Cardiac Troponin Assay Biotin and Hemolysis Interference Table by Manufacturers

IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v040218

			Hemolysis				Biotin					
Company	**Assay**	**Platform**	**Hemolysis Limit**	**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	No interference up to 500 mg/dL	ND	Qualitative	≤10%	No	No	290 ng/mL	≤10%	290 ng/mL	ND
	High Sensitive Troponin-I (8P13)*	Alinity i	No interference up to 500 mg/dL	ND	Qualitative	≤10%	No	No	290 ng/mL	≤10%	290 ng/mL	ND
	Contemporary Troponin-I (2K41) US	ARCHITECT	No interference up to 500 mg/dL	ND	Qualitative	≤10%	No	No	290 ng/mL	Undefined	290 ng/mL	ND
Abbott POC	cTnI	i-STAT	No interference up to 600 mg/dL	(-)			No	No	ND	ND	ND	
Beckman Coulter	cTnI (AccuTnI+3)	DxI / Access 2	No interference up to 500 mg/dL	(-)	Quantitative if using Beckman's integrated platform	• ≤10% @ ~0.50 µg/L • ≤0.006 µg/L @~0.05 µg/L • ≤0.02 µg/L @~0.01 µg/L	No	No	290 ng/mL	• ≤10% @ ~0.50 µg/L • ≤0.006 µg/L @ ~0.05 µg/L • ≤0.02 µg/L @~0.01 µg/L	290 ng/mL	NA
	Access hs-cTnI*	DxI / Access 2	No interference up to 400 mg/dL	(-)	Quantitative if using Beckman's integrated platform	• ≤20% @ >11.5 ng/L • ≤2.30 ng/L @ ≤11.5 ng/L	No	No	ND	ND	ND	NA

bioMerieux			No information provided				No information provided					
ET Healthcare	hs-cTnI		No interference up to 500 mg/dL	(+)	Qualitative (Serum/Plasma); NA (Whole Blood)	±10%	Yes	Yes	200,000 ng/mL	±10%	200,000 ng/mL	ND
LSI Medience	cTnI	PATHFAST	No interference up to 1,000 mg/dL	(-)	Quantitative (Cyanmethemoglobin Method)		No	No	1500 ng/mL	±20%	1500 ng/mL	NA
Ortho-Clinical Diagnostics	Troponin I ES	ECi/ECiQ, 3600, 5600	No interference up to 100 mg/dL @ cTnI conc. of 0.006 ng/mL	(+)	Automated/ Quantitative	≤10%	Yes	No	2.5 ng/mL	≤10% @ 0.400 µg/L		
Radiometer, POC	TnI*	AQT90 FLEX	No interference up to 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	No interference up to 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	No interference up to 100 mg/dL	(-)	Serum indices on pre-analytic module; Qualitative	Recovery within ± 20% @<100 ng/L; ±10% @ >100 ng/L	Yes	Yes (as conjugated Ab, not as free biotin)	82 nmol/L (20 ng/mL)	Recovery within ± 1.4 ng/L @ <14 ng/L; Recovery within ± 10 % @ ≥14 ng/L	70 ng/mL	(-)
Roche Diagnostics POC	Roche CARDIAC POC Troponin T	cobas h 232 POC system	No interference up to 200 mg/dL	(-)	Qualitative	Mean bias vs. reference sample: ≤±15% @ 40-2000 µg/L	Yes	Yes (as conjugated Ab, not as free biotin)	200 ng/mL	Mean bias vs. reference sample: ≤±15% between 40-2000 µg/L	1200 ng/mL	(-)
Siemens Healthineers	High Sensitivity Troponin I (TNIH)*	ADVIA Centaur® XP/XPT Systems	No interference up to 500 mg/dL	≤10%	Qualitative	±10%	Yes	Yes	1500 ng/mL	±10%	1500 ng/mL	<10%

