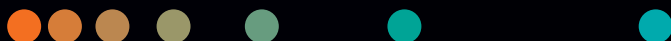


Dimension EXL with LOCI Module Integrated Chemistry System

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® EXL™ LOCI® 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 EXL with LOCI Module Integrated Chemistry 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	4.0–25,000.00 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	1.1 pg/mL (ng/L)
LoD	2.7 pg/mL (ng/L)
LoQ (20% CV)	4.0 pg/mL (ng/L)
LOQ (10% CV)	12.0 pg/mL (ng/L)
99th percentile (n=2010)	Combined: 60.4 pg/mL (ng/L)* Male: 76.2 pg/mL (ng/L) Female: 51.4 pg/mL (ng/L)

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

Dimension EXL 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	13.8	0.65	4.7	0.83	6.0
Serum Pool 2	178.4	2.79	1.6	5.86	3.3
Serum Pool 3	1537.5	21.64	1.4	68.11	4.4
Serum Pool 4	7945.8	163.57	2.1	306.73	3.9
Serum Pool 5	19,524	671.18	3.4	1428.83	7.3
Plasma	48.0	1.11	2.3	2.87	6.0
QC	7411.7	145.59	2.0	246.56	3.3

Precision was evaluated according to the CLSI Document EP05-A3. During each day of testing, two separate runs with two test samples for each test material were analyzed for 20 days for a total of 80 replicates using the Dimension EXL TNIH assay.

Ordering Information

Catalog No.	Contents	Quantity
10471068 RF627	TNIH Flex® Reagent Cartridge	144 tests/kit 4 Flexes x 36 tests each
10719483 RC627	LOCI TNIH CAL (calibrator)	10 vials: Levels 1–5 (10 x 1.0 mL)
10445205 KD692	CTNI SDIL	6 vials/1 level (2.5mL per vial)
10445044 RXV1A	HM reaction vessels	1000 vessels

References:

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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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