Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661895	(X3) Date Survey Completed 07/12/2022
Name of Provider or Supplier Kenosha County Div Of Health Laboratory	**Street Address, City, State** 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 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with a technical consultant, staff A, testing personnel did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for one of two MiscQA-POC events in 2021 used to assess provider performed microscopy (PPM) testing. Findings include: 1. Review of WSLH PT records showed testing personnel did not sign the attestation statement for PPM PT event number one, MiscQA-POC1. 2. Interview with staff A on July 12, 2022 at 10:25 AM confirmed testing personnel did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for one of two MiscQA-POC events in 2021 used to assess provider performed microscopy (PPM) testing. This is a repeat deficiency from June 21, 2010 and November 5, 2020.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities

	to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of the submitted Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 (Centers for Medicare and Medicaid Services) and the laboratory's test menu, and interview with the laboratory director and a technical consultant, staff A, the laboratory director did not ensure notification requirements were met as required at 493.51. Findings include: 1. Review of the CMS 116 for submitted during the survey showed the laboratory no longer performs testing in the Bacteriology subspecialty. 2. Review of the "Test Menu for Kenosha County Division of Health" showed no bacteriology testing listed. Further review showed the laboratory only performs moderate complexity testing with no high complexity testing as per previously classified. 3. Interview with the staff A on July 12, 2022 at 9:15 AM confirmed the laboratory discontinued bacteriology testing in 2020. 4. Interview with the laboratory director and staff A on July 12, 2022 at 10:45 AM confirmed the laboratory director did not ensure the laboratory notified Health and Human Services (HHS) or its designee within six months of discontinuing testing in a subspecialty as required at 493.51 (c).