Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 52D0661895	**(X3) Date Survey Completed** 07/25/2024
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**
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of testing supplies and interview with a Technical Consultant (Staff A), the laboratory did not label one of one KOH (Potassium Hydroxide) dropper bottle used for Provider Performed Microscopy (PPM) procedures with the solution preparation and expiration dates. Findings include: 1. Observation of the KOH used in the clinic for PPM procedures showed the dropper bottle label stated the contents expire when precipitate forms. No preparation date or expiration date was present on the bottle. 2. Interview with Staff A on July 25, 2024, at 12:30 PM revealed Staff A made the KOH solution on site and confirmed the label did not include the required information.
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: Based on surveyor review of laboratory procedures and interview with a technical consultant (Staff B), the laboratory procedure did not define the type, number and frequency of external controls required for the Syva RapidTest d.a.u. test for methamphetamine (mAMP) test, one of one cartridge test system in use in the laboratory, prior to starting testing in March 2024. Findings include: 1. Review of the laboratory procedure, 'Syva RapidTest d.a.u. mAMP', showed the procedure included the following statement concerning external controls. "External Controls may also be used to ensure that the reagents and assay procedures are performing properly. Control should be tested at regular intervals (e.g. once per lot or once per shipment) as part of a good laboratory testing practice." 2. Interview with Staff B on July 25, 2024, at 12:45 PM confirmed the laboratory procedure did not define the type, number, and frequency of external controls required prior to testing patient samples with the Syva RapidTest d.a.u. mAMP test.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and test records and interview with a technical consultant (Staff B), the laboratory did not test a positive and negative control material each day the laboratory performed patient methamphetamine (mAMP) testing in the last four of four months using the Syva RapidTest d.a.u. mAMP cassette test. Findings include: 1. Review of laboratory procedures for the 'Syva RapidTest d.a.u. mAMP' showed the procedure included the following statement concerning external controls. "External Controls may also be used to ensure that the reagents and assay procedures are performing properly. Control should be tested at regular intervals (e.g. once per lot or once per shipment) as part of a good laboratory testing practice." 2. Review of testing records for the Syva RapidTest d.a.u. mAMP showed no evidence the laboratory performed external controls for the test. 3. Interview with Staff B on July 25, 2024, at 12:45 PM confirmed the laboratory had not performed a positive and negative control each day of patient testing and did not develop an IQCP (Individualized Quality Control Plan) for the test system since the laboratory started testing in March 2024.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the verification studies for moderate complexity drug testing and interview with a technical consultant (Staff B), the director did not document review and approval of the verification studies the laboratory performed for thirteen of thirteen drugs tested with the Viva Pro-E analyzer. Findings include: 1. Review of verification studies for testing performed on the Viva Pro-E analyzer showed no evidence of review and approval of the accuracy, precision, and other pertinent performance characteristics of the test methods for amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine metabolites, opiates, methadone, oxycodone, ecstasy, buprenorphine, phencyclidine, fentanyl, and ethyl alcohol. 2. Interview with Staff B on July 25, 2024, at 12:15 PM confirmed the director had not documented the review and approval of the performance specification verification studies for the drugs tested with the Viva Pro-E analyzer to ensure the procedures were adequate to determine the accuracy, precision, and other performance characteristics of the test methods.