

Cardiac Troponin Assay Interference Table Designated by Manufacturer: Hemolysis and Biotin
IFCC Committee on Clinical Applications of Cardiac Biomarkers (C-CB) v092021

			Hemolysis				Biotin					
Company	Assay	Platform	Hemolysis Limit (No Interference Up to Stated Value)	Influence of Hemolysis Above the Threshold (+/-)	End User Hemolysis Assessment	Acceptance Criteria**	Biotinylated Antibody	Biotin Used in Assay Configuration	Interference Threshold	Acceptance Criteria**	Highest Biotin Concentration Tested	Influence of Biotin Above the Threshold (+/-)
Abbott Diagnostics, Alere	High Sensitive Troponin-I (3P25)	ARCHITECT	5.0 g/L (500 mg/dL)	ND	Qualitative	≤10%	No	No	290 µg/L	≤10%	290 µg/L	ND
	High Sensitive Troponin-I (8P13)*	Alinity i	5.0 g/L (500 mg/dL)	ND	Qualitative	≤10%	No	No	290 µg/L	≤10%	290 µg/L	ND
	Contemporary Troponin-I (2K41) US	ARCHITECT	5.0 g/L (500 mg/dL)	ND	Qualitative	≤10%	No	No	290 µg/L	Undefined	290 µg/L	ND
Abbott POC	cTnI	i-STAT	6.0 g/L (600 mg/dL)	(-)			No	No	ND	ND	ND	
Beckman Coulter	Access hs-cTnI	Dxl, Access 2	4.0 g/L (400 mg/dL)	ND	Quantitative if using Beckman's integrated platform	<ul style="list-style-type: none"> • ≤10% @ >11.5 ng/L • ≤2.30 ng/L @ ≤11.5 ng/L 	No	No	ND	ND	ND	NA
	cTnI (AccuTnI+3)	Dxl, Access 2	5.0 g/L (500 mg/dL)	ND	Quantitative if using Beckman's integrated platform	<ul style="list-style-type: none"> • ≤10% @ cTnI ~0.50 µg/L • ≤0.006 µg/L @ ~0.05 µg/L • ≤0.02 µg/L @ ~0.01 µg/L 	No	No	290 µg/L	<ul style="list-style-type: none"> • ≤10% @ cTnI ~0.50 µg/L • ≤0.006 µg/L @ ~0.05 µg/L • ≤0.02 µg/L @ ~0.01 µg/L 	290 µg/L	NA
bioMérieux	hs-cTnI	VIDAS	4.85 g/L (485 mg/dL)	ND	Qualitative	±10%	Yes	Yes	2000 µg/L	<10%	2000 µg/L	ND
ET Healthcare	hs-cTnI*	Pylon 3d	7.0 g/L (700 mg/dL)	(+)	Qualitative (Serum/Plasma); NA (Whole Blood)	±10%	Yes	Yes	2,000,000 µg/L (2 mg/mL)	±10%	2,000,000 µg/L (2 mg/mL)	ND
	hs-cnT*	Pylon 3d	7.0 g/L (700 mg/dL)	(-)	Qualitative (Serum/Plasma); NA (Whole Blood)	≤10%	Yes	Yes	2,000,000 µg/L (2 mg/mL)	≤10%	ND	ND

Fujirebio	hs-cTnI (Lumipulse)	Lumipulse G1200 and G600II	5.10 g/L (510 mg/dL)	ND	CLSI EP7-A2	±10%	No	No	ND	NA	NA	NA
LSI Medience	hs-cTnI*	PATHFAST	10 g/L (1,000 mg/dL)	(-)	Quantitative (Cyanmethemoglobin Method)		No	No	1500 µg/L	±20%	1500 µg/L	ND
	cTnI*	PATHFAST	10 g/L (1,000 mg/dL)	(-)	Quantitative (Cyanmethemoglobin Method)		No	No	1500 µg/L	±20%	1500 µg/L	ND
	cTnI-II	PATHFAST	10 g/L (1,000 mg/dL)	(-)	Quantitative (Cyanmethemoglobin Method)		No	No	1500 µg/L	±20%	1500 µg/L	ND
Ortho-Clinical Diagnostics	Troponin I ES	ECi/ECiQ, 3600, 5600, XT 7600	1.0 g/L (100 mg/dL) @ cTnI conc. of 0.006 µg/L	(+)	Automated/Quantitative	<10%	Yes	Yes	2.5 µg/L	≤10% @ 0.400 µg/L		
	hs Troponin I*	VITROS ECi/ECiQ Immunodiagnostic Systems, VITROS 3600 Immunodiagnostic Systems, VITROS 5600 Integrated System, VITROS XT 7600 System	6 g/L (608 mg/dL)	(-)	Automated/Quantitative	±10%	Yes	Yes (pre-bound)	ND	±10%	3510 µg/L	ND
Quidel/Alere	hs-cTnI	Triage	1.98 g/L (198 mg/dL)	ND	Qualitative	≤10 %	No	No	3600 µg/L	≤10 %	3600 µg/L	NA
	cTnI	Triage	10 g/L (1,000 mg/dL)	(-)	Qualitative	≤10%	No	No	ND	NA	NA	NA
	cTnI SOB*	Triage	5.0 g/L (500 mg/dL)	(-)	Qualitative	≤10%	No	No	ND	NA	NA	NA
	cTnI Cardio*	Triage	1.0 g/L (100 mg/dL)	(-)	Qualitative	≤10%	No	No	ND	NA	NA	NA
Radiometer, POC	TnI*	AQT90 FLEX	10 g/L (1000 mg/dL)	No interference	Qualitative	NA	Yes (pre-bound)	Yes (pre-bound)	No interference up to 3 µg/L***	≤10 %	3 µg/L***	NA***

