Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0964215	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mclaren Northern Michigan Medcenter-Petoskey South	1890 Us 131 South Suite 4, Petoskey, MI	

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 record review and interview, the laboratory failed to authorize the release of their American Proficiency Institute (API) proficiency testing reports to the Health and Human Services (HHS) regulatory agency for two (2017 and 2018) of two years reviewed. Findings include: 1. On January 15, 2019 at 12:15 PM, record review of the CMS database and the API proficiency testing reports revealed there was no documentation to show the facility authorized the release of their reports to the HHS regulatory agency for 2017 and 2018. 2. On January 15, 2019 at 12:15 PM when requested, testing personnel #3 as listed on the CMS-209 called API to investigate and was informed that API did not have the facilities CLIA number on file to report results to HHS. 3. During the interview on January 15, 2019 at 12:15 PM, testing personnel #3 confirmed proficiency testing program was not given the authority to release results to HHS.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to ensure the final hematology and urine microscopic proficiency testing reports were reviewed by the appropriate testing staff for five (1st-3rd events 2017 and 1st-2nd events 2018) of six events reviewed. Findings include: 1. On January 15, 2019 at 12:12 PM, record review of the American Proficiency Institute final proficiency testing reports revealed there was no documentation to show the testing personnel had reviewed the reports to evaluate their performance. 2. During the interview on January 15, 2019 at 12:12 PM, testing personnel #3 as listed on the CMS-209 confirmed the testing personnel did not review the final proficiency testing reports. ***Repeat Deficiency from October 4, 2016 survey***