Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0394447	03/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kaukauna Clinic Sc	305 E 12th St, Kaukauna, 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
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records and interview with the laboratory supervisor, the laboratory's control process for bilirubin does not include controls that would evaluate method performance in the abnormal range of results when neonatal samples are tested. Findings include: 1. Review of bilirubin quality control records show no control results in the expected abnormal range for neonatal specimens. 2. Interview with the laboratory supervisor, staff A, on March 19, 2019 at 3:00 PM confirmed the laboratory does not test additional bilirubin controls with neonatal samples. Further interview confirmed the routine bilirubin control results would not evaluate method performance in the expected abnormal range for neonatal bilirubin results.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

	performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of the hCG (human chorionic gonadotropin) procedure and the Individualized Quality Control Plan (IQCP), and interview with the laboratory supervisor, the procedure and the IQCP required different frequencies for control testing. Findings include: 1. Review of the laboratory procedure for the serum and urine hCG test showed "positive and negative controls should be run weekly and documented on the equivalent Q.C. log". 2. The IQCP for serum hCG testing stated "As per manufacturer, external quality control (negative and positive) will be run monthly and also with each product shipment and new kit lot #." 3. Interview with the laboratory supervisor, staff A, on March 19, 2019 at 12:00 PM confirmed the required frequency for hCG control testing in the procedure and the IQCP were not consistent. Item 2: Based on surveyor review of the hCG (human chorionic gonadotropin) procedure and the Individualized Quality Control Plan (IQCP), and interview with the laboratory supervisor, the laboratory failed to specify the type of quality control (QC) material required and failed to use external QC material with a similar matrix to that of serum patient specimens. Findings include: 1. Review of the laboratory procedure for the serum and urine hCG test showed the procedure did not specify the type of QC material required. 2. The IQCP for serum hCG testing did not specify the type of QC material required. 3. Interview with the laboratory supervisor, staff A, on March 19, 2019 at 12:00 PM confirmed neither the procedure nor the IQCP specified the type of QC material for the hCG test. Further interview confirmed the laboratory uses a urine-based control and does not test matrix matched QC material when performing serum hCG testing on patient samples.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's IQCP (Individualized Quality Control Plan) and interview with the laboratory supervisor, the laboratory has not established and followed written policies and procedures for the ongoing monitoring of the effectiveness of their IQCP. Findings include: 1. The IQCP for human chorionic gonadotropin did not include a quality assessment plan for ongoing monitoring of the IQCP. 2. Interview with the laboratory supervisor on March 19, 2019 at 11:45 AM confirmed the laboratory had not evaluated the ongoing effectiveness of their IQCP and had not established written policies or procedures for monitoring the plan. This is a repeat deficiency, D5791 was previously cited on March 1, 2011.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and interview with the laboratory supervisor, testing personnel did not adhere to the laboratory's QC policies for hCG (human chorionic gonadotropin) testing on serum samples. Findings include: 1. Review of the IQCP for serum hCG testing showed personnel must test a positive and negative external QC sample monthly and with each product shipment and new kit lot number. 2. Review of the external QC records from 2018 for the Quidel hCG test kit showed personnel tested external controls on: Friday, June 29, lot number 703547 Wednesday, August 1, lot number 704265 Monday, October 15, lot number 704379 There is no evidence personnel tested external control samples in July or September 2018. 3. Review of patient records showed the laboratory performed patient hCG tests on September 5, 12, 13, 21, 27 and 28, 2018. Further review showed the laboratory tested patient samples using lot number 704265 through October 15, 2018 when personnel had last tested external controls on August 1, 2018. 4. Interview with the laboratory supervisor, staff A, on March 19, 2019 at 1:45 PM confirmed testing personnel did not test hCG external QC monthly as required in the IQCP.