

SUPPLEMENTAL APPENDIX

Author Relationships With Industry and Other Entities (Comprehensive)— 2022 ACC Expert Consensus Decision Pathway on the Evaluation and Disposition of Acute Chest Pain in the Emergency Department

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
					<ul style="list-style-type: none"> • Ortho Clinical† • Quidel • Roche* • Siemens • Stago† 	<ul style="list-style-type: none"> • SAEM† 	
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This table represents all relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥\$5,000 of the fair market value of the business entity, or if funds received by the person from the business entity exceed 5% of the person’s

gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to <http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy> for definitions of disclosure categories or additional information about the ACC/AHA Disclosure Policy for Writing Committees.

*Significant relationship.

†No financial benefit.

‡ Relationship with this company is limited to enrolling patients in clinical trials. This disclosure was entered under the Clinical Trial Enroller category in the ACC's disclosure system. To appear in this category, the author acknowledges that there is no direct or institutional relationship with the trial sponsor as defined in the ACC/AHA Disclosure Policy for Writing Committees.

ACC = American College of Cardiology; CTSN = Cardiothoracic Surgical Trials Network; DSMB = Data Management Safety Board; JAMA = Journal of the American Medical Association; NHLBI = National Heart, Lung, and Blood Institute; NIH = National Institutes of Health; SAEM = Society of Academic Emergency Medicine; VCSQI = Virginia Cardiac Services Quality Initiative VHAC = Veterans' Health Advisory Council

Table A. Current U.S. Food and Drug Administration–Approved High-Sensitivity Cardiac Troponin I and T Assay Analytical Characteristics Designated by Manufacturer*

Assay	LoD (ng/L)	LoQ (ng/L) [†]	99 th Percentile (ng/L)	% CV at 99 th Percentile ‡	FDA Substantial Equivalence (510k) Decision #
Abbott ARCHITECT STAT hsc-TnI	2	4	Overall: 28 F: 17 M: 35	<5.0%	K191595
Beckman Coulter Access hs-cTnI (UniCel DxI Access platform)	3	3	Overall: 18 F: 15 (plasma); 14 (serum) M: 20	<6.5%	K172783
Beckman Coulter Access hs-cTnI (Access 2 platform)	2	3	Overall: 18 F: 12 M: 20	<6.9%	K172787
Roche Elecsys Troponin T Gen 5 STAT	3 to 5 (depending on type of analyzer)	6	Overall: 19 F: 14 M: 22	<10%	K162895
Siemens ADVIA Centaur High-Sensitivity TnI	2	3	Overall: 47 F: 37 (plasma); 40 (serum) M: 57 (plasma); 58 (serum)	<4.9%	K171274
Siemens ATELLICA High-Sensitivity TnI	2	3	Overall: 45 F: 34 (plasma); 39 (serum) M: 53 (plasma); 54 (serum)	<4.0%	K171566

Siemens Dimension VISTA High-Sensitivity TnI	2	3	Overall: 59 F: 54 M: 79	<5.0%	K182225
Siemens Dimension ExL High-Sensitivity TnI	3	4	Overall: 60 F: 51 M: 76	<5.0%	K190676

