High-Sensitivity Troponin I Assay*

Dimension EXL with LOCI Module Integrated Chemistry System

Key Benefits

- Offers improved cardiac patient care with a true high-sensitivity troponin I assay that meets the current guideline recommendations.[1-3]
- 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® 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 anticardiac 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 anticardiac 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).

*Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.

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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	Repeatability (Within-Run)		Within-Lab (Total Precision)	
	pg/mL;ng/L	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

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Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84 0
siemens.com/healthineers

Local Contact Information
Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

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