

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2181806	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Aurora Health Center - Pleasant Prairie	Street Address, City, State 12500 Aurora Drive, Pleasant Prairie, 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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of personnel records and interview with the technical consultant, the technical consultant did not evaluate and document the performance of three of three testing personnel who have performed testing for more than one year at this laboratory during the first year the individuals performed patient testing. Findings include: 1. Review of personnel records for testing personnel (staff A, B, and C) showed staff A, B, and C had performed testing for more than one year in the laboratory. The competence evaluation records showed no evidence of semiannual competence evaluations for any of the three testing personnel. 3. Interview with the technical consultant on September 13, 2022, at 12:35 PM confirmed the technical consultant did not perform a semiannual evaluation of the performance of three of three testing personnel during the first year the individuals performed patient testing.</p>
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and quality control (QC) records and</p>

interview with the technical consultant, testing personnel did not perform external serum QC every 30 days nine times in the twenty months from January 2021 through August 2022 for the Sure-Vue human chorionic gonadotropin (HCG) test, and testing personnel did not perform the required low positive control as required one of three times testing was performed in January 2022. Findings include: 1. The 'HCG Serum-Urine Sure-Vue' procedure, document number 62525, included the following statement in 'Section VII Quality Control', "If sites are running both serum and urine testing, as a non-waived kit, both serum and urine Quality Control must be performed at a minimum of every 30 days...". The procedure also stated, "At a minimum two levels of QC must be run - a low positive and a negative external QC for serum testing...". 2. Review of the QC record 'Quality Control Log - Qualitative HCG (30 days)' showed the log also instructed personnel to perform a negative and weak positive control at a minimum every thirty days and that serum and urine samples must be tested. Review of the QC records showed testing personnel documented QC results for serum HCG testing on the following days in 2021 and 2022: January 27, February 19, April 28, June 1, July 30, September 8, 9, and 20, October 12, November 22, and December 7, 2021, and January 12, 25 and 27, March 22 and 31, April 26, 8, and 29. No serum QC testing records were available for May through August 2022. The QC logs showed testing personnel did not perform external serum QC testing within 30 days of the previous QC test in March, April, July, August and November 2021, and January, June, July, and August 2022. The results recorded on January 27, 2022 showed testing personnel tested a positive and negative control and did not test a low positive control. 3. Interview with the technical consultant on September 13, 2022 at 3:00 PM confirmed testing personnel did not adhere to the laboratory's quality control policies when they did not perform external QC every thirty days and did not perform the required weak positive control on January 27, 2022.