Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2054920	01/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northwestern Memorial Hospital-Lakeview Radiology	1333 W Belmont, Ste 300, Chicago, IL	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on the surveyor's review of the Report 0096 (CLIA application and Survey Summary), proficiency testing (PT) documents, and an interview with the technical consultant (TC); the laboratory failed to authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance; and (ii) Make PT results available to the public;affecting 5 out 5 PT events. Findings: 1. The Centers of Medicare and Medicaid Services (CMS) survey summary report states that the laboratory is performing tests in the subspecialty of Routine Chemistry; however, in the PT section of the report, no PT scores has been listed. 2. The laboratory's PT documents revealed the following: a). The laboratory is enrolled in a PT program for the analyte, Creatinine; b). The laboratory has participated in 5 PT events during the years of 2017 thru 2018. c). The address displayed on all 5 of the PT documents were not that of the laboratory; and d). There is no visible indication of the laboratory's CLIA number on any of the PT documents, and no visible evidence that the PT program had reported the laboratory's scores to CMS. 3. On a Recertification survey conducted on 01/18/2019 at 11:15 AM, the TC confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's final report, the Test Volume Worksheet, and an interview with the technical consultant (TC); the laboratory failed to ensure test reports include all information as specified in 493.1291(c)(1)- (c)(6), specifically * (c)(2) The name and address of the laboratory location where the test was performed; affecting 448 patients' reports. Findings: 1. The "final report" of 3 out of 3 patients reviewed states that the Creatinine tests were performed at the following location: Northwestern Memorial Hospital Lab 251 E. Huron 7307 Chicago, IL 60611 Lab Director: Gregory Retzinger The documents presented and viewed in the electronic medical record (EMR) system showed that the tests were performed at Lakeview Radiology. 2. The test volume worksheet documents that from January of 2018 to January of 2019, 448 patients were tested for Creatinine at Lakeview facility. 3. On a Recertification survey conducted on 01/18//2019 at 11:15 AM, the TC confirmed the above findings.