

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0678401	<b>(X3) Date Survey Completed</b>  02/21/2020
<b>Name of Provider or Supplier</b>  Froedtert & The Medical College Of Wisconsin	<b>Street Address, City, State</b>  1700 W Paradise Dr, West Bend, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing records from Froedtert and the Medical College of Wisconsin Community Physicians in West Bend (FMCCP-WB) (52D0678401) and Froedtert and Medical College Community Physicians - Mequon 1 (FMCCP-M) (52D2135321), quality assurance records, and interview with a technical consultant, the laboratory did not test the KOH (potassium hydroxide) proficiency samples in the same manner as patient samples during the second event in 2019. Findings include: 1. Testing personnel, staff A, tested the same proficiency samples for KOH (Samples PM3 and PM4) at FMCCP-WB (52D0678401) and FMCCP-M (52D2135321) during the second event of 2019, resulting in inter-laboratory communication. See D2011.</p>
<b>D2011</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results</p>

to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing and quality assurance records, and interview with a technical consultant, the KOH (potassium hydroxide) proficiency test samples (PM3 and PM4) from event two in 2019 were tested by the same person at Froedtert and the Medical College of Wisconsin Community Physicians in West Bend (FMCCP-WB) (52D0678401) and Froedtert and Medical College Community Physicians - Mequon 1 (FMCCP-M) (52D2135321), resulting in inter-laboratory communication of proficiency testing results. Findings include: 1. Review of Wisconsin State Laboratory of Hygiene proficiency testing records from FMCCP-WB and FMCCP-M for the second event in 2019 of the miscellaneous quality assurance point of care (MiscQA\_POC2) module showed: At FMCCP-WB, 52D0678401 \*The Proficiency Testing tracking form showed testing person, staff A, was assigned testing of the PM samples (Provider Performed Microscopy (PPM) including KOH testing on samples PM3 and PM4). \*The Attestation Statement was signed by staff A and dated October 24, 2019. At FMCCP-M, 52D2135321 \*The Proficiency Testing tracking form showed testing person, staff A, was assigned the PPM challenges. The PPM test results include KOH testing on samples PM3 and PM4. \*The Attestation Statement was signed by staff A and dated October 25, 2019. 2. Review of the Mequon Health Center Monthly Quality Assurance Audit Checklist from November 2019 showed the checklist included the following statement: "2019 - MiscQA-POC2 - Failed one cell ID for KOH - Not performed at CP anymore same tech performed this at MQ & WB". (Mequon & West Bend) 3. Interview with a technical consultant, staff B, on January 7, 2020 at 11:15 AM confirmed staff A performed the KOH testing of proficiency testing samples at FMCCP-WB (52D0678401) and FMCCP-M (52D2135321) for the second event in 2019 resulting in inter-laboratory communication of proficiency testing results.