QUIDEL

TriageTrue®

High Sensitivity Troponin I Test

UNPRECEDENTED SENSITIVITY
AT THE POINT OF CARE

It's True.

True High-sensitivity Troponin

TriageTrue hsTnI Test fulfills all requirements of a high-sensitivity cardiac troponin assay.[1]

Analytical Precision[2]

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

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

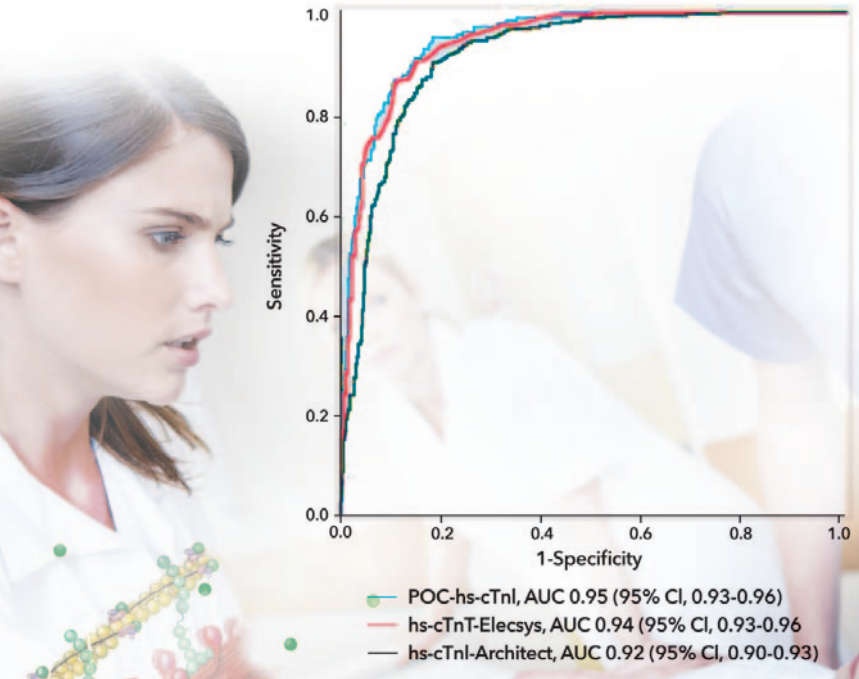
Analytical Sensitivity[2]

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

	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

Diagnostic Accuracy of hs-cTn Assays at Presentation for the Diagnosis of MI[2]



In a recent study, the POC Quidel TriageTrue hsTnI Test demonstrated high diagnostic accuracy in patients with suspected MI with a clinical performance that is at least comparable to that of the best-validated central laboratory assays.[2]

AUC = area under the curve; CI = confidence interval;
cTnI (T) = cardiac troponin I (T); POC = point of care.
*Study on analytical sensitivity and reference population have been run with the same TriageTrue lots.

True Solutions to Improving ED Workflow

TriageTrue hsTnI Tests provide 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 dispositioned within one hour using the concept of the current ESC hs-cTnT/I 0/1-h algorithm.[2,3] 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).
- 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%).[2]

Performance of the Point-of-Care High Sensitivity Cardiac Troponin I TriageTrue Assay in Patients With Suspected Myocardial Infarction[2]

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		Triage by 0/1-Hour Algorithm		
Direct Rule-Out	Direct Rule-In	Rule-Out	Observe	Rule-In
At 0 h <3 ng/l	At 0 h >60 ng/l	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
45%	11%	55%	26%	18%
NPV: 100% (99.4%-100%) **Sens: 100%** (98.0%-100%)	**PPV: 76.8%** (68.9%-83.6%) **Spec: 97.1%** (95.9%-98.0%)	**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.[2]

True Point of Care

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

- Quantitative test results in less than 20 minutes.
- No sample preparation required (175 µL 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
97600EU	Quidel TriageTrue High Sensitivity Troponin I Test	25 Test
97613EU	Quidel TriageTrue High Sensitivity Troponin I Control 1	5 x 0.25 mL
97614EU	Quidel TriageTrue High Sensitivity Troponin I Control 2	5 x 0.25 mL

Simple 3-step test procedure

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

2 Insert test device into the Quidel Triage MeterPro.

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

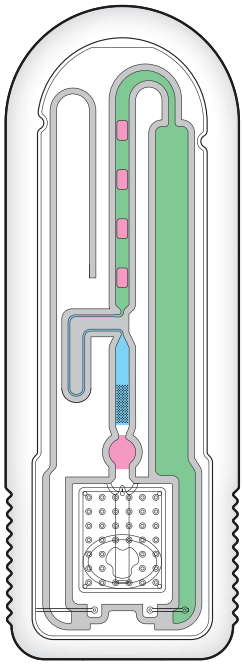
Please refer to Package Insert for complete instructions, limitations and warnings.

True Innovation

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

Microfluidics engineering drives increased sensitivity and precision.

Sample filtration system reduces device to device variation.



Built-in positive and negative controls within device provide additional quality assurance.

Patented flow normalization algorithm provides improved precision.

Triage MeterPro System

Developed for use with the Triage MeterPro, the TriageTrue hsTnl 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	hsTnl	25 Test
98600EU*	Quidel Triage Troponin I Test	TnI (next gen)	25 Test
97500EU*	Quidel Triage Cardio2 Panel	TnI (next gen), BNP	25 Test
97400EU*	Quidel Triage Cardio3 Panel	TnI (next gen), CK-MB, BNP	25 Test
97000HSEU*	Quidel Triage Cardiac Panel	TnI, CK-MB, Myo	25 Test
97300EU*	Quidel Triage Profiler SOB™ Panel	TnI, CK-MB- Myo, BNP, D-dimer	25 Test
98000XREU*	Quidel Triage BNP Test	BNP	25 Test
98700EU*	Quidel Triage NT-proBNP Test	NT-proBNP	25 Test
98100EU*	Quidel Triage D-Dimer Test	D-dimer	25 Test
94600	Quidel Triage TOX Drug Screen, 94600 AMP•mAMP•BAR•BZO•COC•EDDP•OPI•THC•TCA	9 Drug Panel	25 Test

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

QUIDEL | TriageTrue®

It's True.

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 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 Roffi M, Patrono C, Collet J-P, et al., for the ESC Scientific Document Group. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: 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 2016;37:267–315.

Quidel | Rapid Diagnostics | quidel.com | 800.874.1517 | 858.552.1100

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