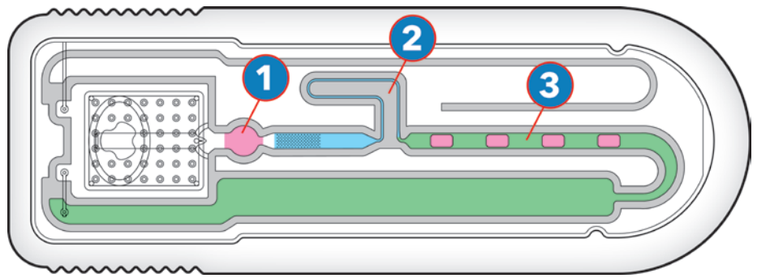
# HEART ATTACK DIAGNOSIS AT THE BEDSIDE CAN NOW TAKE AS LITTLE AS 20 MINUTES

A conversation with CURTIS MARSH, Senior Director of Global Product Management for Quidel, headquartered in San Diego, California.

**When a person is experiencing a heart attack**, every minute counts. Faster diagnosis means faster treatment and less tissue death. But the symptoms of heart attacks are similar to other conditions, such as panic attacks and gastroesophageal reflux disease. All these conditions may lead patients to the emergency department (ED) where they might wait hours for critical test results, while still unsure if they're having a heart attack. Quidel's latest cardiac test, TriageTrue High Sensitivity Troponin I Test, can be used at the patient's bedside as an aid to diagnose a heart attack within 20 minutes. Curtis Marsh explains how this test benefits the patients, doctors and health-care system.




Quidel Corporation

▲ **The redesigned cartridge includes a passive mixing well (1), a microfluidic pinch (2), and an improved normalization algorithm which takes place in the diagnostic lane (3).**

**What does Quidel's TriageTrue test measure?**

TriageTrue measures a protein called troponin, found in heart muscle, which is normally present in the blood at extremely low levels. A damaged heart releases troponin, so elevated levels can mean the patient is having a heart attack.

Since some small amount of troponin is always present in the blood, it's important that a test be sensitive enough to discern normal levels from those that indicate cardiac damage. Given that a heart attack is defined as a change in troponin over time with at least one measurement above the cutoff, multiple readings are required — reinforcing the need for a high-sensitivity test to detect true changes.

**CURTIS MARSH**
*Senior Director of Global Product Management for Quidel*

**What makes TriageTrue a high-sensitivity troponin test?**

Clinical organizations, such as the International Federation of Clinical Chemistry and European Society of Cardiology (ESC), have defined the requirements for a high-sensitivity troponin assay. These requirements include metrics to ensure that the assay performs at a high level of sensitivity, accuracy, and precision. TriageTrue was able to achieve the designation of high sensitivity by fulfilling such analytical requirements.

**How is this test used at the patient's bedside?**

TriageTrue runs on Quidel's near-patient instrument called the Triage MeterPro, which can also analyse a full complement of cardiometabolic biomarkers and toxicology drugs. It's a compact, easy to use fluorimeter that provides quantitative biomarker concentrations.

