Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0860363	07/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
City Of Milwaukee Std Clinic Laboratory	3200 N 36th St, Milwaukee, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory did not report four SARS-CoV-2 antibody test results to the state public health department that the laboratory performed on four days between September 23, 2020 and July 20, 2021. Findings include: 1. Review of laboratory records provided via email on July 21, 2021 showed the laboratory performed four SARS-CoV-2 antibody tests, one test on each of four days between September 23, 2020 and July 20, 2021. The laboratory performed testing on October 7, November 19, and December 16, 2020 and February 1, 2021. 2. During a video conference call interview on July 21, 2021 at 3:15 PM, the laboratory director confirmed the laboratory did not report results for SARS-CoV-2 antibody tests to the state public health department.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer's instructions for the iodine reagent used for gram stains, laboratory procedures and quality control records, and interview with the technical consultant, the laboratory used the iodine reagent past the manufacturer's opened (reconstituted) expiration date for three months and two weeks in 2021. Findings include: 1. The manufacturer's instructions for the Remel Iodine Gram Stain reagent stated, "Use Gram Iodine within 3 months after reconstitution". 2. Review of the laboratory's procedure, 'Gram stain procedure at Keenan Health Center Laboratory' showed no evidence the laboratory limited use of the iodine reagent to three months after reconstitution. 3. Review of quality control records from September 28, 2020 through July 14, 2021 showed the laboratory used Iodine Reagent lot 535469 with an unopened expiration date of November 4, 2021. Further review showed testing personnel used the iodine reagent for gram stains beyond the three-month expiration date after reconstitution. From September 28, 2020 through April 1, 2021, the records show the laboratory opened (reconstituted) the iodine reagent on September 28, 2020 and stated the reagent expiration date was November 4, 2021. The records showed the laboratory used the reagent after the three-month expiration date from December 28, 2020 through April 1, 2021. From April 12, 2021 through July 14, 2021, the records showed the laboratory opened (reconstituted) iodine reagent on March 29, 2021 and stated the reagent expiration date was November 4, 2021. The records showed the laboratory used the reagent after the three-month expiration date from June 30, 2021 to July 14, 2021. 4. Interview with the technical consultant (Staff A) on July 20, 2021 at 12:25 PM confirmed the quality control records showed testing personnel used iodine reagents after the three-month reconstituted expiration date.
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 the laboratory's Individualized Quality Control Plan (IQCP) for the Geenius HIV 1/2 Supplemental Assay and interview with the laboratory director, the laboratory had not specified the required number, type and frequency of control materials in a quality control plan or the methods for monitoring the IQCP in a quality assessment plan. Findings include: 1. Review of the 'Milwaukee Health Department Individualized Quality Control Plan (IQCP) for the Geenius HIV 1 /2 Supplemental Assay' version 2.0, showed the IQCP did not include a quality control plan or a quality assessment plan that met the requirements for an acceptable

	IQCP. The laboratory director approved and signed version 2.0 of the IQCP on July 21, 2021. The plan includes the following: The 'Review Record' dated July 21, 2021 stated the following revision was made, "KHC Laboratory performs external controls weekly to the mitigation plan for "Testing Device not stable for 30 days"". The 'Background and Information' section included the manufacturer's instructions for external quality control including "run positive and negative external control material with each new lot number or shipment and every 30 days thereafter". The section also included this statement, "We have determined that the manufacturer's QC protocol is sufficient for this test, as performed in our laboratory, when the supplemental components outlined above are utilized to control identified risks". The Risk Assessment Table included a column labeled 'Risk Mitigation Plan'. This column included the statement "Our laboratory performs external QC Weekly". The IQCP did not include a separate Quality Control Plan and the column labeled 'Risk Mitigation Plan' did not identify the number, type, and frequency of control materials and did not include the criteria for acceptable results of the quality controls. The IQCP did not show the laboratory established and followed policies and procedures for the ongoing monitoring of their IQCP. 2. Video conference interview with the laboratory director on July 21, 2021 at 3:15 PM confirmed the IQCP for the Geenius HIV 1/2 Supplemental Assay did not include a quality assessment plan.