

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0946874	(X3) Date Survey Completed 03/17/2021
Name of Provider or Supplier Thedacare Physicians Menasha	Street Address, City, State 2005 Midway Rd, Menasha, 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
D5425	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for serum human chorionic gonadotropin (HCG) testing and interview with the technical consultant, the laboratory could not show in-house data, established by the laboratory in its own environment by its own testing personnel, to support the frequency of external quality control (QC) testing for the developed IQCP. Findings include: 1. Review of the IQCP for serum HCG testing failed to show the laboratory used internally collected data to determine the frequency of external QC testing and the other control procedures described in the IQCP. 2. Interview with the technical consultant on March 17, 2021 at 11:50 AM confirmed the laboratory could not show in-house data, established by the laboratory in its own environment by its own testing personnel, to support the frequency of external QC testing in the IQCP for serum HCG testing.</p>