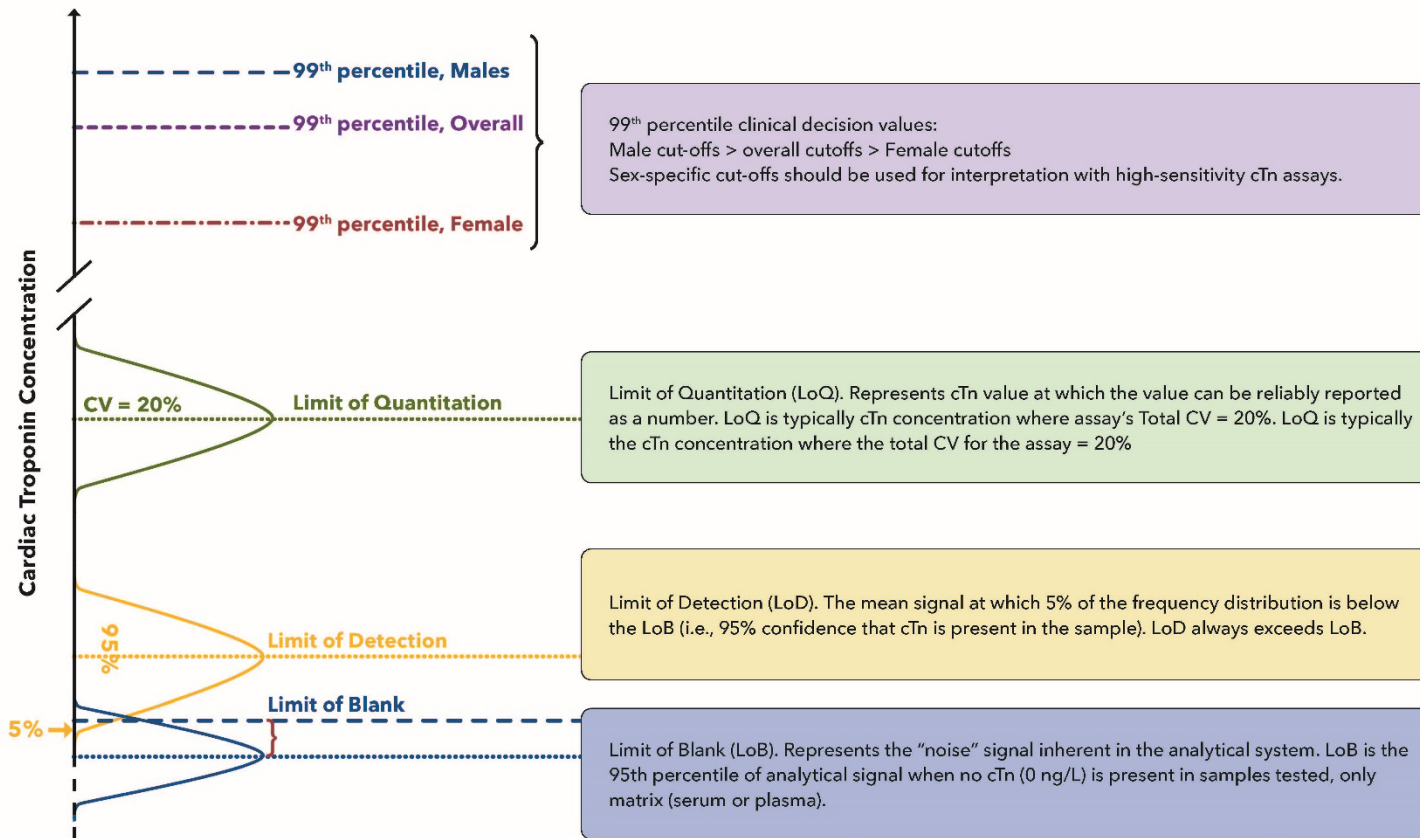
*Values are extracted from documentation provided by manufacturers to the FDA, except where otherwise noted. All decimal values for LoD and LoQ concentrations are rounded up to the next-highest integer; 99th percentile values are rounded up or down to the nearest integer.

†The concentration at 20% CV (also referred to as LoQ 20% CV, or simply LoQ in the United States) is the lowest concentration that can be reported numerically in U.S. clinical practice, as per FDA regulations.

‡Data from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Committee on Clinical Applications of Cardiac Bio-Markers v092021 table, available at <https://www.ifcc.org/media/479205/high-sensitivity-cardiac-troponin-i-and-t-assay-analytical-characteristics-designated-by-manufacturer-v092021-3.pdf>.

