

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0860363	(X3) Date Survey Completed 06/20/2023
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, laboratory records and procedures and interview with a technical consultant, staff A, the laboratory does not examine or testing the proficiency testing samples in the same manner as it's patient specimens for gram stains performed for two of three events in 2022. Findings include: 1. Review of API PT records from 2022 showed the laboratory received a score of eighty percent on gram stain morphology for event 1 in 2022. 2. Review of the "Laboratory Non-Conforming Event & Corrective Action Form" showed under heading "What actions /measures can be taken to avoid reoccurrence?" the laboratory stated, "Further Gram Stain PT reviewed by Senior Microbiologist and Testing Personnel before reported out". 3. Review of the "Gram Stain Procedure" showed testing personnel do not have the senior microbiologist review gram stains prior to resulting in the laboratory information system. 4. Interview with staff A on June 20, 2023, at 10:00 AM confirmed the laboratory does not examine or testing the proficiency testing samples in the same manner as it's patient specimens for gram stains performed in 2022.</p>
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 PT samples into the patient workload using the laboratory's routine methods for two of two MiscQA_POC events, one of two immunology events, one of three HIV/HP/SS1 events, and one of three HIVCombo events in 2022. Findings include: 1. Review of API PT records from 2022 showed testing personnel did not sign the attestation form for MiscQA_POC events 1 and 2, immunology event 1, HIV/HP/SS1 event 1, and HIVCombo event 1 in 2022. 2. Interview with staff A on June 20, 2023, at 9:30 AM confirmed testing personnel did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for five of ten events reviewed in 2022.