

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 35D0409305	<b>(X3) Date Survey Completed</b> 10/08/2019
<b>Name of Provider or Supplier</b> Mercy Medical Center Of Williston	<b>Street Address, City, State</b> 1301 15th Ave W, Williston, ND	
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><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 record review and staff interview, the laboratory failed to ensure treatment of proficiency samples the same as patient samples for five clinical microscopy proficiency events reviewed by sending the proficiency samples to another laboratory for testing, resulting in proficiency testing referral. (Refer to D2013)</p>
<b>D2013</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(4)</p> <p>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</p>

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 record review and staff interview, the laboratory failed to ensure staff did not send proficiency samples to another laboratory for testing for 3 of 3 clinical microscopy proficiency events reviewed (CM [Clinical Microscopy]-A 2018, CM-B 2018, and CM-A 2019), resulting in proficiency testing referral. Findings include: Reviewed on 10/08/19, the laboratory's 2018-2019 proficiency testing attestation statements from the College of American Pathologists (CAP) showed the director designee and testing personnel attested to the performance of the following proficiency testing events: CM-A 2018: Personnel #1 (director designee) and Personnel #2 (testing personnel); CM-B 2018: Personnel #1 and Personnel #3, #4, and #5 (testing personnel); and CM-A 2019: Personnel #1 and Personnel #4 and #6 (testing personnel). During a telephone interview on 10/07/19 at 2:00 p.m., a technical supervisor (Personnel #1) stated Testing Personnel #2, #3, #4, #5, and #6 were not testing personnel at the main laboratory, but performed testing at the off-site clinic. He stated the laboratory ordered clinical microscopy proficiency testing from CAP for their off-site clinic with its own CLIA certificate. CAP shipped the proficiency testing samples to the main laboratory and staff delivered the CAP proficiency samples to the off-site clinic for testing. Testing personnel from the off-site clinic performed the CAP proficiency testing and entered their results on the CAP reporting form. Staff from the off-site clinic brought the CAP reporting form with their results to the main laboratory where a technical supervisor (Personnel #1) entered the clinic's results into CAP's online reporting system.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on record review and staff interview, the laboratory director failed to ensure staff did not send proficiency samples to another laboratory for testing for five clinical microscopy proficiency events reviewed, resulting in proficiency testing referral. (Refer to D6089)

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to ensure staff did not send proficiency samples to another laboratory for testing for 3 of 3 clinical microscopy proficiency events reviewed (CM [Clinical Microscopy]-A 2018, CM-B 2018, and CM-A 2019) resulting in proficiency testing referral. Findings include: Reviewed on 10/08/19, the laboratory's 2018-2019 proficiency testing attestation statements from the College of American Pathologists (CAP) showed the director designee and testing personnel attested to the performance of the following proficiency testing events: CM-A 2018: Personnel #1 (director designee) and Personnel #2 (testing personnel); CM-B 2018: Personnel #1 and Personnel #3, #4, and #5 (testing personnel); and CM-A 2019: Personnel #1 and Personnel #6 and #4 (testing personnel). During a telephone interview on 10/07/19 at 2:00 p.m., a technical supervisor (Personnel #1) stated Testing Personnel #2, #3, #4, #5, and #6 were not testing personnel at the main laboratory, but performed testing at the off-site clinic. He stated the laboratory ordered clinical microscopy proficiency testing from CAP for their off-site clinic with its own Clinical Laboratory Improvement Amendments (CLIA) certificate. CAP shipped the proficiency testing samples to the main laboratory and staff delivered the CAP proficiency samples to the off-site clinic. Testing personnel from the off-site clinic performed the CAP proficiency testing and entered their results on the CAP reporting form. Staff from the off-site clinic brought the CAP reporting form with their results to the main laboratory where a technical supervisor (#1) entered the clinic's results into CAP's online reporting system.