Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2152949	06/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Marquette University	Schroeder Health Complex Room 267a, 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 laboratory records and proficiency testing (PT) registration, and interview with the laboratory director, the laboratory had not enrolled in a PT program from August 2018 through May 2019 for Chlamydia and Neisseria gonorrhoeae testing performed on the Hologic Panther platform. Findings include: 1. Review of laboratory worksheets and test lists showed the laboratory performed Chlamydia and Neisseria gonorrhoeae testing. 2. Review of PT registration records for the laboratory showed the laboratory did not enroll in a PT program for Chlamydia and Neisseria gonorrhoeae testing until May 2019. 3. Interview with the laboratory director on June 5, 2019 at 10:30 AM confirmed the laboratory started patient testing in August 2018 and had not enrolled in a PT program until May 2019 for Chlamydia and Neisseria gonorrhoeae testing as required in subpart I.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1)

	The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor review of test requisitions and interview with the laboratory director, the test requisition did not include the name and address of the authorized person requesting the test or the name and address of the laboratory submitting the specimen. Findings include: 1. Review of test requisitions showed no indication of either the name and address of the authorized person requesting the test or the name and address of the laboratory submitting the specimen. 2. Interview with the laboratory director on June 5, 2019 at 11:00 AM confirmed the laboratory receives specimens from two referring laboratories and that the requisition did not include the name and address of the authorized person requesting the test or the name and address of the laboratory submitting the specimen.