immobilised three enzyme system, mediator
Gln	Two enzyme oxidant for glutamine, mediator
Glu	Glutamate oxidase immobilised enzyme, mediator
Gluc	Glucose oxidase immobilised enzyme, mediator
Hb	Lysing reagent and oxidant, mediator
Ket	Beta-hydroxybutyrate immobilised enzyme, mediator
Lac	Lactate oxidase immobilised enzyme, mediator
***P*O_2**	O_2 membrane, O_2 reduction by cathode, mediator
Uric Acid	Uricase immobilised enzyme, mediator

Conductivity (whole blood)

Hct	Electrical resistance, Na corrected

Immunochemistry (whole blood or urine)

HbA1c	Hemoglobin A1c, immunoagglutination
Lipids	High/Low density cholesterol and triglycerides, immunoagglutination
UA	Urine albumin, immunoagglutination
UC	Urine creatinine, immunoagglutination

Science

Spectrophotometry (plasma or cell culture media)

Creat	Modified Jaffe, alkaline picrate rate absorbance
Gly	Glycerol absorbance endpoint
IgG	Affinity binding assay, absorbance
PO_4	Absorbance endpoint
tHb	Cyanmethemoglobin absorbance
TMg	Methylthymol blue, absorbance, endpoint
TP	Biuret, absorbance, endpoint

Optical (whole blood)

COHb	Multi-wavelength spectral scanning of whole blood
Hb	Multi-wavelength fiber optic reflectance plus conductivity, sodium correction
HbF	Multi-wavelength spectral scanning of whole blood
MetHb	Multi-wavelength spectral scanning of whole blood
O_2Hb	Multi-wavelength spectral scanning of whole blood
RHb	Multi-wavelength spectral scanning of whole blood
sHb	Multi-wavelength spectral scanning of whole blood
SO_2%	Multi-wavelength fiber optic reflectance (oximetry)
tBil	Multi-wavelength spectral scanning of whole blood
tHb	Multi-wavelength spectral scanning of whole blood
PT/INR	Prothrombin time optical aggregation

Ellipsometry (saliva or urine)

Herpes	Light reflectance
Influ A	Light reflectance
Influ B	Light reflectance

Imaging (cell culture)

Cell Density	Cell staining followed by digital imaging
Cell Diameter	Cell staining followed by digital imaging
Cell Viability	Cell staining followed by digital imaging

Critical Care Blood Gas Analyzers

STAT PROFILE Prime+®

A Technology Evolution in Critcal Care Testing

Prime Plus is a comprehensive, rapid, critical care analyzer that measures 22 tests including blood gases, electrolytes, metabolites, and CO-Oximetry in about 1 minute from 135 µL of whole blood. Prime Plus combines maintenance-free, replaceable cartridge technology for sensors and reagents with patented, new, maintenance-free, and non-lysing whole blood CO-Oximetry. It adds clinically important, new critical care tests for iMg, urea, and creatinine. Prime Plus houses all of this capability in a compact analyzer with a space-saving footprint, which is essential for POC settings.

Test Menu:

pH, pCO_2, pO_2, SO_2%, Na, K, Cl, iCa, TCO_2, iMg, Glu, Lac, BUN (Urea), Creat, Hct, O_2Hb, COHb, MetHb, HHb, tHb, HbF*, tBil*, and 32 calculated results

Dimensions:

Width: 36.1 cm (14.2 in)
Depth: 39.4 cm (15.5 in)
Height: 46.2 cm (18.2 in)
Weight: 27.7 kg (69 lb)

STAT PROFILE Prime®

Exceptional Simplicity for Critical Care Testing

Stat Profile Prime combines new consumer based micro-electronics with new technology micro-sensor cartridges to produce 7 models of smaller, faster, more powerful, and less expensive analyzers for blood gas, electrolyte, and metabolite testing. Stat Profile Prime's 10-test critical care profile is ready in 1 minute, with throughput of up to 45 samples per hour. Prime's maintenance-free calibrator and sensor cartridges lower costs. Simple, color touchscreen operation and automated, liquid quality control (QC) are standard features.

