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LOCI Cardiac Troponin I Assay Specifications

LOCI Troponin I Assay on the Dimension EXL and Dimension Vista Systems

Meeting the Standards for Better Cardiac Care

Use of a sensitive cardiac troponin (cTn) assay facilitates expeditious detection and assessment of change—important in the differentiation of an acute myocardial infarction (AMI) related to myocardial ischemia from other causes of myocardial necrosis. The 99th percentile of a normal population is recommended by the NACB/IFCC as the value above which a troponin level is considered elevated. Troponin assays should have a total imprecision (%CV) of $\leq 10\%$ at the 99th percentile of the reference population.^{1,2}

A third universal definition of myocardial infarction was published in 2012 by the joint European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation (ESC/ACCF/AHA/WHF) that integrates new knowledge and takes into account that a very small degree of myocardial injury or necrosis can be detected by cardiac troponin and/or imaging.³

The introduction of troponin assays with improved sensitivity has increased the number of chest-pain patients presenting at admission with cTn values exceeding the 99th percentile as a result of causes other than AMI. This complicates the appropriate triage of patients.^{4,5,6} To assist with such triage, assessing cTn kinetics with serial testing should be used in the clinical evaluation of chest-pain patients. A fast-track rule-out protocol (3 hours instead of 6 hours), recommended by the European Society of Cardiology in the 2011 guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation, advises cardiac troponin measurement at admission and then 3 hours after the time of presentation.^{7,8}

The LOCI® Cardiac Troponin I assay on the Dimension® EXL™ and Dimension Vista® systems meets this standard of performance for accurate and rapid results required for timely AMI diagnosis.

*ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Eur Heart J. 2011;32:2999-3054.

Analytical Benefits

- Reduces the risk of interference and increases accuracy with a low sample volume
- Improves laboratory workflow with same tube Troponin testing with other STAT chemistry assays

Clinical Benefits

- Allows for earlier detection by meeting the guidelines criterion for $\leq 10\%$ CV at the 99th percentile. Unique oxygen channeling technology provides greater precision and low background signal with minimal noise improves sensitivity
- Supports rapid triage of chest-pain patients and improves acute care workflow between serial measurements (6h reduced to 3h protocols)* with a time to first result in 12 minutes or less

Answers for life.

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LOCI Cardiac Troponin I Performance Summary

	Dimension EXL	Dimension Vista
Sample Type	Serum, Plasma (Na or Li Heparin)	Serum, Plasma (Na or Li Heparin)
Sample Volume	20 µL	20 µL
Assay Range	17–40,000 ng/L (pg/mL)	15–40,000 ng/L (pg/mL)
Time to First Result	11 minutes	12 minutes
On-board Stability	Sealed on-board (at 2–8° C): 30 days	Sealed on-board (at 2–8° C): 30 days
Open well stability	3 days	7 days
Calibration Interval	21 days	30 days
Dilution	Manual dilution – 1:5	1:5
Limit of Detection	17 ng/L (pg/mL)	15 ng/L (pg/mL)
10% CV (Limit of Quantitation)	50 ng/L (pg/mL)	40 ng/L (pg/mL)
99th Percentile	56 ng/L (pg/mL)	45 ng/L (pg/mL)

Dimension EXL Ordering Information		
Catalog No.	Contents	No. of Tests
RF621	TNI Flex® Reagent Cartridge	144
RC621	LOCI TNI CAL	10 vials, 5 levels – 2 x 2.0 mL each
KD692	CTNI SDIL	6 vials/carton

Dimension Vista Ordering Information		
Catalog No.	Contents	No. of Tests
K6421	CTNI Flex® Reagent Cartridges	120
KC678	CTNI CAL	12 vials, 6 levels – 3 x 2.0 mL each
KD692	CTNI SDIL	6 vials/carton

References:

1. Academy of Clinical Biochemistry and IFCC Committee for standardization of markers of cardiac damage laboratory medicine practice guidelines: analytical issues for biochemical markers of acute coronary syndromes. Clin Chem. 2007;53:547-551.
2. Universal definition of myocardial infarction. Kristian Thygesen, Joseph S. Alpert, and Harvey D. White on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction Task Force Members. Eur Heart J. 2007;28, 2525-2538.
3. Thygesen K, et al. Third universal definition of myocardial injury and infarction. Eur Heart J. 2012;33(20):2551-2567.
4. Melanson SEF. Earlier detection of myocardial injury in a preliminary evaluation using a new troponin I assay with improved sensitivity. Am J Clin Pathol. 2007;128:282-286.
5. Reichlin T, et al. Early diagnosis of myocardial infarction with sensitive cardiac troponin assays. N Engl J Med. 2009;361:858-867.
6. Keller T, et al. Sensitive troponin I assay in early diagnosis of acute myocardial infarction. N Engl J Med. 2009;361:868-877.
7. ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Eur Heart J. 2011;32:2999-3054.
8. Mueller C. Sensitive cardiac troponin I in the distinction of acute myocardial infarction from acute cardiac non-coronary artery disease, to be published in 2014 (APACE Study).

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Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

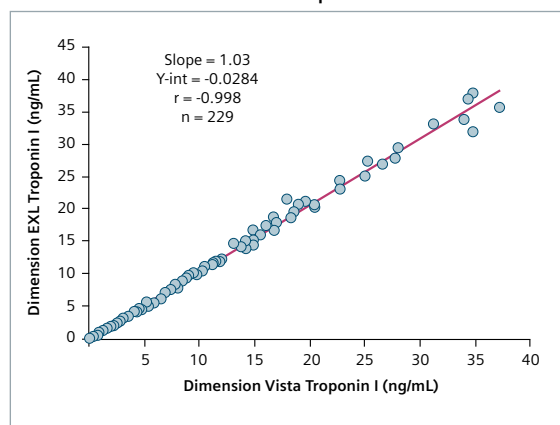
Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Germany
Telephone: +49 9131 84-0
www.siemens.com/healthcare

Global Division

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
www.siemens.com/diagnostics

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Dimension EXL LOCI Cardiac Troponin I vs. Dimension Vista LOCI Cardiac Troponin I



Dimension EXL LOCI Cardiac Troponin I vs. Dimension RxL LOCI Cardiac Troponin I

