

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2108757	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Norton Children's Medical Group-Dixie	Street Address, City, State 4420 Dixie Highway, Suite 126, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual, review of proficiency testing results from the American Academic of Family Physicians (AAFP) proficiency testing agency, and staff interview on 11/06/2019, the laboratory failed to ensure proficiency testing samples were tested by all testing personnel who routinely perform patient testing for five (5) out of six (6) testing events. Findings include: 1. Review of the Proficiency Testing Procedure stated "testing performed by lab staff on a rotating basis." 2. There was no evidence of any other testing personnel listed on the CMS-209 form performing proficiency testing save one (1) individual, as indicated by the signatures on the attestation sheets for events A, B and C in 2018 and events A and B in 2019. 3. Testing personnel acknowledged in an interview at 10:15 AM on 11/06 //2019, the laboratory failed to have a system to ensure established policy was followed and proficiency testing samples were rotated among all testing personnel responsible for patient testing.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of proficiency testing results from American Association of Family Physicians (AAFP) proficiency company and interview with staff on 11/6/2019, the laboratory director failed to ensure proficiency test results were reviewed by the director for 2 (two) out of 3 (three) events in 2019. Findings include: 1.) The director failed to sign proficiency testing results for 2 (two) out of 3 (three) events in 2019. The director signed the event C in 2019, but failed to sign the proficiency results for events A and B. 2. The general supervisor acknowledged in an interview at 10:15 AM on 11/06/2019, the laboratory director failed to establish a system to ensure proficiency testing results were reviewed by appropriate staff in a timely manner.