Models and Test Menus:

Comprehensive Critical Care System
pH, pCO_2, pO_2, Na, K, Cl, iCa, Glu, Lac, Hct

Critical Care System
pH, pCO_2, pO_2, Na, K, Cl, iCa, Hct

Blood Gas System
pH, pCO_2, pO_2

Comprehensive Electrolyte System Plus**
Na, K, Cl, iCa, iMg, pH, Hct

Comprehensive Electrolyte System
Na, K, Cl, iCa, iMg

Basic Electrolyte System
Na, K, Cl

Electrolyte System Plus**
Na, K, Cl, Hct

Dimensions:

Width: 30.5 cm (12 in)
Depth: 36.5 cm (14.35 in)
Height: 39.06 cm (15.38 in)
Weight: 8.119 kg (17.9 lb)

STAT PROFILE pHOx® Ul

Stat Profile pHOx Ultra Analyzer**

pHOx Ultra is a critical care blood gas analyzer providing 20 tests. It can be custom configured to satisfy any department's menu requirements, with as many as 20 tests to as few as 7. The full critical care profile is performed with only 2 drops of whole blood in 2 minutes.

Test Menu:

pH, pCO_2, pO_2, SO_2%, Na, K, Cl, iCa, iMg, Glu, Lac, BUN (Urea), Creat, Hb, Hct, O_2Hb, HHb, COHb, MetHb, tBil

Dimensions:

Width: 56.7 cm (22.34 in)
Depth: 43.8 cm (18.7 in)
Height: 43.7 cm (17.22 in)
Weight: 27.7 kg (61 lb)

*Not yet available in the U.S. or Canada
**Available in FDA required and self-declared coutries
†Available in Japan only

Capillary Blood Chemistry Analyzers

tra™

Stat Profile pHOx Analyzer**

Stat Profile pHOx's advanced optics, long-life biosensors, rugged electromechanical design, and computer automation provide cost-effective blood gas assays for hospital use.

Models and Test Menus:

pHOx
pH, pCO_2, pO_2

pHOx Plus
pH, pCO_2, pO_2, Hct, Hb, SO_2%, Glu, Na, K, iCa or Cl

pHOx Plus C
pH, pCO_2, pO_2, Hct, Hb, SO_2%, Glu, Na, K, iCa, Cl

pHOx Plus L
pH, pCO_2, pO_2, Hct, Hb, SO_2%, Glu, Lac, Na, K, iCa or Cl

pHOx Plus M†
pH, pCO_2, pO_2, Na, K, iCa, iMg, Glu, Lac

Allegro®

A Fast, Simple Capillary Blood Analyzer*

Allegro is a fast, simple, test-selective capillary blood analyzer for POC or office testing. It features 13 measured and 7 calculated, clinically important tests to monitor glycaemic control, assess cardiac risk with a full lipids panel, and assess kidney function. All tests are measured with single-use cartridges or biosensors, and are easily performed by POC or office staff. Fingerstick capillary sampling eliminates the need for venipuncture or a trained phlebotomist. Allegro is very compact at 20 centimeters (8 inches) wide and easily fits in clinics, offices, and outpatient locations.

Test Menu:
HbA1c, Blood Glu, eAG, Blood Creat, eGFR, Urine Creat, Urine Albumin, Albumin/Creat Ratio, Total Cholesterol, HDL Cholesterol, Cholesterol/HDL Ratio, Non-HDL Cholesterol, LDL Cholesterol, Triglycerides, PT/INR, CRP

Dimensions:
Width: 20.3 cm (8 in)
Depth: 38.1 cm (15 in)
Height: 35.6 cm (14 in)
Weight: 10.43 kg (23 lb)

StatEMS® Data Link

GLUCOSE/KETONE/LACTATE/ HEMOGLOBIN/HEMATOCRIT*

With data storage plus full data transmission and connectivity

StatEMS® Basic

GLUCOSE/KETONE/LACTATE/ HEMOGLOBIN/HEMATOCRIT*

With data storage

Ambulance and Emergency Blood Testing

Measures Glucose, Ketone, Hemoglobin, Hematocrit and Lactate for early assessment, triage, and treatment. All tests use capillary blood samples and precalibrated, single test, disposable test strips. Results as fast as 6 seconds.