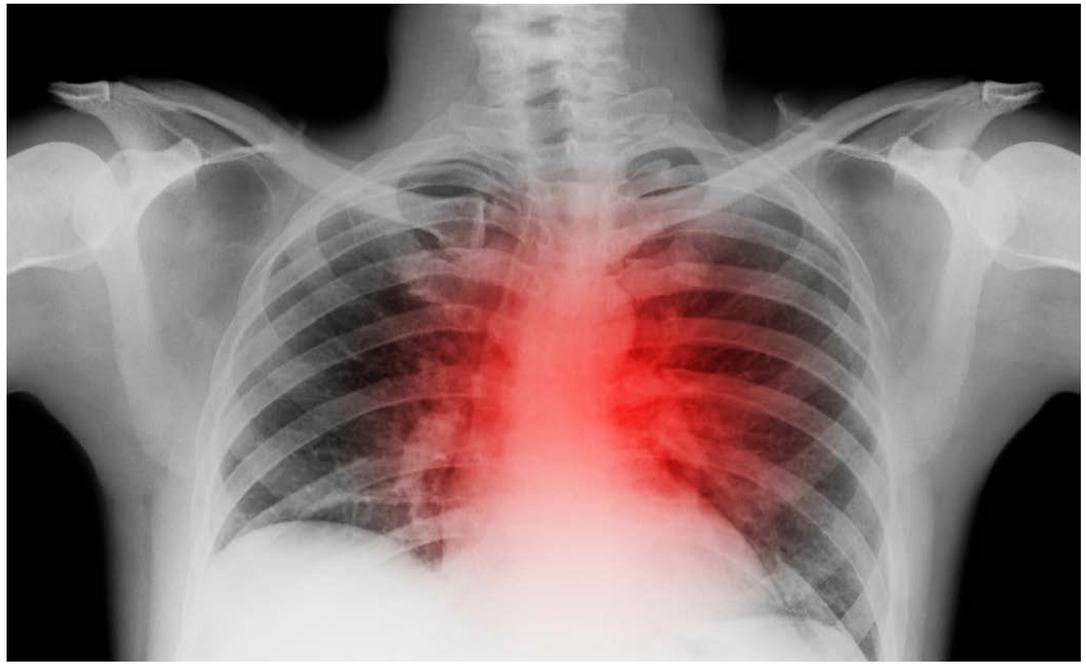
The test cartridge runs a whole blood or plasma sample and works as a lateral flow immunoassay. When the patient sample is added, it flows through the cartridge by first mixing with the fluorescently labeled antibodies which bind to the biomarker (in this case, troponin). These biomarker–antibody conjugates are then captured on the diagnostic lane, where the meter's laser and photodiode determine the fluorescent signal, apply an algorithm, and calculate the biomarker concentration. This process takes less than 20 minutes.

**How does TriageTrue achieve high sensitivity?**

We redesigned several features of our cartridge. The improved filter pocket is extremely efficient at separating red blood cells and conditioning the sample. We also added a 'passive mixing well' to make the sample treatment more homogenous.

The major contributors to the sensitivity and precision of the assay are the 'microfluidic pinch' and the normalization process. The pinch slows the flow of the sample, increasing the mixing and binding between troponin and the antibodies. This allows for significant signal, even with low levels of troponin.

Normalization works by comparing assay and control signals generated in the diagnostic lane. When these immunofluorescence signals are compared and then converted to a concentration, the result is normalized. Normalization is used in many immunoassays to adjust for any signal variation attributed to deviations in total available fluorescence, binding, interferences, and so forth.



Peter Dazeley/Getty Images

▲ **Several conditions, such as chest pain, have similar symptoms to a heart attack. Doctors need to be able to distinguish between them quickly and confidently.**

**Why does high-sensitivity testing at the point of care matter?**

The benefit is the quick time to result for every patient, especially given the tightening guidelines. It used to be that two troponin tests given six or three hours apart was adequate for diagnosing a heart attack; now the guidelines recommend two high-sensitivity tests, one hour apart. However, current troponin testing is often done in a hospital's central lab, which isn't close to the ED. Therefore, the time to get the troponin result can be an hour or more, hindering the doctor's ability to rapidly diagnose the patient.

TriageTrue replaces this time-consuming process, allowing doctors to quickly and reliably get high-sensitivity troponin results within 20 minutes and thereby accelerate the diagnosis. The earlier the diagnosis, the earlier doctors can give the correct treatment, leading to better outcomes.

The healthcare system also ultimately benefits from this advancement. Of all the patients in the ED with chest pain, most of them aren't having a heart attack. But until that diagnosis is made, these patients are taking up a bed in the ED, nervously waiting for a diagnosis. TriageTrue can improve ED workflow by quickly identifying low risk or non-cardiac patients, who can then be triaged faster and more confidently.

**What's the status of TriageTrue in Europe and the US?**

TriageTrue was launched in Europe in 2019. In March 2020, TriageTrue's performance in the APACE study was published by Jasper Boeddinghaus, who is part of Christian Mueller's team at the Cardiovascular Research Institute Basel (Boeddinghaus, J., *et al. J Am Coll Cardiol* **75**, 1111 [2020]). The publication independently demonstrated that TriageTrue had very high diagnostic accuracy and clinical performance, comparable to central lab assays. Also, the study validated a 0/1-hour algorithm for TriageTrue, which was independently published in the guidelines of the ESC.

TriageTrue is not yet available in the United States. The clinical trial to support an FDA submission is underway. ■

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