

StatStrip cleared for capillary testing with critically ill

October 2018—Nova Biomedical's StatStrip Glucose Hospital Meter System has been cleared by the FDA for fingerstick capillary testing with critically ill patients. The FDA granted this 510(k) clearance to StatStrip after extensive prospective and retrospective studies were performed at the Mayo Clinic, Rochester, Minn., and Johns Hopkins Bayview Medical Center, Baltimore. The submission data comprised 16,778 patients ranging from one month to 106 years old who were receiving intensive medical intervention/therapy in critical and intensive care settings including burn, cardiac, medical, orthopedic, neurological, and surgical. StatStrip's capillary results were equivalent to the arterial and venous plasma results measured on a central laboratory IDMS traceable reference method.

[Nova Biomedical](#), 781-894-0800