

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0860363	(X3) Date Survey Completed 05/29/2025
Name of Provider or Supplier City Of Milwaukee Std Clinic Laboratory	Street Address, City, State 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with a technical consultant (Staff A), the procedure for one of one new test performed on the Architect analyzer was not approved, signed, and dated by the current laboratory director before use for patient testing in June of 2024. Findings include: 1. Review of the current Hepatitis C Antibody Screen procedure showed the laboratory director signed the procedure on May 14, 2025. The previous version of the procedure showed no evidence the current laboratory director approved, signed or dated the procedure. 2. Interview with Staff A on May 29, 2025, at 12:20 PM revealed the laboratory performed Hepatitis C Antibody tests starting in 2019 but discontinued testing after the last survey and restarted testing in June 2024. Further interview confirmed the laboratory director had not approved the procedure in use when the laboratory restarted Hepatitis C Antibody patient testing.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this</p>

section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

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 Assay and control records and interview with testing personnel (Staff B), the laboratory did not perform external quality control every 30 days as required in their IQCP. Testing personnel did not perform external quality controls during four of the last seventeen months. Findings include: 1. Review of the IQCP for the Geenius HIV 1 / 2 Assay showed the laboratory required external control testing with each new lot and shipment, when the ambient temperature was outside the acceptable range, and every 30 days. 2. Review of control records for the Geenius HIV 1 / 2 from January 2024 through May 2025 showed personnel did not test external controls in February, June or November 2024 or March 2025. 3. Interview with Staff B on May 29, 2025, at 11:15 AM confirmed staff did not test external controls every 30 days with the Geenius HIV 1 / 2 Assay as required by the laboratory's IQCP.