



# High-Sensitivity Troponin I Assay

## Dimension Vista Intelligent Lab System

### Key Benefits

- Offers improved cardiac patient care with a true high-sensitivity troponin I assay that meets the current guideline recommendations.<sup>1-3</sup>
- Allows you to measure slight, yet critical, changes between serial troponin I values, giving you confidence in patient results at the low end of the assay range.
- Delivers proven, trusted LOCI technology coupled with three new monoclonal antibodies.

### Assay Description

The Dimension Vista® TNIH assay is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI technology. The LOCI reagents include two synthetic bead reagents and two biotinylated anti-cardiac troponin I monoclonal antibody fragments. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a third anti-cardiac troponin I monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibodies to form bead-cardiac troponin I-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from the Sensibeads that diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the cardiac troponin I concentration in the sample.<sup>4-6</sup>

Product availability may vary from country to country and is subject to varying regulatory requirements.

### Intended Use

The High-Sensitivity Troponin I (TNIH) assay is for in vitro diagnostic use in the quantitative measurement of cardiac troponin I in human serum or plasma using the Dimension Vista® Intelligent Lab System. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).

## Performance Summary

Sample type	Human serum, plasma (lithium heparin)
Sample volume	10 µL
Assay range	3.0–25,000.00 pg/mL (ng/L)
Time to first result	10 minutes
Throughput	Up to 200 tests/hour
On-board stability	7 days open well 30 days onboard unpunctured
LoB	1.0 pg/mL (ng/L)
LoD	2.0 pg/mL (ng/L)
LoQ (20% CV)	3.0 pg/mL (ng/L)
LOQ (10% CV)	10.0 pg/mL (ng/L)
99th percentile (n=2010)	Combined: 58.9 pg/mL (ng/L)* Male: 78.5 pg/mL (ng/L) Female: 53.7 pg/mL (ng/L)

\*99th percentile value determined using combined gender data and lithium heparin sample type.

## Dimension Vista TNIH Assay Precision

Sample Types	Mean	Repeatability (Within-Run)		Within-Lab (Total Precision)	
		SD pg/mL (ng/L)	% CV	SD pg/mL (ng/L)	% CV
Serum Pool 1	14.6	0.61	4.2	0.79	5.4
Serum Pool 2	187.7	2.85	1.5	4.42	2.4
Serum Pool 3	1643.3	17.45	1.1	93.12	5.7
Serum Pool 4	8802.9	126.47	1.4	200.35	2.3
Serum Pool 5	23,295.6	517.80	2.2	868.21	3.7
Plasma	48.9	1.12	2.3	3.05	6.2
QC	8088.5	99.54	1.2	200.36	2.5

## Ordering Information

Catalog No.	Contents	Quantity
10471067 K6427	TNIH Flex® Reagent Cartridge	120 tests /kit 2 flex x 60 tests
10719482 KC627	TNIH CAL (calibrator)	10 vials: Levels A-E (10 x 1.0 mL)
10445205 KD692	CTNI SDIL	6 vials/1 level (2.5mL per vial)
KS855	LOCI Reaction Vessels	1000 vessels

### References:

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