



## Letters to the Editor

### Incidence and Etiology of Poor Duplicate Ortho High-Sensitivity Cardiac Troponin I Results in a Community Hospital Emergency Department

#### To the Editor:

The prevalence of nonreproducible false-positive results obtained with the Ortho high-sensitivity cardiac troponin I (hs-cTnI) assay (Ortho Clinical Diagnostics, Raritan, NJ) is higher, compared to that obtained with other cardiac troponin assays in patients with an acute phase response, in both the academic and community hospital settings.<sup>1-3</sup> This difference is in contrast to testing performed in patients with a suspected acute coronary syndrome, for whom Ortho hs-cTnI concentrations are typically lower than Abbott hs-cTnI (Abbott Laboratories, Chicago, IL) concentrations.<sup>1</sup> Initial estimates of poor reproducibility for Ortho hs-cTnI concentrations, in samples collected from emergency department (ED) patients for whom the ED physician requested hs-cTnI testing, was approximately 5%.<sup>3</sup> Here, we describe and report on the number of poor duplicate results obtained with the Ortho hs-cTnI assay (laboratory algorithm) over 1 year, from ED patients presenting to a community hospital within our hospital network.<sup>2</sup>

Briefly, duplicate testing (laboratory initiative) for the Ortho hs-cTnI assay was performed with the average result reported if the 2 results met the prespecified criteria for agreement (Supplemental Table S1).<sup>3,4</sup> Samples yielding poor repeat measurements were not reported for the Ortho hs-cTnI assay, with the sample sent immediately for testing with the Abbott hs-cTnI assay.<sup>2,3</sup> Data were obtained from January 14, 2021 to February 8, 2022 from the laboratory information

system on samples from ED patients that were not reported with the Ortho hs-cTnI assay due to poor reproducibility. The patient list was cross-checked with the non-reported Ortho hs-cTnI concentrations, the Abbott hs-cTnI results, and other variables, including patient disposition (admit or discharged home), with the primary impression of the ED physician on the patient condition being recorded.

Over 13 months, 3350 patients had hs-cTnI assays ordered from an ED location. A total of 44 patients (1.3%; 95% confidence interval: 1.0-1.8) had samples (n = 48) that yielded poor duplicate Ortho hs-cTnI assay results. The median age of these patients was 70 years (interquartile range: 59-75), with 48% being female and 59% being discharged home. The median imprecision from the duplicate Ortho hs-cTnI assay concentrations was 28% (interquartile range: 22%-42%), with 43 of the 44 patients yielding at least one Ortho hs-cTnI assay concentration above the sex-specific 99th percentile (compared to 6 with the Abbott hs-cTnI assay). Most of the patients (75%) had an ED diagnosis with an infective etiology (Supplemental Table S2), with 4 patients having serial samples with poor reproducibility with the Ortho hs-cTnI assay (Table 1).

Duplicate testing will detect poor reproducible Ortho hs-cTnI results which, if reported, could lead to a misclassification of acute myocardial injury. The majority of these poor duplicate results are from patients with an infection.

Peter A. Kavsak, PhD  
kavsakp@mcmaster.ca

Basma Ahmed, MBCh, PhD  
Mathew Hulett, MLT

**Table 1.** Patients with poor reproducible Ortho hs-cTnI results that were not reported on serial sampling

Age, y	Sex	Blood draw	Ortho result 1, ng/L	Ortho result 2, ng/L	Absolute difference, Ortho 2nd from 1st	Percent difference, Ortho 2nd from 1 <sup>st</sup> , %	Abbott reported result, ng/L	ED physician primary impression	Disposition
69	F	First	<b>46.0</b>	<b>69.0</b>	23.0	50	12	Pneumonia	Discharged
		Second	<b>31.3</b>	<b>86.5</b>	55.2	176	12		
60	M	First	<b>34.3</b>	<b>60.2</b>	25.9	76	11	Rule out ACS	Discharged
		Second	8.9	<b>14.0</b>	5.1	57	12		
52	M	First	<b>16.6</b>	<b>45.9</b>	29.3	177	5	COVID-19	Admitted
		Second	<b>44.6</b>	<b>64.7</b>	20.1	45	5		
61	M	First	<b>21.9</b>	<b>26.6</b>	4.7	21	7	Chest infection	Discharged
		Second	<b>27.1</b>	<b>38.1</b>	11.0	41	9		

Patients with Ortho hs-cTnI assay (Ortho Clinical Diagnostics, Raritan, NJ) concentration results that have poor reproducibility (ie, difference > 3 ng/L or > 20% between values) that were not reported on serial sampling (Ortho female 99th ≤ 9 ng/L; Ortho male 99th ≤ 13 ng/L). The corresponding concentrations measured with Abbott hs-cTnI assay (Abbott Laboratories, Chicago, IL) were reported in the patient medical record (Abbott female 99<sup>th</sup>: ≤16 ng/L; Abbott male 99<sup>th</sup> ≤ 34 ng/L). Bolded hs-cTnI concentrations are those values that are above the 99th percentile.

Abbott, Abbott hs-cTnI assay; ACS, acute coronary syndrome; ED, emergency department; F, female; hs-cTnI, high-sensitivity cardiac troponin I; M, male; Ortho, hs-cTnI assay.

Andrew Worster, MD, MSc  
*McMaster University, Hamilton, Ontario, Canada*

### Ethics Statement

Ethics approval: HiREB 2179.

### Acknowledgements

We thank the laboratory staff within the Hamilton Regional Laboratory Medicine Program for performing the duplicate testing for the Ortho hs-cTnI assay.

### Funding Sources

The authors have no funding sources to declare.

### Disclosures

P.A.K. has received grants/reagents/honoraria from and/or served as advisor/consultant to the following: Abbott Laboratories, Abbott Point of Care, Beckman Coulter, Ortho Clinical Diagnostics, Quidel, Randox Laboratories, Roche Diagnostics, Siemens Healthcare Diagnostics, and Thermo Fisher Scientific. McMaster University has filed patents with P.A.K. listed as an inventor in the acute cardiovascular biomarker field. The other authors have no conflicts of interest to disclose.

### References

1. Kavsak PA, Mondoux S, Worster A, et al. Misclassification of myocardial injury by a high-sensitivity cardiac troponin I assay. *Can J Cardiol* 2021;37:523.e7-8.
2. Kavsak PA, Um K, Mondoux S, et al. Important differences between manufacturers when transitioning from a contemporary cardiac troponin assay to a high-sensitivity cardiac troponin assay. *CJC Open* 2021;3: 841-2.
3. Kavsak PA, Mondoux SE, Martin J, et al. Disagreement between cardiac troponin tests yielding a higher incidence of myocardial injury in the emergency setting. *J Cardiovasc Dev Dis* 2021;8:31.
4. Lafrenière MA, Tandon V, Ainsworth C, et al. Storage conditions, sample integrity, interferences, and a decision tool for investigating unusual high-sensitivity cardiac troponin results [e-pub ahead of print]. *Clin Biochem.* <https://doi.org/10.1016/j.clinbiochem.2022.06.007>. Accessed June 27, 2022.

### Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at <https://www.cjopen.ca/> and at <https://doi.org/10.1016/j.cjco.2022.10.002>.