

# TriageTrue<sup>®</sup>

High Sensitivity Troponin I Test

Unprecedented Sensitivity  
at the Point of Care



QuidelOrtho<sup>™</sup>

# True High-sensitivity Troponin

TriageTrue hsTnI Test fulfills all requirements of a high-sensitivity cardiac troponin assay.<sup>1</sup>

## Analytical Precision<sup>2</sup>

Analytical precision of <10% CV at the 99th percentile URL.

Population	99th Percentile URL	CV
Overall	20.5 ng/L	5.6%
Female	14.4 ng/L	5.9%
Male	25.7 ng/L	5.4%

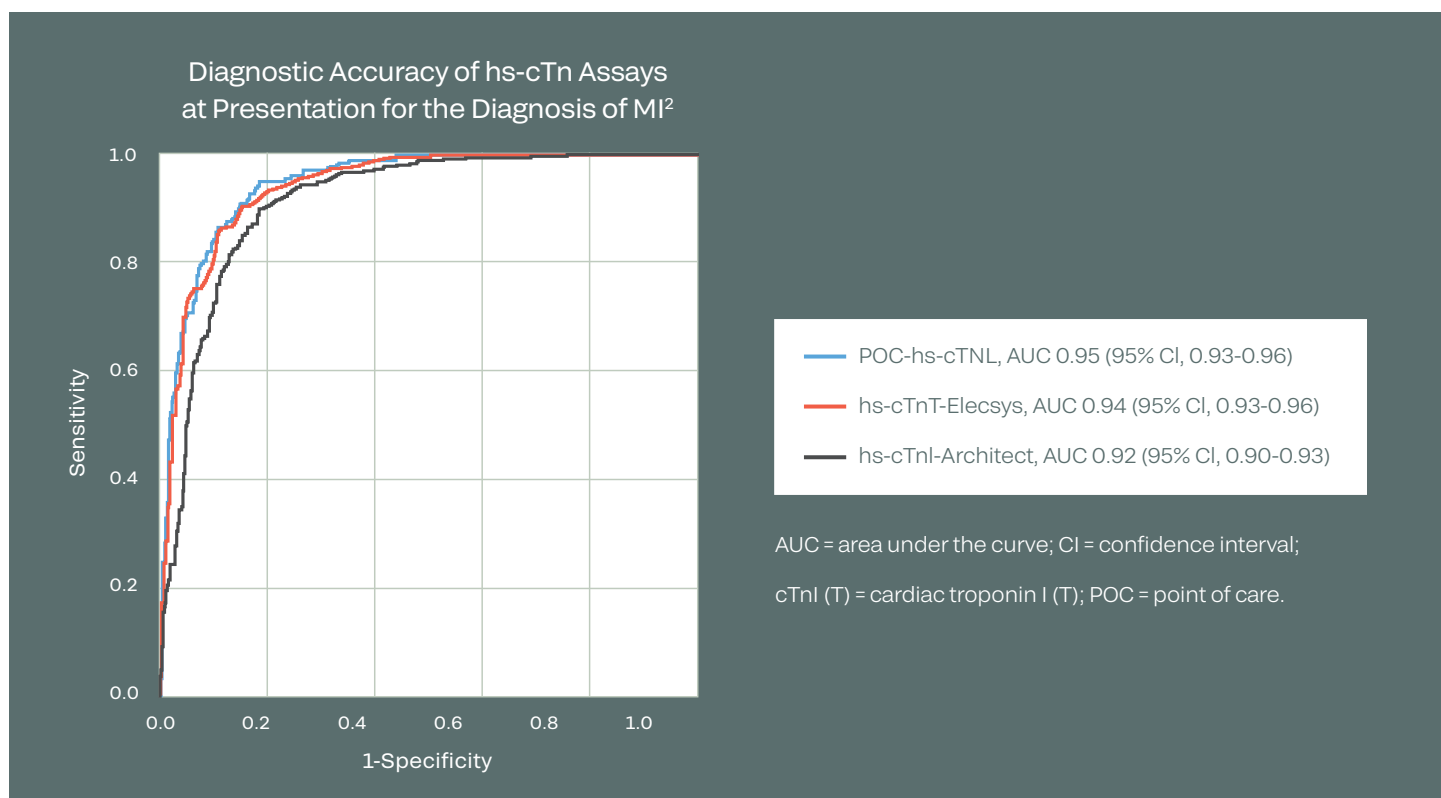
## Analytical Sensitivity<sup>2</sup>

Measures 72% of a healthy reference population above the Limit of Detection.\*

Population	Plasma	Whole Blood
Limit of Blank (LOB)	0.6 ng/L	0.6 ng/L
Limit of Detection (LOD)	1.5 ng/L	1.7 ng/L
Limit of Quantitation 20% CV	2.1 ng/L	2.8 ng/L
Limit of Quantitation 10% CV	4.6 ng/L	6.2 ng/L

## Comparable to Central Laboratory High-sensitivity Troponin Assays<sup>2</sup>

In a recent study, the Quidel TriageTrue hsTnI Test demonstrated high diagnostic accuracy in patients with suspected Myocardial Infarction (MI) with a clinical performance that is at least comparable to that of the best-validated central laboratory assays.<sup>2</sup>



\*Study on analytical sensitivity and reference population have been run with the same TriageTrue lots.

