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

Waltham, MA—Nova Biomedical today announced the U.S. Food and Drug Administration (FDA) has cleared its Stat Profile Prime Plus critical care blood gas analyzer for point-of-care (POC) use. This clearance allows POC personnel to perform bedside critical care testing with lab-quality results in as little as one minute. Prime Plus features maintenance-free sensor technology to provide 19 essential critical care tests including blood gases, electrolytes, metabolites, hematology, and co-oximetry, providing clinicians with a rapid, detailed diagnostic profile, including a comprehensive metabolic panel.

The Prime Plus MicroSensor Card™ provides a critical care panel which includes pH, PCO_2 , PO_2 , $SO_2\%$, Na, K, Cl, iCa, iMg, glucose, lactate, urea, creatinine, Hct, Hb, O₂Hb, COHb, MetHb, and HHb and requires a small 60µl minimum sample volume. Prime Plus features patented, non-lysing whole blood co-oximetry technology, which eliminates corrosive lysing reagents and mechanical complexity while improving instrument reliability and reducing costs.

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.

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.

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.

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