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Stat Profile Prime Plus Analyzer Receives FDA Clearance for Point-of-Care Use

Waltham, MA—Nova Biomedical today announced that its Stat Profile Prime critical care analyzer has been cleared by the U.S. Food and Drug Administration (FDA) for point-of-care (POC) use, allowing non-laboratory POC personnel to perform bedside critical care testing with lab-quality results. Prime Plus features maintenance-free sensor technology to provide 20 essential critical care tests including blood gases, electrolytes, metabolites, hematology, and co-oximetry. Prime Plus also provides new and patented, non-lysing whole blood co-oximetry technology, along with automated quality control (QC), powerful data management, bidirectional connectivity, and extensive cybersecurity protection. This new FDA clearance establishes that Stat Profile Prime is simple enough to use and provides lab-quality results in POC settings whether testing is performed by POC or laboratory personnel.



Prime Plus delivers a comprehensive critical care panel including pH, PCO₂, PO₂, SO₂%, Na, K, Cl, iCa, iMg, glucose, lactate, urea, creatinine, Hct, Hb, O₂Hb, COHb, MetHb, and HHb. This provides clinicians the most detailed diagnostic profile, including a comprehensive metabolic panel, with test results available in as little as one minute.

Prime Plus incorporates Nova's innovative, maintenance-free sensor technology with individual MicroSensor Cards™, calibrator cartridges, and quality control cartridges. This design eliminates sensor and co-oximeter maintenance, improves analyzer uptime, and reduces testing costs for the compact and easy-to-use Prime Plus.

The MicroSensor Card supports 20 critical care assays including co-oximetry and unique critical care assays for urea, creatinine, and ionized magnesium with a small 60µl minimum sample volume. Prime Plus offers a complete co-oximetry panel without chemically or mechanically lysing the blood, which eliminates corrosive lysing reagents and mechanical complexity while improving instrument reliability and reducing costs.

A unique safety sample port allows for easy docking and hands-free sampling, and the Clot Block™ sample flow path protects sensors from blood clot blockages and related downtime.

Compact, lightweight, and simple to operate with a color touchscreen, Stat Profile Prime Plus may be used in a fixed location virtually anywhere in the hospital or operated on a mobile cart with a battery back-up. Stat Profile Prime Plus provides real-time supplemental quality monitoring with automated QC that verifies analyzer accuracy and precision. The on-board assayed liquid controls meet or exceed all current regulatory guidelines and do not require the development of an Individualized Quality Control Plan (IQCP). Supplemental quality monitoring electronically tracks and verifies analytical performance between QC intervals and for each analysis and calibration.

About Nova Biomedical

Incorporated in 1976 and based in Waltham, MA, Nova Biomedical is a world leader in the development and manufacturing of state-of-the-art, whole blood, point-of-care and critical care analyzers, as well as providing the biotechnology industry with the most advanced instruments for cell culture monitoring. Nova is one of the fastest growing in vitro diagnostic companies in the world. Nova's biosensor technology is incorporated in products ranging from handheld meters for glucose self- and point-of-care testing to critical care whole blood analyzers designed for rapid measurement of over 20 analytes. Nova's biotechnology-specific BioProfile line has pioneered comprehensive cell culture testing, providing over 20 critical cell culture tests with over 12 unique instrument offerings for broad range of cell culture applications. Nova employs over 1,300 people worldwide and has wholly owned subsidiaries located in Brazil, Canada, Great Britain, France, Spain, Italy, Germany, Switzerland, and Japan. Certified by the International Organization for Standardization, Nova has manufacturing operations located in the U.S. and Brazil.

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