

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0720169	(X3) Date Survey Completed 03/11/2020
Name of Provider or Supplier Medical College Of Wisconsin Pathology	Street Address, City, State 9200 W Wisconsin Ave, 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
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 (PT) records and interviews with a technical supervisor and general supervisors from the Medical College of Wisconsin (MCW) (52D1043369), proficiency testing materials were transferred from the Medical College of Wisconsin Pathology Reference Laboratories (MCWPRL) (52D0720169) to MCW, and MCW submitted results to the College of American Pathologists (CAP) Proficiency Testing program for sample MMR-01 from the "MMR-A 2019 DNA Mismatch Repair" event. Findings include: 1. The MCWPRL (52D0720169) transferred proficiency testing materials for the CAP "MMR-A 2019 DNA Mismatch Repair" event to the MCW laboratory (52D1043369). The MCW laboratory submitted test results for the event to CAP. See D 2013.</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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</p>

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 and interview with a technical supervisor and general supervisors from the Medical College of Wisconsin (MCW) laboratory at 8701 Watertown Plank Road (52D1043369), the Medical College of Wisconsin Pathology Reference Laboratories at 9200 W Wisconsin Avenue (MCWPRL) (52D0720169) transferred their proficiency testing materials for sample MMR-01 from the College of American Pathologists (CAP) event "MMR-A 2019 DNA Mismatch Repair" to the Medical College of Wisconsin (MCW) (52D1043369). The MCW laboratory (52D1043369) submitted the test results for the event to CAP. Findings include: 1. Review of the CAP proficiency testing records for sample MMR-01 in event "MMR-A 2019 DNA Mismatch Repair" at the MCW (52D1043369) laboratory showed: The CLIA number on the "Original Evaluation" report and "Attestation / Use of Other Form" is 52D0720169. Staff from MCW (52D1043369), including the laboratory director (staff C), a general supervisor / testing personnel (staff A), and pathologist / testing personnel (staff D), signed the attestation statement for this event. The record includes written communication from staff A to staff D requesting review of the slides from the CAP PT event MMR-A 2019. The page also includes hand-written instructions dated July 2, 2019 to staff C requesting a signature on page ten (Attestation / Use of Other Form), and staff E (general supervisor) with instructions for submission of results to CAP. "Slide Detail Reports" printed on December 17, 2019 for Sample MMR-01 from the Dako Immunohistochemical (IHC) Stainer showed staff A processed the slides on June 21, 2019. The report headers identified the laboratory as GSPMC PML (Genomic Sciences and Precision Medicine Center, Precision Medicine Laboratory) at 8701 Watertown Plank Road. 2. During interview on December 17, 2019 at 10:05 AM, staff B (technical supervisor at MCW 52D1043369) stated pathologists that interpreted IHC PT slides for MCW (52D1043369) were testing personnel for the MCW laboratory and stated the pathologists interpreted the slides at their offices across campus. 3. Interview with a general supervisor at MCW 52D1043369 (staff E) on December 17, 2019 at 11:15 AM confirmed the MCW laboratory received proficiency testing materials from MCWPRL (52D0720169) and reported results for the samples to the CAP Proficiency Testing Program. 4. Staff A stated during interview on December 17, 2019 at 11:30 AM that the MMR-01 slides were stained in the MCWPRL laboratory, interpreted by staff D, reviewed and signed off by staff C and reported from MCW (52D1043369) to the CAP PT program.