

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0323690	(X3) Date Survey Completed 10/26/2018
Name of Provider or Supplier Norton Children's Medical Group-Frankfort	Street Address, City, State 202 Limestone Street South, Suite 1a, Frankfort, 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
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 staff interview and record review of proficiency testing results, on October 26, 2018, the Laboratory Director failed to review proficiency test results for three (3) out of three (3) events during 2017, and 2018. Findings include: Record review of proficiency testing results from The American Academy of Family Physicians on October 26, 2018, revealed no documented evidence the Laboratory Director reviewed proficiency test results for Hematology test results for one (1) out of one (1) event in 2017; and two (2) out of two (2) events in 2018. Interview on 10/26/18 at 10:00 AM, with the testing staff, revealed there was no system established to ensure the testing results were reviewed by the Laboratory Director.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on October 26, 2018, the Laboratory Director failed to perform Quality Assurance from December 30, 2017 through October 25, 2018. Findings include: Record Review on October 26, 2018, revealed no</p>

documented evidence the Quality Assurance Plan outlined by the Laboratory Director on December 20, 2017, was performed from Dec 21, 2017 through October 25, 2018. Interview with staff on 10/26/18 at 11:05 AM, revealed there was no system in place to document the Quality Assurance Plan on a quarterly basis as outlined by the Laboratory Director.

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 October 26, 2018, the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personal. Competency assessment was performed using zero (0) of six (6) methods of assessment for eight (8) out of eight (8) employees from June 14, 2017 through January 15, 2018. Findings include: Record review on October 26, 2018, revealed there was no documented evidence the Technical Consultant performed and documented competency assessments between June 14, 2017 and January 15 2018, for eight (8) employees that included the following: direct observation of routine patient test performance; direct observation of performance of instrument maintenance function checks and calibration; 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 problem solving skills. Interview on 10/26/18 at 10:23 AM, with staff, revealed the facility failed to have a system in place between June 14, 2017 and January 15, 2018 to ensure competency was performed using all six (6) mandated competency assessment requirements.