FDA Clears Nova’s Stat Profile Prime Plus Analyzer for Micro Capillary Sample Mode

Nova Biomedical is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for a micro capillary sample mode on the Stat Profile Prime Plus® Critical Care analyzer. Prime Plus now performs an 11-test panel including pH, PCO2, PO2, Na, K, iCa, iMg, Cl, glucose, lactate, and hematocrit with just 90 microliters of capillary blood, or a complete 22-test profile on just 135 microliters of blood. The micro capillary sampling mode adds to Prime Plus blood conservation capabilities for critical care diagnostic testing and is available as a standard feature on all Prime Plus analyzers.

Stat Profile Prime Plus provides the most modern and clinically effective critical care test menu including pH, PCO2, PO2, SO2%, Na, K, iCa, iMg, Cl, TCO2, glucose, lactate, creatinine, urea, hematocrit, hemoglobin, MCHC, estimated plasma volume, CO-Oximetry panel, and 34 calculated results in a simple, compact analyzer. Prime Plus combines maintenance-free, replaceable cartridge technology for sensors and reagents with patented, maintenance-free, whole blood CO-Oximetry technology.

Blood loss for laboratory testing of critically ill patients has been shown to be a major contributor to severe anemia and increased administration of blood products, which is furthermore associated with prolonged hospital stay and increased mortality rate.[1] According to Terry Austin, Sales Product Line Manager for Prime Plus analyzer, “Prime Plus microsample volume and comprehensive test menu provide a major blood-saving benefit for diagnostic testing of critically ill patients. Prime Plus delivers gases, electrolytes, glucose, lactate, hematocrit, or any subset of these tests on just two drops (90 microliters) of blood. A basic metabolic panel of electrolytes, glucose, lactate, creatinine, urea, and hematocrit is available on 135 microliters, 1/50th the volume of blood needed for the same tests in the central laboratory.”

The use of small-volume microcapillary blood collection tubes with Prime Plus eliminates sample over-draws, dead volume, and sample waste of syringe or vacuum tube devices. Prime Plus comprehensive test menu enables scheduled bundling of tests to eliminate multiple sample draws, use of multiple sample containers, and amount of blood drawn for critical care testing.

Source: Nova Biomedical

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