Cardiac Troponin Assay Interference Table Designated by Manufacturer: Hemolysis and Biotin
IFCC Committee on Clinical Applications of Cardiac Biomarkers (C-CB) v072618

			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	DxI, Access 2	4.0 g/L (400 mg/dL)	ND	Quantitative if using Beckman's integrated platform	• ≤10% @ hs-cTnI >11.5 ng/L • ≤2.30 ng/L @ ≤11.5 ng/L	No	No	ND	ND	ND	NA
	cTnI (AccuTnI+3)	DxI, Access 2	5.0 g/L (500 mg/dL)	ND	Quantitative if using Beckman's integrated platform	• ≤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	• ≤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	5.0 g/L (500 mg/dL)	(+)	Qualitative (Serum/ Plasma); NA (Whole Blood)	±10%	Yes	Yes	200 µg/L	±10%	200,000 µg/L	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 (Cyanmeth emoglobin Method)		No	No	1500 µg/L	±20%	1500 µg/L	ND
	cTnI*	PATHFAST	10 g/L (1,000 mg/dL)	(-)	Quantitative (Cyanmeth emoglobin Method)		No	No	1500 µg/L	±20%	1500 µg/L	ND
	cTnI-II	PATHFAST	10 g/L (1,000 mg/dL)	(-)	Quantitative (Cyanmeth emoglobin Method)		No	No	1500 µg/L	±20%	1500 µg/L	ND
Ortho-Clinical Diagnostics	Troponin I ES	ECi/ECiQ, 3600, 5600	1.0 g/L (100 mg/dL) @ cTnI conc. of 0.006 µg/L	(+)	Automated/ Quantitative	≤10%	Yes	No	2.5 µg/L	≤10% @ 0.400 µg/L		
Quidel	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	MODULAR E170, 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)	21 µg/L	Recovery within ± 1.4 ng/L @ <14 ng/L; Recovery within ± 10 % @ ≥14 ng/L	70 µg/L	(-)
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
Singulex	hs-cTnI	Clarity	4.55 g/L (455 mg/dL)	(-)	Visual/ Qualitative	±10%	Yes	Yes	10,000 µg/L	±10%	10,000 µg/L	(-)
Tosoh	ST AIA-PACK cTnI 2nd 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

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