Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0661895	06/23/2026
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) (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 and interview with the provider performed microscopy (PPM) testing personnel (Staff B), the individual testing the PT samples and laboratory director did not attest to the routine integration of the PT samples into the patient workload using the laboratory's routine methods for two of two PT events in 2025 that were used to assess PPM testing. Findings include: 1. Review of the laboratory's PT records showed the laboratory submitted and received results for event one and event two for 'Misc QA POC' (Miscellaneous Quality Assessment Point of Care) challenges with the Wisconsin State Laboratory of Hygiene (WSLH) PT program in 2025. The attestation statements for the two events showed no evidence the individual testing the PT samples and the laboratory director signed the forms. 2. Interview with Staff B on June 23, 2026, at 3:20 PM confirmed the individual who performed the test and the laboratory director did not attest to the routine integration of the samples into the patient workload by signing the attestation statements for the two PT events in 2025 that were used to assess PPM testing. This is a repeat deficiency previously cited on July 12, 2022.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) reports from Wisconsin State Laboratory of Hygiene (WSLH), laboratory records and interview with the provider performed microscopy (PPM) testing personnel (Staff B), the laboratory did not document review of one of one non-consensus result to verify the accuracy of the non-consensus score for a vaginal wet prep image identification in the second event in 2025 of the 'Misc QA POC' (Miscellaneous Quality Assessment Point of Care) challenge. Findings include: 1. Review of the 'Misc QA POC' PT report from the WSLH PT program for the second event of 2025 showed the laboratory received a "Non-consensus-Self Assessment Needed" result for the vaginal wet prep sample PM-4. The records showed no indication the laboratory reviewed the non-consensus result to verify the accuracy. 2. During an interview on June 23, 2026, at 3:20 PM, Staff B revealed she and the laboratory director did discuss the non-consensus result, but did not document the review and verification of the accuracy of the vaginal wet prep image.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's procedures, individualized quality control plan (IQCP) and interview with the laboratory supervisor (Staff A), the laboratory director did not approve one of one test procedure for the Siemens Syva Rapid Test d.a.u. mAMP (methamphetamines) test kit when the laboratory changed how it performed quality control (QC). Findings include: 1. Review of the test procedure, approved with effective date August 12, 2024, 'Siemens Syva Rapid Test d. a.u. mAMP', stated, in part, "External Controls Syva Level 0 (N) and Level 5 (P) run daily before patient samples". 2. Review of Document No: QC-007, approved with effective date October 1, 2024, 'Individualized Quality Control Plan', stated, "Perform QC testing with positive and negative controls with each new lot number of dip cards and with every shipment. Perform external controls if storage conditions change." 3. Interview with Staff A on June 23, 2026, at 2:45 PM confirmed the laboratory performed QC following the IQCP and confirmed the information in the approved test procedure for the Siemens Syva Rapid Test d.a.u. mAMP did not reflect current practice. Further interview confirmed the laboratory director did not approve, sign, and date the change to the test procedure when the laboratory established the IQCP.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the

	manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with the laboratory supervisor (Staff A), the laboratory did not perform and document one of two of the previous rotator time checks required when starting a new lot of antigen for the rapid plasma reagin (RPR) test. Findings include: 1. Review of the procedure, 'RPR Syphilis Serology', includes a step to check the RPR rotator time with each new lot of antigen. 2. Review of the laboratory records revealed testing personnel opened new lots of antigen on June 20, 2025 (lot# 5C24R3) and December 12, 2025 (lot # 5K15R3). Further review of the 'RPR Rotator Time Check' form revealed testing personnel performed a time check on December 12, 2025, for lot# 5K15R3. There was no evidence testing personnel performed a time check when starting lot# 5C24R3 on June 20, 2025. 3. Interview with Staff A on June 23, 2026, at 2:25 PM confirmed the laboratory did not follow its procedural step to perform and document RPR rotator time checks for the RPR test before patient testing was conducted.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 two of two patient test reports and interview with the laboratory supervisor (Staff A), the test reports did not indicate the name and address of the performing laboratory. Findings include: 1. Review of the test reports revealed no indication of the name and address of the performing laboratory. 2. Interview with Staff A on June 23, 2026, at 4:00 PM confirmed the test reports did not indicate the name and address of the performing laboratory.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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: Item 1: Based on surveyor review of laboratory records, the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209), Laboratory Personnel Report (CLIA), and interview with the laboratory supervisor (Staff A), the laboratory director failed to delegate in writing technical consultant duties performed by one of one staff member and did not document evaluation of competency of the staff member in performing the delegated duties. Findings include: 1. Review of the Form CMS-209 showed the director identified Staff A as the technical consultant. 2. Review of laboratory records showed no evidence the director delegated the technical consultant responsibilities to Staff A. Further review revealed the laboratory director did not document evaluation of competency for the staff member in performing the delegated duties. 3. Interview with Staff A on June 23, 2026, at 10:50 AM confirmed the laboratory director delegated technical consultant responsibilities to Staff A without documenting the delegation in writing and confirmed the laboratory director did not document evaluation of the staff member's competency in performing the delegated duties. Item 2: Based on surveyor review of laboratory records, and interview with the laboratory supervisor (Staff A), the director failed to delegate in writing and assess competency for one of one testing personnel (Staff C) who performed the technical consultant responsibility of competency evaluation of peer testing personnel. Findings include: 1. Review of competency records revealed Staff C assessed Staff D's competency during Staff D's initial competency evaluation in January 2026. 2. Review of laboratory records showed no evidence the director delegated the technical consultant responsibility of performing testing personnel competency evaluation to Staff C. Further review revealed the laboratory director did not document evaluation of competency for the staff member in performing the delegated duty. 3. Interview with Staff A on June 23, 2026, at 10:50 AM confirmed Staff C assessed Staff D's competency in performing test procedures. Further interview confirmed the laboratory director did not delegate this responsibility in writing or assess Staff C's competency in performing competency assessment of peer testing personnel.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on surveyor review of competency evaluations and interview with the laboratory supervisor (Staff A), the technical consultant did not evaluate and document competency evaluation for three of three testing personnel in performing testing using the Siemens Syva Rapid Test d.a.u. mAMP (methamphetamine) test kit system. Findings include: 1. Review of instrument print outs containing results of the Siemens Syva Rapid Test d.a.u. mAMP test kit showed Staff A, C, and D performed and reported patient methamphetamine test results. 2. Review of competency evaluation records showed no documented evaluation of the six competency assessment procedures for Staff A, C, and D in performing testing using the Siemens Syva Rapid Test d.a.u. mAMP test kit. 3. Interview with Staff A on June 23, 2026, at

	9:45 AM confirmed the technical consultant did not evaluate and document competency evaluation for three of three testing personnel who performed testing using the Siemens Syva Rapid Test d.a.u. mAMP test kit.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel competency records and interview with the laboratory supervisor (Staff A), the technical consultant did not evaluate and document semiannual competency assessment of testing performance during the first year the individual performed moderate complexity patient testing for two of three new testing personnel. Findings include: 1. Review of testing personnel competency records for Staff A and Staff C revealed the laboratory documented initial competency assessments on individual test system forms. The laboratory documented Staff A's initial competency during January and February 2025, and Staff C's initial competency during April and May 2025. Further review revealed no evidence the laboratory documented a semiannual competency evaluation for the two testing personnel. 2. Interview with Staff A on June 23, 2026, at 9:45 AM confirmed the technical consultant did not evaluate and document semiannual competency assessment for two testing personnel during the first year they performed moderate complexity patient testing.