

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2149063	(X3) Date Survey Completed 09/23/2019
Name of Provider or Supplier Women's Care Of Wisconsin	Street Address, City, State 200 Theda Clark Medical Plaza Suite 130, Neenah, 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
D2000	<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 Women's Care of Wisconsin in Appleton (52D0921590) and interview with the technical consultant from the Appleton laboratory, the Women's Care of Wisconsin in Neenah (52D2149063) received provider performed microscopy proficiency testing images from the Appleton laboratory in 2018 (event two) and 2019 (events one and two). The Neenah laboratory communicated results for the images to the Appleton laboratory and did not notify CMS of the receipt of the samples. Findings include: 1. The laboratory engaged in inter-laboratory communications pertaining to proficiency testing samples. See D2011. 2. The laboratory received proficiency testing images from another laboratory and did not notify CMS of the receipt of the images. See D2013.</p>
D2011	<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</p>

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 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 records from Women's Care of Wisconsin in Appleton (52D0921590) and interview with the technical consultant from the Appleton laboratory (52D0921590), testing personnel at the Women's Care of Wisconsin in Neenah (52D2149063) communicated the results of proficiency testing samples during three events (2018 event two, 2019 events one and two) with the technical consultant from the Women's Care of Wisconsin Appleton laboratory (52D0921590). Findings include: 1. Review of American Proficiency Institute (API) proficiency testing records from Women's Care of Wisconsin in Appleton (52D0921590) showed fern tests, vaginal wet prep, and vaginal KOH (potassium hydroxide) provider performed microscopy tests were performed by staff A from CLIA ID#52D2149063, on July 17, 2018 (2018 event two), March 27, 2019 (2019 event one), and July 18, 2019 (2019 event two). The provider performed microscopy tests are included in the API Hematology, Coagulation, and Urinalysis program. 2. The API Proficiency Schedule showed results for the second event of the Hematology, Coagulation, and Urinalysis program in 2018 were due on July 27, 2018. The results for the first event of 2019 were due on March 29, 2019. The results for the second event of 2019 were due July 26, 2019. 3. Interview with the technical consultant from CLIA ID# 52D0921590, identified as staff B, on September 23, 2019 at 10:30 AM and 11:35 AM confirmed Staff A from CLIA #52D2149063 performed proficiency testing for fern, vaginal wet prep and vaginal KOH provider performed microscopy testing for event 2 in 2018 and events 1 and 2 in 2019 on proficiency testing samples issued to CLIA ID# 52D0921590. Staff A from CLIA ID# 52D2149063 performed the testing on proficiency test kits issued to Women's Care of Wisconsin-CLIA ID# 52D0921590 and communicated the results to staff B.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing records from Women's Care of Wisconsin in Appleton (52D0921590) and interview with the technical consultant from the Appleton laboratory, the Women's Care of Wisconsin in Neenah (52D2149063) received and tested proficiency testing images from the Appleton laboratory in 2018 and 2019 and did not notify CMS of the receipt of the samples. Findings include: 1. Review of American Proficiency Institute proficiency testing records from Women's Care of Wisconsin in Appleton showed fern tests, vaginal wet prep, and vaginal KOH (potassium hydroxide) provider performed microscopy tests were performed by staff A, a certified nurse midwife, on July 17, 2018 (2018 event two), March 27, 2019 (2019 event one), and July 18, 2019 (2019 event two). 2. Interview with the technical consultant on September 23, 2019 at 10:30 AM and 11:35 AM confirmed the technical consultant transported the proficiency testing images from event two in 2018 and events one and two in 2019 for fern testing, vaginal wet prep and vaginal KOH provider performed microscopy for CLIA #52D0921590 to another CLIA certified laboratory - Women's Care of Wisconsin - CLIA # 52D2149063 for analysis. Further interview confirmed Staff A from CLIA #52D2149063 performed testing on the fern testing, vaginal wet prep and vaginal KOH provider performed microscopy images for 2018 event 2 and 2019 events one and two for CLIA #52D0921590.