

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396765	(X3) Date Survey Completed 11/08/2023
Name of Provider or Supplier Prevea Health - Chippewa Falls	Street Address, City, State 2509 County Rd I, Ste 500, Chippewa Falls, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and manufacturer's instructions, and interview with the technical consultant, the laboratory did not update one of one Mini VIDAS Lyme procedure to include revised calibration requirements and did not have a quality assessment process in place to ensure updating of procedures when the manufacturer revised their instructions. Findings include: 1. Review of the laboratory procedure, Mini VIDAS Lyme, showed the laboratory required calibration of the assay "for each new lot received and every fourteen days thereafter". 2. Review of the laboratory's 'VIDAS Calibration Log' showed the laboratory calibrated the Lyme IgG and IgM assays once per month from June through October 2023. 3. Review of the manufacturer's instructions showed the manufacturer required calibration every 28 days. 4. Interview with the technical consultant on November 8, 2023, at 12:30 PM confirmed the laboratory did not update the procedure to reflect the changed manufacturer's calibration requirements. Further interview confirmed the laboratory did not have a process to ensure the laboratory integrated changes in the manufacturer's instructions into their procedures.</p>