

Dimension Vista Intelligent Lab System

High-Sensitivity Troponin I Assay

[siemens-healthineers.com/TNIH](https://www.siemens-healthineers.com/TNIH)



Key Benefits

- Offers improved patient care with a true high-sensitivity cardiac troponin I assay that meets the current IFCC guideline recommendations.¹⁻³
- Allows for fast, accurate, and actionable results to leverage faster protocols.
- Provides confidence in results due to minimal assay interferences.

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.⁴⁻⁶



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).

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

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 pg/mL (ng/L) | 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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4. Ullman EF, Kirakossian H, Switchenko AC, Ishkanian J, et al. Luminescent oxygen channeling assay (LOCI®): sensitive, broadly applicable homogeneous immunoassay method. Clin Chem. 1996;42(9):1518-26.
5. Ullman EF, Kirakossian H, Sharat S, Ping Wu Z, Irvin BR, et al. Luminescent oxygen channeling immunoassay: measurement of particle binding kinetics by chemiluminescence. Proc Natl Acad Sci USA. 1994 Jun;91:5426-30.
6. Ullman EF. Homogeneous immunoassays. In: Wild D, ed. The immunoassay handbook, 2nd ed., 2001; p. 192-194.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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