Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0661895	11/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Kenosha County Div Of Health Laboratory	8600 Sheridan Rd Ste 600, Kenosha, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records from 2019 and 2020 and interview with the laboratory director, the laboratory director did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. Findings include: 1. Review of PT records showed the laboratory director did not sign the following attestation statements for Bacteriology and Syphilis testing: 2019 event one; bacteriology and syphilis 2019 event two; bacteriology 2020 event one; bacteriology and syphilis 2020 event two; bacteriology and syphilis 2020 event three; bacteriology and syphilis 2. Interview with the laboratory director on November 5, 2020 at 10:35 AM confirmed the laboratory director did not sign the attestation statements for PT events in 2019 and 2020. This is a repeat deficiency previously cited on June 21, 2010.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on surveyor review of manufacturer's instructions, laboratory records, and interview with the technical consultant, the laboratory has not followed the manufacturer's instructions for the BD (Becton Dickinson and Company) Macro-Vue RPR (Rapid Plasma Reagin) test system in 2019. Findings include: 1. The manufacturer's instructions for the BD Macro-Vue RPR Cards stated the antigen suspension should be warmed to room temperature (23 - 29 degrees Celsius (C), 73.4 - 84.2 degrees Fahrenheit) before use. 2. Review of documented room temperatures in the laboratory in 2019 showed the laboratory recorded temperatures on 246 days. Only 20 of the 246 recorded temperatures in 2019 showed an entry at or above 73.4 degrees. There were zero days from April 24 to November 18, 2019 with recorded room temperatures acceptable for testing with the Macro-Vue RPR Cards. 3. Interview with the technical consultant, staff A, on November 5, 2020 at 11:50 AM confirmed room temperatures recorded in the laboratory in 2019 did not meet the manufacturer's requirements for RPR testing. This is a repeat deficiency previously cited on June 12, 2014.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor review of temperature records and interview with the technical consultant, the laboratory had not documented corrective actions when room temperatures were not within the acceptable range. Findings include: 1. Review of the 2019 "Thermometer Temperature Record" for room temperature documentation in the laboratory showed the acceptable range was 73 to 78 degrees Fahrenheit. Of the 246 recorded temperatures in 2019, 106 were not within the laboratory's acceptable range. There is no evidence of any corrective actions taken. 2. Interview with the technical consultant, staff A, on November 5, 2020 at 11:50 AM confirmed the laboratory had not documented corrective actions taken when temperatures did not meet acceptable parameters.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports and interview with the technical supervisor, the test report did not include the actual test report date. Findings include: 1. Review of patient test reports showed the reports include a field labeled "Result

	Received Date & Time". The Gonorrhea Culture report for patient 1 showed "09-25-2020" in both the "Result Received Date & Time" field and in the "Lab Ordered Date" field. A comment was included on the report "Analyzed in the lab on 09/29/2020". The report does not show the date the laboratory reported the results. 2. Interview with the technical supervisor, staff A, on November 5, 2020 at 12:10 PM confirmed test reports did not show the test report date. Further interview confirmed the date entered in the "Result Received Date & Time" field was the date the specimen was collected.