Point-of-Care, Whole Blood for Professional Use

Stat Strip GLUCOSE

With data storage plus full data transmission and connectivity

Stat Strip GLUCOSE and KETONE*

(Two Test Strips)

With data storage plus full data transmission and connectivity

Stat Strip LACTATE and HEMOGLOBIN/HEMATOCRIT

(Two Test Strips)

With data storage plus full data transmission and connectivity

Stat Strip Xpress 2 GLUCOSE

With data storage

Blood Glucose Monitoring

The world's most accurate hospital glucose meter technology—proven in over 200 publications of hospital studies. The only glucose meters cleared by the U.S. FDA for use with critically ill patients.

Stat Strip Xpress 2 GLUCOSE/KETONE*

(Two Test Strips)

With data storage

Blood Glucose and Ketone Monitoring

The world's most accurate hospital glucose meter technology adds ketone measurement with a separate biosensor.

Meter can be used either as a single purpose meter for Glucose only or Ketone only, or as a dual purpose meter.

Stat Strip Xpress 2 LACTATE and HEMOGLOBIN/HEMATOCRIT*

(Two Test Strips)

With data storage

Lactate Assessment and Monitoring

Lactate is a biomarker for assesing and guiding therapy for tissue hypoxia in sepsis and septic shock.

- 0.6 µL, results in 13 seconds

and

Anemia and Blood Donor Screening

Measures, not calculates, both hemoglobin and hematocrit.

- 1.6 µL, results in 40 seconds

Meters can be used either as a single purpose for Lactate only or Hemogobin/Hematocrit only, or as a dual purpose meters.

*Not yet available in the U.S. or Canada

Analyzers

Self-Testing Meters

StatSensor® CREATININE

With data storage plus full data transmission and connectivity

NovaPro™ URIC ACID

With data storage

Gout Assessment and Monitoring

Measures uric acid from 2 µL of capillary blood. Single-use biosensors provide accurate results in just 15 seconds.

nova Max® URIC ACID

URIC ACID

With data storage

Gout Assessment and Monitoring

Blood uric acid testing to manage gout. Disposable test strips measure uric acid in 15 seconds from a small blood sample, with no coding required.

LACTATE PLUS LACTATE

With data storage

Optimizes Athletic Endurance Training and Conditioning

For elite athletes, Nova offers a meter for blood lactate—a key indicator for aerobic conditioning and training intensity.

STAT SENSOR Xpress® CREATININE *

With data storage

Kidney Function Assessment

Creatinine and eGFR are used for kidney function assessment in radiology, oncology, and other settings.

- 1.2 µL, results in 30 seconds
- Also measures lactate

NovaPro™ GLUCOSE and KETONE *

(Two Test Strips)

With data storage

Blood Glucose and Ketone Monitoring

Economical meter for POC glucose and ketone testing in hospitals and clinics. Single-use biosensors measure glucose in 4 seconds and ketones in 10 seconds from 0.8 µL whole blood samples.

Meter can be used either as a single purpose meter for Glucose only or Ketone only, or as a dual purpose meter.

nova Max® PLUS™ GLUCOSE and KETONE

(Two Test Strips)

With data storage

Blood Glucose and Ketone Monitoring

Glucose and ketone testing with one meter, with proven accuracy. Glucose results in 5 seconds and ketone results in 10 seconds, from a 0.3 µL sample. No coding required.

