Stat Profile Prime Plus FDA cleared for POC use

April 15, 2020—Nova Biomedical announced the FDA has cleared its Stat Profile Prime Plus critical care blood gas analyzer for point-of-care use. This clearance allows POC personnel to perform bedside critical care testing with results in one minute.

The Prime Plus MicroSensor Card provides 19 essential critical care tests, including blood gases, electrolytes, metabolites, hematology, and co-oximetry, and requires a 60 μ L minimum sample volume. A 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 regulatory guidelines and do not require the development of an individualized quality control plan. Supplemental quality monitoring electronically tracks and verifies analytical performance between QC intervals and for each analysis and calibration.