

Investigation of Falsely Decreased Creatinine Measurements from the Abbott I-STAT Point of Care Testing Device in Use for Testing Specimens from Ambulatory Oncology Patients

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Renal impairment in oncology patients often results in the need for blood creatinine measurement to assess renal function prior to selected treatments including chemotherapy. In several ambulatory settings in our health system in 2011, we observed multiple instances of falsely decreased creatinine results in selected patients receiving chemotherapy when using the Abbott I-STAT (Abbott Diagnostics, Abbott Park, IL) for POCT creatinine analysis. Creatinine is determined on the I-STAT by amperometry using anticoagulated whole blood specimens (lithium heparin). Our studies employed lithium heparin tubes without a gel separator as required by the manufacturer. The falsely decreased, discrepant creatinine results we observed in selected patients were 30-70% lower on the I-STAT compared to our Core Laboratory's Beckman Coulter DxC 800 (Beckman-Coulter, Inc., Brea, CA). On the DxC 800, creatinine (lithium heparin) results are determined by the rate Jaffe assay. In this study cohort, 30 of 58 oncology patient specimens analyzed from three ambulatory oncology locations over a 2 month period demonstrated I-STAT creatinine results that were $\geq 35\%$ lower than the comparison DxC 800 creatinine result.

As our investigation expanded working with our institutional QA and pharmacy colleagues, similar occurrences of this problem were also reported on AACC's POCT list serve by individuals at other centers in ambulatory settings where specimens from oncology patients were tested for creatinine using the I-STAT. Our additional study efforts included multiple comparisons showing good agreement and correlation between the current methods (i.e., I-STAT and DxC 800 creatinine) in patients not receiving chemotherapy. This excellent level of agreement between the methods was consistent with our initial time I-STAT creatinine validations as well as in routine, ongoing, QA studies. Based on review of patient EMR's, our preliminary analyses failed to identify a specific cause. This evaluation included review of patient records from the initial 58 patient specimen oncology cohort as well as additional studies including reporting to, and working with the manufacturer of I-STAT. Our assessment was not effective in determining if the falsely decreased creatinine results were due to a sole specific drug. However, it was clear this discrepant creatinine problem only occurred in ambulatory oncology patients who had received chemotherapy in specimens often collected prior to initiation of their next dose of chemotherapy. Discrepant creatinine measurements were not observed in all patients receiving chemotherapy over this study period. No discrepant creatinine results were observed in study groups or patients not receiving chemotherapy.

Our inability to do POCT creatinine in ambulatory oncology settings has continued to have a negative impact on patient care. Therefore, we recently launched a new study to determine if the problem of discrepant creatinine results in selected oncology patient specimens tested on the I-STAT persisted. This study was approved by our Institutional Review Board. Earlier this year, excess whole blood from lithium heparin specimens collected by our cancer center phlebotomists from 85 oncology patients seen in clinic were analyzed for creatinine on the I-STAT and DxC800. While the differences are not as great as seen in earlier studies, the mean % difference between I-STAT and Core Lab creatinine results was I-STAT 7.6% lower in the control group (patients not on chemotherapy, n=42) versus I-STAT 14.3% lower in the study group (patients receiving chemotherapy within 20 days, n = 43). In an independent t-test analysis, the % difference between these groups was significant, $p = 0.026$.

Our group presently believes that there is current evidence to suggest that some unspecified interference may cause falsely decreased I-STAT creatinine measurements in specimens from selected oncology patients. Further studies are underway to expand the size of our study groups, to increase the specimen types analyzed (lithium heparin with and without gel separator) and to include another comparison POCT creatinine method recently approved by the FDA. Our long-term goal is to identify a suitably performing POCT creatinine method that can be reliably used in our ambulatory settings where patients who are receiving chemotherapy are being cared for.