# True Solutions to Improving ED Workflow

The TriageTrue hsTnI Test provides high diagnostic accuracy with results available in less than 20 minutes. Faster time to results may contribute to faster patient disposition, reduced length of stay, and increased ED throughput.

Recent results from the Advantageous Predictors of Acute Coronary Syndromes Evaluation study [APACE] using the TriageTrue hsTnI Test suggests patients with suspected MI may be triaged within one hour using the concept of the current ESC hs-cTnT/I 0/1-h algorithm.<sup>2,3</sup> The results of this algorithm demonstrated high overall efficacy:

- Nearly three-fourths of patients assigned to either the rule-in or rule-out category within one hour. (The remaining patients were moved to the observe zone).<sup>2</sup>
- 43% of patients triaged without the need for serial hs-cTnI sampling which was higher than hs-cTnT-Elecsys (25%) and hs-cTnI-Architect (22%).<sup>2</sup>

## Performance of the Point-of-Care High Sensitivity Cardiac Troponin I TriageTrue Assay in Patients With Suspected Myocardial Infarction<sup>2</sup>

1,261 Patients  
With Suspected Non-ST-Segment Elevation Myocardial Infarction (NSTEMI)

### Point-of-Care High-Sensitivity Cardiac Troponin I Measured at 0 h and at 1 h

#### Triage by Single Cut-Offs

Direct Rule-Out	Direct Rule-In
At 0 h <3 ng/l	At 0 h >60 ng/l
45%	11%
NPV: 100% (99.4%-100%) Sens: 100% (98.0%-100%)	PPV: 76.8% (68.9%-83.6%) Spec: 97.1% (95.9%-98.0%)

#### Triage by 0/1-Hour Algorithm

Rule-Out	Observe	Rule-In
At 0 h <4 ng/l* OR At 0 h <5 ng/l AND Delta 1 h <3 ng/l	Others	At 0 h ≥60 ng/l OR Delta 1 h ≥8 ng/l
55%	26%	18%
NPV: 100% (98.8%-100%) Sens: 100% (95.9%-100%)	NSTEMI: 8%	PPV: 76.8% (67.2%-84.7%) Spec: 95.0% (92.5%-96.8%)

All-Cause Death of Patients Ruled-Out by the 0/1 h-Algorithm  
0% at 30 Days and 1.6% at 2 Years of Follow-up

\*If chest pain onset >3 h before presentation to the emergency department.

**The availability of TriageTrue hsTnI Test could allow extending the use of the hs-cTnI 0/1-h algorithm to settings without a central laboratory including smaller hospitals and general practices when properly validated within these sites.<sup>2</sup>**

# True Point of Care

Utilization of the TriageTrue hsTnI Test on the Triage MeterPro provides a true point of care test that significantly reduces the time to result without compromising accuracy.

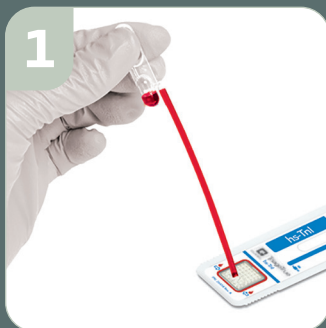
- Quantitative test results in less than 20 minutes.
- No sample preparation required (175  $\mu$ L EDTA whole blood or plasma samples.)
- Ease of use can simplify workflow.
- Devices stored at 2°C to 8°C; stable at operating temperature (18°C to 28°C) for 31 days.
- Integrated QC features in MeterPro, software and test device.
- Low maintenance instrumentation.

The TriageTrue hsTnI Test is intended to be used as an aid in the diagnosis of MI.



