

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394662	(X3) Date Survey Completed 08/25/2026
Name of Provider or Supplier Luxemburg Clinic A Prevea Health Center	Street Address, City, State 101 School Creek Trail, Luxemburg, 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
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor review of documented humidity readings in the laboratory and interview with a Technical Consultant (Staff A), the Laboratory Director did not ensure the humidity in the laboratory was appropriate for the testing performed on the Sysmex hematology analyzer in January 2026, for twenty-two of twenty-two days the laboratory recorded humidity results. Findings include: 1. Review of the 'Temperature Chart' record from January 2026 showed the laboratory documented minimum and maximum relative humidity readings in the laboratory on 22 days. The report identified the acceptable relative humidity range as 20 - 80%. Testing personnel documented minimum humidity readings that were less than 20% each of the 22 days in January 2026. Personnel documented maximum humidity readings less than 20% on 19 of the 22 days. 2. Interview with Staff A on August 25, 2026, at 2:25 PM revealed the laboratory defined the acceptable relative humidity range to meet the manufacturer's requirements for the Sysmex hematology analyzer. Further interview confirmed the laboratory humidity was not within the defined range when personnel performed hematology testing in January 2026 and confirmed the director did not ensure the laboratory could maintain the humidity levels as defined by the analyzer manufacturer during winter months.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i) (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

Based on surveyor review of competency assessment records and interview with a technical consultant (Staff A), the technical consultants did not document site specific direct observation of routine patient testing at this location for five of five testing personnel in 2025. Findings include: 1. Review of testing personnel competency assessment records showed the form used identified multiple laboratory locations for each test system. The form included the statement, "Each of our laboratories perform testing in the same manner, specified in MediaLab. The only differences between locations are where testing and materials are located. This competency proves that I am competent for each test system at all of the sites I rotate between. This eliminates the need for multiple competencies for the same test system." Review of the forms showed the technical consultants did not consistently document the laboratory location where they observed testing personnel and did not show a technical consultant completed direct observation of each test system for each testing person at this laboratory. 2. Interview with Staff A on August 25, 2026, at 11:00 AM confirmed the technical consultants did not perform direct observation at this laboratory for each non-waived test system for each of the five testing personnel.