

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2002460	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Thedacare Physicians Darboy	Street Address, City, State 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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control records and interview with the laboratory Technical Consultant the laboratory does not use an elevated serum bilirubin control for monitoring the abnormal range of neonatal bilirubin testing. Findings include: 1. Review of laboratory quality control (QC) records for the bilirubin assay show that two levels of QC are performed on a daily basis. The QC records for the bilirubin assay show that an elevated serum based bilirubin control for monitoring the abnormal range of neonatal bilirubin's is not assayed when performing neonatal bilirubin testing. 2. Interview with the Technical Consultant on February 22, 2018 at 12:30 PM confirms that an elevated serum based bilirubin control is not used to monitor the abnormal range of neonatal bilirubin's.</p>