CV = coefficient of variation; F = female; FDA = Food and Drug Administration; hs-cTnI = high sensitivity cardiac troponin I; LoD = limit of detection; LoQ = limit of quantification; M = male

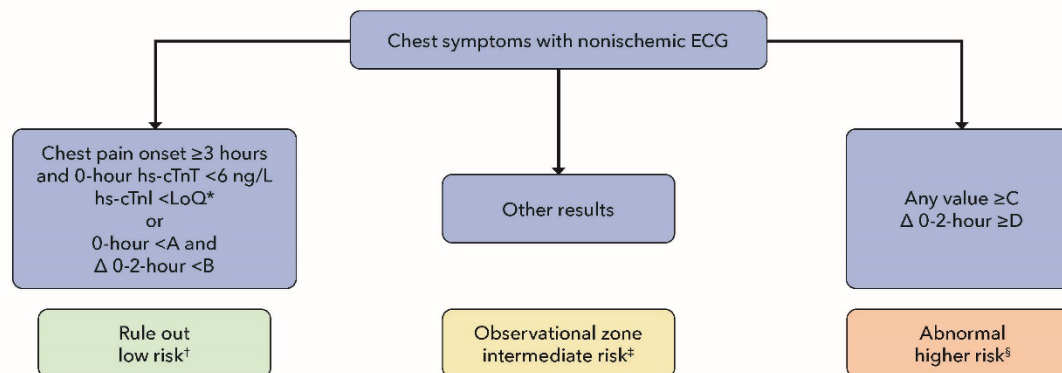
Figure A. Summary of Analytic Definitions



Modified with permission from Januzzi JL Jr, Mahler SA, Christenson RH, Rymer J, Newby LK, Body R, Morrow DA, Jaffe AS. Recommendations for institutions transitioning to high-sensitivity troponin testing: JACC Scientific Expert Panel. *J Am Coll Cardiol.* 2019 Mar 12;73(9):1059-1077.

cTn = cardiac troponin; CV = coefficient of variation; LoB = limit of blank; LoD = limit of detection; LoQ = limit of quantitation

Figure B. Modified European Society of Cardiology 0/2-Hour CDPs for Ruling Out MI



Assay	LoQ*	A	B	C	D
Roche Elecys hs-cTnT	6	14	4	52	10
Abbott Architect hs-cTnI	4	6	2	64	15
Beckman Coulter Access hs-cTnI	3	5	5	50	20
Siemens ADVIA Centaur hs-cTnI	3	8	7	120	12

Note that many variations of these rapid CDPs have been implemented in different centers, and modification of the algorithms shown may be considered based on local considerations

* The LoQ may differ slightly from 0-hour rule-out thresholds tested in individual studies. Using a cutoff of <5 ng/L can also be considered instead of the LoQ for the 0-hour rule-out threshold for hs-cTnI assays.

† See sections 5.6 and 5.8 for recommendations on follow-up and testing.

‡ Additional evaluation should include at least additional observation with hs-cTn measurement at 6 hours, with classification of myocardial injury as described in section 8 on chronic myocardial injury, acute myocardial injury, type 1 myocardial infarction (MI) and type 2 MI, as per the Universal Definition of Myocardial Infarction.

§Patients with acute MI should be managed according to standard practice guidelines.

CDP = clinical decision pathway; ECG = electrocardiogram; hs-cTnI= high-sensitivity cardiac troponin I; hs-cTnT = high-sensitivity cardiac troponin T; MI = myocardial infarction

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Table B. Subtypes of Myocardial Infarction

Type		Definition
Type 1		A myocardial infarction precipitated by plaque disruption (rupture erosion) in the presence of atherosclerotic coronary artery disease
Type 2		A myocardial infarction occurring in the setting of an imbalance between myocardial oxygen supply and demand and unrelated to acute coronary atherothrombosis
Type 3		Sudden cardiac death presumed secondary to myocardial infarction due to the presence of preceding symptoms suggestive of ischemia or proven myocardial infarction detected on subsequent autopsy examination
Type 4	a	A percutaneous coronary intervention–related myocardial infarction occurring within 48 hours of the index procedure
	b	A myocardial infarction due to stent/scaffold thrombosis associated with percutaneous coronary intervention
	c	A myocardial infarction due to in-stent restenosis associated with percutaneous coronary intervention
Type 5		A myocardial infarction associated with coronary artery bypass grafting