Radiometer, POC	TnT*	AQT90 FLEX	2.0 g/L (200 mg/dL)	No interference	Qualitative	NA	No	No	No interference up to 50 µg/L***	≤9 %	50 µg/L***	NA***
Response Biomedical	No information provided						No information provided					
Roche Diagnostics	cTnT-hs* and TnT Gen 5 STAT	cobas e411, e601, e602, e801	1.0 g/L (100 mg/dL)	(-)	Serum indices on pre-analytic module; Qualitative	Recovery within ±1.4 ng/L with a conc. <14 ng/L; Recovery ±10 % with a conc. ≥ 14 ng/L	Yes	Yes (as conjugated Ab, not as free biotin)	1200 µg/L (only available in CE in 04/2019)	Recovery within ± 1.4 ng/L @ <14 ng/L; Recovery within ± 10 % @ ≥14 ng/L	3600 µg/L (only available in CE beginning in 04/2019)	(-)
Roche Diagnostics POC	Roche CARDIAC POC Troponin T	cobas h 232 POC system	2.0 g/L (200 mg/dL)	(-)	Qualitative	Mean bias vs. reference sample: ≤±15% @ 40-2000 µg/L	Yes	Yes (as conjugated Ab, not as free biotin)	200 µg/L	Mean bias vs. reference sample: ≤±15% between 40-2000 µg/L	1200 µg/L	(-)
Siemens Healthineers	High Sensitivity Troponin I (TNIH)	ADVIA Centaur® XP/XPT Systems	5 g/L (500 mg/dL)	ND	Qualitative	±10%	Yes	Yes	3500 µg/L	±10%	3500 µg/L	ND
	High Sensitivity Troponin I (TNIH)	Atellica™ IM Analyzer	5.0 g/L (500 mg/dL)	ND	Quantitative	±10%	Yes	Yes	3500 µg/L	±10%	3500 µg/L	ND
	High Sensitivity Troponin I (TNIH)	Dimension® EXL™ System	4.0 g/L (400 mg/dL)	ND	Quantitative	±10%	Yes	Yes	300 µg/L	±10%	1200 µg/L	(-)
	High Sensitivity Troponin I (TNIH)	Dimension Vista® System	4.0 g/L (400 mg/dL)	ND	Quantitative	±10%	Yes	Yes	300 µg/L	±10%	1200 µg/L	(-)
	TnI-Ultra	ADVIA Centaur® CP/XP/XPT Systems	5.0 g/L (500 mg/dL)	ND	Qualitative	±10%	Yes	Yes	10 µg/L	±10%	1500 µg/L	(-)
	TnI-Ultra	Atellica™ IM Analyzer	5.0 g/L (500 mg/dL)	ND	Quantitative	±10%	Yes	Yes	10 µg/L	±10%	1500 µg/L	(-)
	TNI	Dimension® EXL™ System	5.0 g/L (500 mg/dL)	ND	Quantitative	±10%	Yes	Yes	100 µg/L	±10%	1200 µg/L	(-)
	CTNI	Dimension® RXL™ System	10 g/L (1000 mg/dL)	ND	Quantitative	±10%	No	No	ND	NA	NA	NA

	CTNI	Dimension Vista® System	5.0 g/L (500 mg/dL)	ND	Quantitative	±10%	Yes	Yes	100 µg/L	±10%	1200 µg/L	(-)
	Troponin-I	IMMULITE® 2000/2000 XPi Systems	5.0 g/L (512 mg/dL)	ND	Qualitative	±10%	Yes	Yes	1500 µg/L	±10%	1500 µg/L	ND
	Troponin-I	IMMULITE®/IMMULITE® 1000 Systems	5.7 g/L (570 mg/dL)	ND	Qualitative	±10%	Yes	Yes	1500 µg/L	±10%	1500 µg/L	ND
	Troponin-I	IMMULITE® Turbo System	5.12 g/L (512 mg/dL)	<10%	Qualitative	±10%	Yes	Yes	1500 µg/L	±10%	1500 µg/L	ND
Tosoh	ST AIA-PACK cTnl 2 nd Gen	AIA Series (AIA-1800, AIA-2000, AIA-600II, AIA-900, AIA-360, etc...)	4.3 g/L (430 mg/dL)			±10%	No	No	ND	NA	NA	NA
	CL AIA-PACK hs-cTnl	AIA Series	4.4 g/L (440 mg/dL)			±10%	No	No	ND	NA	NA	NA

ND: Not Determined

NA: Not Applicable

* Not yet cleared by the FDA for clinical use in the United States

**Acceptance criteria were those defined in the package insert for determining whether interference was considered significant or not

*** Under further investigation