

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2084061	(X3) Date Survey Completed 05/18/2018
Name of Provider or Supplier Norton Community Medical Associates	Street Address, City, State 100 Mallard Creek Road Suite 320, Louisville, KY	
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
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 05/18/2018, the laboratory failed to return the proficiency test results to the American Academy of Family Physicians for the third (3rd) event of 2017, resulting in an unsatisfactory score of Zero (0) percent (%) for all analytes. The staff acknowledged that the proficiency testing was not tested and submitted for the third (3rd) Event of 2017. Review of the Proficiency test results for the third (3rd) event revealed that no corrective action or investigation was conducted.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results from The American Academy of Family Physicians and interview with the technical staff on 05/18/2018 , the laboratory director failed to ensure proficiency test results were reviewed by the director during 2016, 2017, and 2018. Findings include: There was no review of Hematology test results for all three events in 2016. There was no review of Hematology test results for all three events in 2017. There was no review of</p>

Hematology test results for 1st event of 2018. The testing staff acknowledged in an interview at 1:10 pm on 05/18/2018, the laboratory director failed to establish a system to ensure proficiency testing results were reviewed.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 05/18/2018, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. Humidity was not recorded from May 25, 2016 through May 17, 2018. Findings include: Manufacturer's Instructions for the XP-300 analyzer states that the analyzer recommend the Range of Humidity for the analyzer during operation to be between thirty percent (30%) and eighty five percent (85%). Review of Maintenance log revealed no documented evidence that the humidity had been monitored from May 25, 2016 through May 17, 2018. Testing personnel acknowledged in an interview at 12:41 pm on 05/18/2018 the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 05/18/2018, the Technical Consultant failed to perform and document annual competency using the 6 mandated competency assessment requirements for testing personnel. No Competency assessment was performed for one (1) out of three (3) employees from January 1, 2017 through December 31, 2017. Findings include: Record review revealed competency assessments failed to include monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples, and assessing the skills for solving problems. An interview with the staff on 05/18/2018 at 1:15pm, revealed the facility failed to have a system in place to ensure competency was performed using the six mandated competency assessment requirements.