

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0992761	(X3) Date Survey Completed 06/16/2022
Name of Provider or Supplier Thedacare Physicians Oshkosh	Street Address, City, State 600 N Westhaven Dr, Oshkosh, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, procedures, and the laboratory information system (LIS) and interview with testing personnel and a technical consultant, testing personnel did not document all Quality Control (QC) activities and corrective actions taken for glucose testing on June 7, 2022, one of thirteen analytes tested that day. Findings include: 1. Review of the Beckman Coulter AU680 analyzer "RB / CAL / QC Log" (Reagent Blank / Calibration / QC) printed June 7, 2022 at 7:26 AM showed QC results for thirteen analytes. The glucose results were: Level I: 79.06 Level II: 266.07 The printed log and the corrective action log showed no corrective action steps taken on June 7, 2022. A "Data Log" from June 7, 2022 showed two Glucose test result, Sample 00029 and 00030. The results were Sample 00029: 81.03 mg/dL Sample 00030: 266.74 mg/dL 2. Review of QC results in the LIS showed the glucose QC results from the RB/CAL/QC Log were not in the QC records. The LIS QC record did not show both levels of controls were unacceptable and did not show documentation of any corrective actions. The control results for glucose in the LIS on June 7, 2022 matched the results from Samples 00029 and 00030. 3. Interview with testing personnel (staff A) on June 16, 2022 at 11:45 AM revealed the glucose control results on June 7, 2022 were initially unacceptably low and that staff A changed the values in the LIS to the results obtained by testing the control material as a patient sample. 4. The "Laboratory Quality Control Policy", ADMIN13, included the following statement in the QC corrective action section, "All corrective action taken is documented." The policy did not include instructions to test controls as patient samples or to replace control values in the LIS as part of the investigation or</p>

corrective action process for unacceptable controls. 5. Interview with the technical consultant (staff B) on June 16, 2022 at 12:15 PM confirmed staff A did not document all quality control activities.