Table 1. Analytical characteristics of commercial and research cardiac troponin I and T assays declared by the manufacturer.

Commercially available assays - Company/ platform(s)/ assay	**LoB[#] (ng/L)**	**LoD* (ng/L)**	**99th % (ng/L)**	**%CV at 99th %**	**10% CV (ng/L)**	**Risk Stratification**	**Epitopes recognised by Antibodies**	**Detection Antibody Tag**
Abbott AxSYM ADV	20		40	14.0	160	Yes	C 87-91, 41-49; D 24-40	ALP
Abbott ARCHITECT	<10		28	14.0	32	Yes (No in US)	C 87-91, 24-40; D: 41-49	Acridinium
Abbott i-STAT	20		80	16.5	100	Yes	C: 41-49, 88-91; D: 28-39, 62-78	ALP
Alere Triage SOB	50		NAD	NA	NA	No	C: NA; D: 27-40	Fluorophor
Alere Triage Cardio 3 (r)	10		NAD	17.0 (at 20)	NA	No	NA	Fluorophor
Beckman Coulter Access Accu	10		40	14.0	60	Yes	C: 41-49; D: 24-40	ALP
bioMerieux Vidas Ultra	10		10**	27.7	110	No	C: 41-49, 22-29; D: 87-91, 7B9	ALP
Mitsubishi Chemical PATHFAST	8		29	5.0	14	No	C: 41-49; D: 71-116, 163-209	ALP
Ortho VITROS Troponin I ES	7	12	34	10.0	34	Yes	C: 24-40, 41-49; D: 87-91	HRP
Radiometer AQT90 FLEX TnI		9.5	23	17.7	39	NA	C: 41-49, 190-196; D: 137-149	Europium
Radiometer AQT90 FLEX TnT		10	17	15.2	25	NA	C: 125-131; D: 136-147	Europium
Response Biomedical RAMP	30		NAD	18.5 (at 50)	210	No	C: 85-92; D: 26-38	Fluorophor
Roche Cardiac Reader cTnT	<50		NAD	NA	NA	No	C: 125-131; D:136-147	Gold particles
Roche E 2010 /cobas e 411 / E 170 / cobas e 601 / 602 TnT (4th gen)	10		NAD	NA	30	Yes	C: 125-131; D:136-147	Ruthenium
Roche E 2010/cobas e 411 / E 170 / cobas e 601 / 602 hs-TnT		5	14	10.0	13	NA	C: 125-131; D: 136-147	Ruthenium
Roche E 2010/cobas e 411 / Roche E 170/cobas e 601 / 602 cTnI		160	160**	NA	300	No	C: 87-91, 190-196; D: 23-29, 27-43	Ruthenium
Siemens Centaur Ultra	6		40	8.8	30	Yes	C: 41-49, 87-91; D: 27-40	Acridinium
Siemens Dimension RxL	40		70	20.0	140	Yes	C: 27-32; D: 41-56	ALP
Siemens Dimension EXL	17		56	10.0	50	Yes	C: 27-32; D: 41-56	Chemiluminescence
Siemens Immulite 2500 STAT	100		200	NA	420	No	C: 87-91; D: 27-40	ALP
Siemens Immulite 1000 Turbo	150		NA	NA	640	No	C: 87-91; D: 27-40	ALP
Siemens Stratus CS	30		70	10.0	60	Yes	C: 27-32; D: 41-56	ALP
Siemens VISTA	15		45	10.0	40	Yes	C: 27-32; D: 41-56	Chemiluminescence
Tosoh ST AIA-PACK	60		60**	8.5	NA	No	C: 41-49; D: 87-91	ALP

Research assays - not commercially available								
Beckman Coulter Access hs-cTnI	2.0		8.6	10.0	8.6	NA	C: 41-49; D: 24-40	ALP
Nanosphere VeriSens hs-cTnI	0.2		2.8	9.5	0.5	NA	C: 136-147; D: 49-52, 70-73, 88, 169	Gold-nanoparticles
Singulex hs-cTnI	0.09		10.1	9.0	0.88	NA	C: 41-49; D: 27-41	Capillary flow fluorescence

