

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396765	(X3) Date Survey Completed 01/15/2020
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs and laboratory procedures, and observation of refrigerator storage, and interview with the technical consultant, the laboratory has not defined storage conditions that are consistent with the manufacturer's instructions for bacteriology and hematology quality control materials. Findings include: 1. Review of "Laboratory Daily Temperature Log" has the "Lab Refrig" and "Extra Refrig" temperature ranges as 0 to 10 degrees Celsius (C) on the temperature logs. 2. Observation of the refrigerators on January 15, 2020 at 12:00 PM revealed Sysmex hematology and Affirm VP II quality control material stored in the refrigerators. The manufacturer's package inserts for each respective control material showed the acceptable storage temperature range is 2 to 8 degrees C. 3. Interview with the technical consultant on January 15, 2020 at 12:45 PM confirmed the laboratory defined acceptable storage temperature range is not consistent with the manufacturer's instructions.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of quality control records, patient test records, and procedures, and interview with the technical consultant, the laboratory has not tested a positive and negative control material once each day of patient testing for 5 out of 11 days in January 2020 on the Becton Dickinson (BD) Affirm VPIII Microbial Identification System, and the laboratory does not have an Individualized Quality Control Plan (IQCP). Findings include: 1. Review of the "Affirm VPII Procedure" states external quality control is performed as follows: "Positive and Negative External controls are performed: Daily--when testing is performed, With each shipment and/or new lot, When test results are in question, With each untrained operator." Review of laboratory records show that the laboratory does not have an IQCP to perform equivalent quality control testing. 2. Review of quality control and patient test records for the BD Affirm VPIII Microbial Identification System showed the laboratory did not test positive and negative quality control material 5 out of 11 days in January 2020 in which patient testing was performed. 3. Interview with the technical consultant on January 15, 2020 at 12:15 PM confirmed the laboratory did not test quality control material each day of patient testing and confirmed the laboratory had not developed an IQCP for the test system.