Meter can be used either as a single purpose meter for Glucose only or Ketone only, or as a dual purpose meter.

nova Max CHOL™ CHOLESTEROL *

With data storage

Blood Cholesterol Monitoring

Nova Max meter and disposable biosensor use electrochemical technology to provide accurate cholesterol results from a tiny capillary fingerstick blood sample. Cholesterol results are available in just 30 seconds.

Biotechnology Cell

BIOPROFILE®
FLEX2

BioProfile FLEX2 Analyzer

FLEX2 is an automated and comprehensive cell culture analyzer that combines groundbreaking MicroSensor Card™ technology with optical cell imaging technology and freezing point osmometry. These technologies reduce maintenance, increase analyzer speed, and reduce sample volume. 16 key cell culture tests are ready in 4.5 minutes from a 265 µL sample. The modular FLEX2 Analyzer can be configured with chemistries and gases, plus any combination of cell density/viability and osmolality modules.

Test Menu:

Gluc, Lac, Gln, Glu, NH_4^+, pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, total cell density, viable cell density, viability, cell diameter, osmolality

BIOPROFILE®
FLEX2
BASIC

BioProfile FLEX2 Basic Chemistry Analyzer

FLEX2 Basic, with MicroSensor Card technology, provides rapid, simultaneous analysis of 11 key nutrients, metabolites, and gases in cell culture and fermentation processes. Features include: maintenance-free sensors, extended analytical ranges, no sample preparation, one-button automated operation, and results in 2 minutes.

Test Menu:

Gluc, Lac, Gln, Glu, NH_4^+, Na^+, K^+, Ca^{++}, pH, pCO_2, pO_2

Culture and Fermentation Analyzers

STAT PROFILE Prime®

Stat Profile Prime Analyzer

A new generation cell culture analyzer that combines the revolutionary micro-electronics of the consumer world with Nova Biomedical's innovative MicroSensor Card technology for a simpler, smaller, faster, and less expensive chemistry Analyzer.

Test Menu:

pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Gluc, Lac

BIOPROFILE® pHOx®

BioProfile pHOx Analyzer

A compact, easy-to-use analyzer that provides rapid and accurate pH, PCO_2, and PO_2 measurement in the wide ranges necessary for cell culture and fermentation processes. Results are available in 45 seconds. The industry's only pH and gas Analyzer specifically designed for cell culture applications. Onboard, automated QC saves time and labor.

Test Menu:

pH, pCO_2, pO_2

Corporate Commitment to Quality

Nova Biomedical's success is based on our commitment to providing world-class quality to customers. This begins with research and development, manufacturing, and delivery, and continues through medical and scientific affairs and customer support. Nova's quality system is organised around product line quality committees, which consist of cross-functional teams who meet monthly to proactively address improvements. Nova's quality system is also regularly audited by third parties including the FDA, TÜV SÜD, and independent diagnostics companies whose products we build. All design processes and manufacturing procedures comply with FDA quality system regulations and ISO requirements.

Best-in-Industry Customer Technical Support

Nova provides customers with comprehensive programs to meet all technical and support needs. Nova and our distributors maintain a staff of technical support specialists, training and implementation representatives, technical product specialists, IT connectivity specialists, and technical assistance personnel. Customer support for our products begins with product installation, staff training, and implementation performed by specialists in these areas. Upon completion of training and implementation, Nova's technical assistance representatives are available 24/7 to answer questions and provide technical assistance via telephone. In the event that onsite assistance is needed, our technical field specialists respond rapidly. Our customer support personnel and services have helped us earn a worldwide reputation for providing best-in-industry technical support.

Over 40 Years of Experience

Nova Biomedical is a reliable, experienced IVD device company with more than 40 years of successful product development, manufacturing, sales, and service experience. Since our incorporation in 1976, Nova has developed over 100 IVD products cleared by the FDA, and has sold over 20,000 laboratory critical care analyzers and over 600,000 hospital POC meters for glucose, ketone, creatinine, and lactate assays. We have never received an FDA warning letter, had an FDA mandated recall, or any interruption in product supply.

nova® biomedical

novabiomedical.com

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Specifications current as of revision date.

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