	High Sensitivity Troponin I (TNIH)*	Atellica™ IM Analyzer	No interference up to 500 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	1500 ng/mL	±10%	1500 ng/mL	<10%
	High Sensitivity Troponin I (TNIH)*	Dimension® EXL™ System	No interference up to 400 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	300 ng/mL	±10%	1500 ng/mL	<10%
	High Sensitivity Troponin I (TNIH)*	Dimension Vista® System	No interference up to 400 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	300 ng/mL	±10%	1500 ng/mL	<10%
	TnI-Ultra	ADVIA Centaur® CP/XP/XPT Systems	No interference up to 500 mg/dL	≤10%	Qualitative	±10%	Yes	Yes	10 ng/mL	±10%	1500 ng/mL	<10%
	TnI-Ultra	Atellica™ IM Analyzer	No interference up to 500 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	10 ng/mL	±10%	1500 ng/mL	<10%
	TNI	Dimension® EXL™ System	No interference up to 500 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	100 ng/mL	±10%	1500 ng/mL	<10%
	CTNI	Dimension® RXL™ System	No interference up to 1000 mg/dL	≤10%	Quantitative	±10%	No	No	NA	NA	1500 ng/mL	NA
	TNI	Dimension® EXL™ System	No interference up to 500 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	100 ng/mL	±10%	1500 ng/mL	<10%
	CTNI	Dimension Vista® System	No interference up to 500 mg/dL	≤10%	Quantitative	±10%	Yes	Yes	100 ng/mL	±10%	1500 ng/mL	<10%
	Troponin-I	IMMULITE® 2000/2000 XPi Systems	No interference up to 512 mg/dL	<10%	Qualitative	±10%	Yes	Yes	1500 ng/mL	±10%	1500 ng/mL	<10%
	Troponin-I	IMMULITE® /IMMULITE® 1000 Systems	No interference up to 570 mg/dL	<10%	Qualitative	±10%	Yes	Yes	1500 ng/mL	±10%	1500 ng/mL	<10%
	Troponin-I	IMMULITE® Turbo System	No interference up to 512 mg/dL	<10%	Qualitative	±10%	Yes	Yes	1500 ng/mL	±10%	1500 ng/mL	<10%
Siemens	CTNI	Dimension Vista	No interference up to 500 mg/dL	(-)	Quantitative	±10%	Yes	Yes	***	±10%	1500 ng/mL	<10%

	TNI	Dimension EXL	No interference up to 500 mg/dL	ND	Quantitative	±10%	Yes	Yes	100 ng/mL	±10%	1500 ng/mL	<10%
	TNIH	Dimension Vista	No interference up to 400 mg/dL	(-)	Quantitative	±10%	Yes	Yes	300 ng/mL	±10%	1500 ng/mL	<10%
	TNIH	Dimension EXL	No interference up to 400 mg/dL	(-)	Quantitative	±10%	Yes	Yes	300 ng/mL	±10%	1500 ng/mL	<10%
Singulex	hs-cTnI	Clarity	No interference up to 500 mg/dL	(-)	Visual/ Qualitative	±10%	Yes	Yes	290 ng/mL	±10%	290 ng/mL	(-)
Tosoh	ST AIA-PACK cTnI 2nd Gen	AIA Series (AIA-1800, AIA-2000, AIA-600II, AIA-900, AIA-360, etc…)	No interference up to 430 mg/dL			±10%	No	No	NA	NA	NA	NA

ND: Not Determined
NA: Not Applicable

Hemolysis assessment: is determination of hemolysis performed visually (qualitative) by the end user, or automated to give a quantitative value.
* Not for sale in the US
**Acceptance criteria were those defined in the package insert for determining whether interference was considered significant or not.
*** Not in current IFU
**** Under further investigation

Hemolysis Assessment: the answer should either be Qualitative or Quantitative. This refers to how hemolysis is determined by the medical technologist/end user when using the assay/device. Does the instrument automatically assess for hemolysis and give a quantitative value so the medical technologist knows the result isn't valid? Or does it require the medical technologist to visually assess the specimen to determine if it is hemolyzed and results are unable to be reported?

Influence of Biotin Above the Threshold: the answer should either be positive or negative (or not determined). When biotin concentrations exceed the biotin interference threshold (column 3 of biotin section), are the troponin/natriuretic peptide results falsely high or low?