Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1043369	12/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical College Of Wisconsin	8701 W Watertown Plank Rd, 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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing records and procedures, and interview with a technical supervisor and general supervisors, the Medical College of Wisconsin (MCW) (52D1043369) received proficiency testing materials from the Medical College of Wisconsin Pathology Reference Laboratories (MCWPRL) (52D0720169) and 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 and did not notify CMS (Centers for Medicare and Medicaid Services) of the receipt of the samples. Findings include: 1. The MCW (52D1043369) laboratory received proficiency testing materials for sample MMR-01 from MCWPRL (52D0720169), did not notify CMS of receipt of the sample, and submitted test results to CAP, the proficiency testing provider. See D 2013.
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 (PT) records and procedures, and interview with general supervisors and a technical supervisor, the Medical College of Wisconsin at 8701 Watertown Plank Road (MCW) (52D1043369) received PT materials from the Medical College of Wisconsin Pathology Reference Laboratories at 9200 W Wisconsin Avenue (MCWPRL) (52D0720169), and submitted results to the College of American Pathologists (CAP) Proficiency Testing program for the "MMR-A 2019 DNA Mismatch Repair" event and did not notify CMS (Centers for Medicare and Medicaid Services) of the receipt of PT materials. Findings include: 1. Review of the CAP proficiency testing records for sample MMR-01 in event "MMR-A 2019 DNA Mismatch Repair" showed: The CLIA number on the "Original Evaluation" report and "Attestation / Use of Other Form" is 52D0720169. The laboratory director of MCW 52D1043369 (staff C), a general supervisor / testing personnel (staff A), and pathologist / testing personnel (staff D), signed the attestation statement for this event. The proficiency testing 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. Review of "Slide Detail Reports" printed on December 17, 2019 for Sample MMR-01 from the Dako Immunohistochemical (IHC) Stainer shows 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. The 50690-545 GSPMC PML "CTRL QA CAP Proficiency Testing and Alternative Assessment" procedure states: "Proficiency testing (PT) must be performed by personnel at the laboratory (CAP/CLIA number) for which PT was ordered. In addition, results must be reported by personnel at the laboratory where PT was performed." The procedure also states, "It's strictly prohibited to refer Proficiency testing specimens to other laboratories and are not accepted from other laboratories for analysis". 3. During interview on December 17, 2019 at 10:05 AM, staff F (technical supervisor) stated the pathologists that interpreted IHC PT slides were testing personnel for the MCW (52D1043369) laboratory. Staff F also stated the pathologists interpreted the slides at their offices across campus. 4. Interview with a general supervisor, staff E, on December 17, 2019 at 11:15 AM confirmed the MCW laboratory (52D1043369) received proficiency testing materials from MCWPRL (52D0720169) and reported results for the samples to the CAP Proficiency Testing Program. 5. 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.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of staff credentials and interview with a general supervisor (staff A), the laboratory did not have documentation to show one of three testing personnel who operate the high complexity immunohistochemical stainer met the qualification requirements for performing high complexity testing. Findings include: 1. Documentation is not available showing one of three high complexity testing personnel met the qualification requirements for high complexity histology testing on the Autostainer Link 48 immunohistochemical stainer. See D 6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such

	training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel credentials and interview with a general supervisor, the laboratory did not have documentation to show one of three testing personnel who perform staining on the Dako Autostainer Link 48 met the testing requirements for high complexity testing. Findings include: 1. Review of credentials for testing personnel showed no academic credentials were available for staff B. 2. Interview with a general supervisor, staff A, on December 17, 2019 at 10: 40 AM revealed staff B was one of three testing personnel responsible for immunohistochemical staining using the Dako Autostainer Link 48. Further interview at 12:05 PM confirmed the laboratory did not have documentation showing staff B met the qualification requirements for high complexity testing.