Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2002460	04/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Thedacare Physicians Darboy	W5282 Amy Ave, Appleton, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory proficiency testing (PT) records from the American Proficiency Institute (API) PT program and interview with a technical consultant (Staff A), the laboratory did not identify that the laboratory's results fell outside of the expected range and did not verify the accuracy of the total bilirubin test for two of three PT events in 2025, when the PT program did not obtain the agreement required for scoring and provided "Not Graded" results. Findings include: 1. Review of the API PT Performance Evaluation reports for two chemistry-core PT events in 2025 for total bilirubin revealed the laboratory received three "Not Graded" scores in event two, and two "Not Graded" scores in event three. The reports from the two events showed the following samples received a "Not Graded" score for the total bilirubin test: Sample | Reported Result | Expected Result PT Event 2-2025 CH-07 | 3.1 | 1.8-2.9 CH-09 | 2.2 | 1.3-2.2 CH-10 | 4.0 | 2.4-3.7 PT Event 3-2025 CH-12 | 2.4 | 1.4-2.3 CH-15 | 1.7 | 1.0-1.9 Further review of the report revealed the laboratory's results were not within the expected result range for samples CH-07, CH-10, and CH-12. There was no evidence the laboratory took action to investigate and verify the accuracy of the total bilirubin test. 2. Interview with Staff A on April 30, 2026, at 11: 50 AM confirmed the laboratory received "Not Graded" results on the two PT events for total bilirubin and confirmed the laboratory did not verify the accuracy for the total bilirubin samples in the two PT events when the PT program did not obtain the agreement required for scoring.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of a 'Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) Application for Certification' form (Form CMS-116) and the laboratory's procedure manual, and interview with a technical consultant (Staff A), the current laboratory director failed to approve the laboratory's procedure manual since assuming the role of laboratory director, including for four of four random procedures reviewed. Findings include: 1. Review of a Form CMS-116 submitted to the State CLIA office showed the laboratory requested a laboratory director change to Staff B effective October 1, 2025. 2. Review of four of the laboratory's procedures revealed no evidence the current laboratory director had approved the procedures for performing testing on the Beckman Coulter AU 680 analyzer, performing serum pregnancy testing, including the serum pregnancy individualized quality control plan (IQCP), and the Siemens DCA Vantage analyzer IQCP. 3. Interview with Staff A on April 30, 2026, at 12:38 PM confirmed the current laboratory director had not approved, signed, and dated the laboratory procedures since assuming the laboratory director role.