Cat. #	Description	Kit Size
97600CA	Quidel TriageTrue High Sensitivity Troponin I Test	25 Tests
97613EU	Quidel TriageTrue High Sensitivity Troponin I Control 1	5 x 0.18 mL
97614EU	Quidel TriageTrue High Sensitivity Troponin I Control 2	5 x 0.18 mL

## Simple 3-step test procedure



1 Add the sample to test device using transfer pipette included in each kit.



2 Insert test device into the Triage MeterPro.

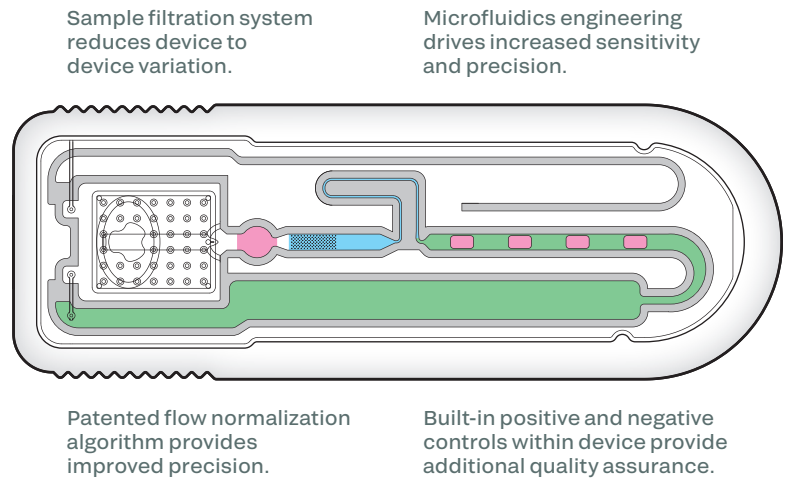
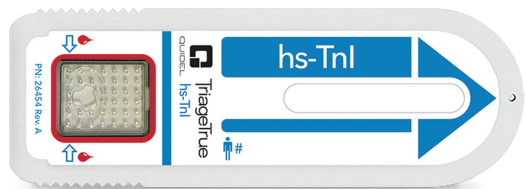


3 Read results on screen, or press "Print" for a hard copy. Complete in less than 20 minutes.

Please refer to Package Insert for complete instructions, limitations and warnings.

# True Innovation

High-sensitivity troponin testing at the point of care is now possible with TriageTrue hsTnI Test. This innovative test achieves unprecedented sensitivity and precision when used with the Triage MeterPro.



## Triage MeterPro System

Developed for use with the Triage MeterPro, the TriageTrue hsTnI Test provides lab quality testing with point of care advantages including small footprint, LIS connectivity and ease-of-use on a fluorescent immunoassay platform.

Get additional flexibility with the broad range of cardiovascular and toxicology products available for use with the Quidel Triage MeterPro.

Cat. #	Description	Parameters	Kit Size
97600EU*	Quidel TriageTrue High Sensitivity Troponin I Test	hsTnI	25 Tests
98600EU*	Quidel Triage Troponin I Test	TnI (next gen)	25 Tests
97500EU*	Quidel Triage Cardio2 Panel	TnI (next gen), BNP	25 Tests
97400EU*	Quidel Triage Cardio3 Panel	TnI (next gen), CK-MB, BNP	25 Tests
97000HSEU*	Quidel Triage Cardiac Panel	TnI, CK-MB, Myo	25 Tests
97300EU*	Quidel Triage Profiler SOB™ Panel	TnI, CK-MB- Myo, BNP, D-dimer	25 Tests
98000XREU*	Quidel Triage BNP Test	BNP	25 Tests
98700EU*	Quidel Triage NT-proBNP Test	NT-proBNP	25 Tests
98100EU*	Quidel Triage D-Dimer Test	D-dimer	25 Tests
94600	Quidel Triage TOX Drug Screen, 94600 AMP·mAMP·BAR·BZO·COC·EDDP·OPI·THC·TCA	9 Drug Panel	25 Tests

\*For Export Only. Not for sale in the United States.

- 1 Apple FS, Jaffe AS, Collinson P, et al. IFCC educational materials on selected analytical and clinical applications of high sensitivity cardiac troponin assays. *Clin Biochem* 2015; 48: 201-203.
- 2 Boeddinghaus J, Nestelberger T, Koechlin L, et al. Early Diagnosis of Myocardial Infarction With Point-of-Care High-Sensitivity Cardiac Troponin I, *J Am Coll Cardiol*. 2020 Mar 17;75(10):1111-24.
- 3 Collet J-P, Thiele H, Barbato E, et al., for the ESC Scientific Document Group. 2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: The Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC). *Eur Heart J*. (2020) 00, 1-79.



At QuidelOrtho, we transform diagnostic data into answers, understanding and action, illuminating the path forward for all. For more than 80 years, we've pursued the unknown with a passion and purpose to improve health. And we'll continue to transform the power of diagnostics into a healthier future for all.

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