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#LoB, limit of blank, formerly called the limit of detection; *LoD, limit of detection, was determined according to Clinical and Laboratory Standards Institute guideline protocol CLSI EP17-A **(1)**; NAD, the 99th percentile concentration of the value distribution of a reference population is indeterminate; NA, data are not available; **a 99th percentile concentration equal to an assay's LoD is unlikely to have acceptable imprecision for reliable troponin measurement. In practice imprecision of >30% CV is reported to occur at close to the LoD **(2, 3)**; 99th %, 99th percentile concentration; 10% CV, lowest concentration that has been shown to have a 10% CV (total imprecision); risk stratification claim per US Food and Drug Administration (FDA); epitopes (amino acid residues) recognised by antibodies were supplied by manufacturers; C, capture antibody(s); D, detection antibody(s); (r), revised assay, CE mark, not currently available in the US; ALP, alkaline phosphatase; hs, high sensitivity designation per manufacturers; HRP, horseradish peroxidase. NB – assays cannot be compared by the stated values in the table since they are derived with different metrics for the various assays.

Preamble:

The IFCC WG-TNI has revised the table of troponin analytical characteristics such that two tables are available on the website, one showing troponin concentrations in µg/L and the other in ng/L. These will assist those laboratories that are reporting troponin in whole numbers in ng/L. Note that the non-SI units ng/mL and pg/mL are not recommended.

'Research assays' refers to those troponin assays that are more analytically sensitive than current 2nd generation cTnI assays and the 4th generation cTnT assay. The analytical characteristics of both commercially available assays, including the Roche 5th generation hs-TnT assay, which is available world wide save in the United States and research assays that currently are not commercially available are shown. A Reference List of published peer-reviewed papers that describe the analytical characteristics of troponin I and hs-TnT assays is also available on the IFCC website. The cited papers give a realistic assessment of the performance of manufacturer's assays in routine clinical laboratories.

An interpretation of some nomenclature is given as follows:

Limit of detection (LoD) – refers to the lowest amount of troponin detected with 99% probability, using an estimation procedure partly based on nonparametric statistics. LoD is the *lowest analyte concentration* likely to be reliably distinguished from the limit of blank (LoB) and at which detection is feasible. It is recommended that manufacturers should perform LoB, LoD and limit of quantitation (LoQ) studies for troponin according to the Clinical and Laboratory Standards Institute guideline CLSI EP17-A (1). Assessment using more than one analyser and one lot of reagent are required to determine the variability that users can expect to encounter in the routine laboratory.

99th percentile concentration – refers to the troponin concentration at the *99th percentile upper reference limit (URL) of a distribution of values* measured in a healthy reference population. If the symbol '<URL' is used this implies that the distribution of troponin values is unknown (refer to 'NAD' in the tables). Different studies using manufacturer's troponin methods and platforms have shown variability of the 99th percentile depending on the reference population used, the skewness of the distribution and the number of outliers (4, 5). Depending on which 99th percentile is used, different clinical classification is likely for laboratories using different cTnI assays or different cut-off values for the same assay. Clinicians should refer to their local laboratory for information about the analytical performance of the troponin assay and the clinical decision limit in use at their site.

Functional sensitivity or LoQ – refers to the lowest troponin concentration at which the analyte cannot only be reliably detected but at which some *predefined goals for bias and imprecision* are met. This may be a predetermined coefficient of variation, e.g. imprecision of 10% CV for troponin that is recommended for clinical diagnosis of AMI (6), or a desirable total error goal of 24% CV based on the biological variability of cTnI for example (7, 8).

Assay imprecision – laboratories should understand the precision capability of their troponin assay over the entire measuring range concentration. This requires the determination of imprecision at low-level concentrations close to the clinical decision limit for troponin which may be the 99th percentile of a reference population value distribution. Laboratories should do a comprehensive imprecision study at the time of initial evaluation of a new assay and determine the LoQ that is clinically relevant.

The Study Group on Biomarkers in Cardiology of the European Society of Cardiology (ESC) Working Group on Acute Cardiac Care endorses the guidelines recommendation of the ESC/AACF/AHA/WHF Task Force that troponin imprecision of 10% or less at the 99th percentile is desirable (5). The group recommends no longer using troponin assays with an imprecision at the 99th percentile of above 20% CV because of the significant risk of misclassification of patients and that more precise commercial assays are available to routine laboratories.

References:

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