FDA clears Siemens' TnIH assays

July 30, 2018—Siemens Healthineers announced FDA clearance of its High-Sensitivity Troponin I assays (TnIH) for its Atellica IM and Advia Centaur XP/XPT in vitro diagnostic analyzers to aid in the early diagnosis of myocardial infarctions.

The high sensitivity of the TnIH assays "offers the ability to detect lower levels of troponin at significantly improved precision at the 99th percentile and detect smaller changes in a patient's troponin level as repeat testing occurs," the company said in a statement.

Troponin indicates damage to the heart muscle, and greater precision measures slight yet critical changes so physicians can triage patients sooner.

"Our emergency department is overcrowded with patients. If we can do a more efficient job at triaging patients to receive the proper level of care and to discharge the patients who do not need to stay in the emergency department, this will have a tremendous economic advantage for our health care system," Alan Wu, PhD, chief of clinical chemistry and toxicology at Zuckerberg San Francisco General Hospital and Trauma Center, said in the release.

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