Improve triaging in the ED A new assay delivers a higher standard of cardiac care



"Is it a heart attack, or something less serious?"

Every day, thousands of symptomatic patients ask emergency department (ED) physicians that very question. Over the years, as diagnostic tools for acute myocardial infarction (AMI), commonly known as a heart attack, have advanced, physicians can provide increasingly accurate answers to that question. Unfortunately, diagnostic gaps still exist that can result in poor patient outcomes.

Diagnostic ambiguity is costing us

There are more than 6 million¹ ED visits annually in the U.S. for chest pain, resulting in expenditures of \$5.5 billion² for diagnostic testing on these patients. Yet fewer than 4 percent of these patients are ultimately diagnosed as having a heart attack. Our healthcare system is paying a high price for diagnostic uncertainty. Additionally, it is estimated that as many as 2 percent of those with chest pain discharged from the ED are actually having a heart

attack and should not have been sent home.³ That could all change with a new lab test that can help bring greater clarity as an aid in diagnosing heart attacks.

The Elecsys® Troponin T Gen 5 STAT (TnT Gen 5 STAT) from Roche Diagnostics is the first highly sensitive Troponin

T test cleared by the Food and Drug Administration (FDA) for use in the U.S.,⁴ and it promises to bring greater confidence to cardiac care. This biomarker revolutionizes cardiac care by identifying lower levels of troponin with excellent precision. Cardiac troponin is released into the bloodstream when cardiac cells are being damaged, and

it's the preferred biomarker for the aid in diagnosis of a heart attack in clinical practice.⁵

World-class accuracy, now within reach

TnT Gen 5 STAT isn't new to the ED. It's been available in the rest of the world for the past seven years, during which time clinicians have rapidly adopted it. However, it's new to the U.S.

Compared to other troponin assays on the market, TnT Gen 5 STAT can detect lower levels of troponin precisely, enabling physicians to more accurately identify patients experiencing a heart attack. In fact, it's the only FDA-approved assay that meets International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

guidelines⁶ for high sensitivity, and delivers optimal precision per the Third Universal Definition of Myocardial Infarction.⁷ In addition, the new assay delivers industry-leading speed, with results in nine minutes. What does this mean for the emergency doctor who's on the frontlines of diagnosing heart attacks?

"FDA clearance of this new Roche TnT assay is easily the best news in the last decade for emergency medicine patients presenting with chest pain," says Frank Peacock, MD, FACEP, FACC, Emergency Medicine Research Director at Baylor College of Medicine in Houston. "We're about to change the whole world of biomarkers relative to myocardial infarction."

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Lower troponin levels detected and less wait time in the ED

Historically, troponin assays could detect only very high levels of troponin, says Dr. Peacock, who is a leading ED physician with more than 450 publications on cardiology, emergency medicine and clinical trials.⁸

"Because you couldn't detect low levels of troponin, you had to repeat the test six hours later," he explains. "If the second troponin was negative, we'd hospitalize the high-risk patients and send the low-risk patients home. That approach gives me a whole bunch of people in the middle."

It also meant a lot more patients remained in the ED, waiting for answers.

With the increased sensitivity of the TnT Gen 5 STAT assay, emergency physicians have better help in identifying patients who are experiencing a heart attack, and, according to Dr. Peacock, more confidently identify those who are not.

"Nobody wants to spend six to eight hours unnecessarily in the ED. Now, we have an assay that can detect troponin levels that were previously undetectable, but have significant clinical relevance," Dr. Peacock says. "In other words, an assay that can't detect these lower troponin levels could potentially have a negative impact on patient."

Cardiologist and Associate Professor of Medicine at UC San Diego Health System Pam R. Taub, MD, FACC, believes that the new assay may help reduce wait time for the patient and speed up triaging in the ED.

"The reason to go with a more high-sensitivity troponin assay is the confidence you get when the result is normal in discharging a patient from the ED," Dr. Taub says. "If you have an ED that's impacted, and you're not getting a lot of patients through, you're not filling up your hospital beds as quickly as you can."

Dr. Taub continues, "I believe this new assay will shorten wait time in our ED, which could have a positive impact on patient satisfaction as well."

Increased sensitivity leads to improved care

More important, with highly sensitive troponin, those patients who need cardiac care that may have previously gone undetected can receive the treatment they need—whether they're having a heart attack or another condition that affects the heart.

"It's always a true positive when part of the structural proteins of your heart leaks out," Dr. Peacock says. "It just may not be a heart attack. There are a lot of things that can kill heart muscle. As a physician, you have to find out why the troponin is elevated."

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While results from the increased troponin sensitivity could potentially lead to more cardiology consultations, Dr. Taub doesn't necessarily see that as a bad thing.

"You're going to pick up a lot more people you might have missed from a less sensitive assay," Dr. Taub says. "Even if the elevated troponin does not represent an immediate problem, such as impending heart attack, it is still worthwhile for the cardiologist to see the patient and institute strategies to prevent future adverse cardiovascular events."

Dr. Taub explains, "Patients with minimal elevations in troponin levels have a worse prognosis than patients with no elevation."

New protocols are good for the heart - and the hospital

It's true that as hospitals adopt this highly sensitive troponin, EDs will need to implement new protocols in diagnosing patients who present chest pain and other heart attack symptoms.

However, it will also mean physicians will be able to triage and treat these patients with greater confidence, so they can provide optimal cardiac care to those patients who need it. By delivering greater accuracy in industry-leading time, the TnT Gen 5 STAT helps enable emergency physicians to focus on the right patient and give the right treatment.

"With advances in technology and analytics over the past 30 years, we've been improving troponin sensitivity over time," Dr. Taub says. "Now we are able to work with unprecedented sensitivity, which we believe will lead to even better patient care."

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"Now we are able to work with unprecedented sensitivity, which we believe will lead to even better patient outcomes."

Pam R. Taub, MD, FACC, Cardiologist and Associate Professor of Medicine at UC San Diego

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That's just the answer that patients, physicians and hospital administrators are seeking.

To learn more, visit <u>cardiac.roche.com</u>.

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