

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396585	(X3) Date Survey Completed 01/16/2020
Name of Provider or Supplier Prevea Family Medicine-Eau Claire	Street Address, City, State 617 W Clairemont Ave, Eau Claire, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical supervisor, the laboratory has not established written policies and procedures to assess testing personnel, general supervisor, and technical supervisor competency. Findings include: 1. Review of laboratory procedures showed no evidence of a written procedure for the evaluation of testing personnel, general supervisor, and technical supervisor competency. 2. Interview with the technical supervisor on January 16, 2020 at 11:50 AM confirmed the laboratory did not have a procedure for evaluation of testing personnel, general supervisor, and technical supervisor competency.</p>
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: Item 1: Based on surveyor review of laboratory records, policies and procedures, and interview with the technical supervisor, the laboratory does not have a quality assessment policy or procedure to address how the laboratory monitors, assesses, and</p>

corrects problems identified in the lab. Findings include: 1. Review of laboratory quality control records, corrective action logs, and policies and procedures shows the laboratory does not have a quality assessment procedure to define laboratory quality control and corrective action processes. 2. Interview with the technical supervisor on January 16, 2020 at 11:50 AM confirms the laboratory does not have a written procedure that addresses how the laboratory monitors, assesses, and corrects laboratory and quality control problems. Item 2: Based on survey observation of refrigerator and freezer reagent storage, review of laboratory temperature records, and interview with the technical supervisor, the laboratory had not taken corrective action to correct temperature storage problems to prevent recurrence when the "Extra Freezer" and "Extra Refrigerator" reagent and control storage unit was not in acceptable defined range for 34 out of 273 days for the freezer and 12 out of 106 days for the refrigerator in September 2018 through December 2019. Findings include: 1. Observation of the "Extra Freezer" and "Extra Refrigerator" storage unit shows that chemistry reagents and controls used for patient testing are stored in both the freezer and refrigerator. 2. Review of the "Laboratory Daily Temperature Chart" from September 2018 through December 2019 shows the each unit was out of acceptable temperature range for several dates as follows and no corrective action to prevent recurrence was taken: "Extra Freezer" September 2018 6 out of 19 days October 2018 3 out of 23 days November 2018 2 out of 21 days December 2018 6 out of 19 days January 2019 1 out of 22 days February 2019 2 out of 19 days May 2019 1 out of 22 days June 2019 1 out of 20 days July 2019 2 out of 22 days August 2019 3 out of 22 days October 2019 2 out of 23 days November 2019 3 out of 20 days December 2019 2 out of 21 days TOTAL: 34 out of 273 days "Extra Refrigerator" May 2019 3 out of 22 days June 2019 1 out of 20 days October 2019 1 out of 23 days November 2019 2 out of 20 days December 2019 5 out of 21 days TOTAL: 12 out of 106 days 3. Interview with the technical supervisor on January 16, 2020 at 12:05 PM confirmed that the laboratory did not perform corrective action to prevent recurrence of out of acceptable range temperatures on the refrigerator/freezer storage unit used to store chemistry reagents and controls.