

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0722317	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Mclaren Northern Michigan Medcenter -Petoskey Nort	Street Address, City, State 116 W Mitchell Street, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to have a written request for patient testing from an authorized person for the hematology testing for one (#8) of 17 patient charts reviewed. Findings include: 1. On January 15, 2019 at 10:25 AM, record review conducted revealed the laboratory did not have a written request for the hematology complete blood cell count testing that was performed and documented in the electronic medical record (EMR) file. 2. During the interview on January 15, 2019 at 10:25 AM, testing personnel #12 as listed on the CMS-209 confirmed there was no written order for the hematology testing on the superbill.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p>

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to have the final microscopic urinalysis report maintained as part of the patient's chart or medical record for one (#14) of 16 patient charts reviewed. Findings include: 1. On January 15, 2019 10:40 AM, record review revealed the patient's electronic medical record (EMR) file contained a report with no results recorded on the report for the microscopic urinalysis testing. 2. During the interview on January 15, 2019 at 10:40 AM, testing personnel #12 as listed on the CMS-209 confirmed the final urinalysis microscopic report did not show any documentation of the patient's results.

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 for four (1st and 3rd events in 2017 and 2018) of six events the final American Proficiency Institute (API) proficiency testing reports were reviewed by the appropriate testing personnel (TP). Findings include: 1. On January 15, 2019 at 9:12 AM, record review of the final hematology and urinary sediment proficiency testing reports revealed there was no review by the TP as follows: a. 2017 - events #1 and #3 b. 2018 - event #1 and #3 2. During the interview on January 15, 2019 at 9:12 AM, testing personnel #12 as listed on the CMS-209 confirmed the testing personnel did not review the final graded proficiency testing reports.