

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2002460	<b>(X3) Date Survey Completed</b>  09/10/2020
<b>Name of Provider or Supplier</b>  Thedacare Physicians Darboy	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control records, email correspondence with the technical consultant and interview with the technical consultant and testing personnel, the laboratory did not evaluate patient test results after the last acceptable quality control (QC) run to determine if patients had been adversely affected when the cholesterol quality control failed to meet the laboratory's established criteria for acceptability. Findings include: 1. Review of quality controls records showed cholesterol quality control performance on July 7, 2020: Time / Cholesterol Value/ Comment (milligrams/deciliter) 7:42 AM / 273.6 mg/dL/ Repeat 7:56 AM /288.3 mg /dL/ Fresh QC 8:14 AM /266.9 mg/dL/After Cal 8:31 AM /265.5 mg/dL/ Repeat 8:58 AM /264.2 mg/dL/ New Reagent 9:12 AM /256.4 mg/dL/After Cal Further review showed the acceptable range for cholesterol quality control was 249-263 and the previous acceptable run was July 6, 2020 at 0753. 2. Email correspondence with the technical consultant on September 17, 2020 at 9:50 AM stated fourteen patient cholesterol tests were performed on July 6, 2020. 3. Interview with the technical consultant and Staff A on September 10, 2020 at 12:26 PM, confirmed the laboratory did not evaluate patient tests results from samples tested between the acceptable QC</p>

performed on July 6, 2020 and the unacceptable QC attempts on July 7, 2020 to determine if the patient test results had been adversely affected when the QC test failed to meet the laboratory's established criteria for acceptability.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on surveyor review of competency assessment records and interview with the technical consultant, the technical consultant's evaluation of competency for three of three testing personnel was not specific for ThedaCare Physicians Darboy location in 2018 and 2019. Findings include: 1. Review of competency assessment records in 2018 and 2019 showed no evaluation of competency specific for the ThedaCare Physicians Darboy location for Staff B, C and D. 2. Interview with the technical consultant on September 10, 2020 at 9:03 AM, confirmed the technical consultant's evaluation of the testing personnel competency was not specific for the ThedaCare Physicians Darboy location.