

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0976510	(X3) Date Survey Completed 03/05/2018
Name of Provider or Supplier Norton Children's Medical Group-Shelbyville	Street Address, City, State 150 Frankfort Rd, Ste 101, Shelbyville, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 03/05/2018, the laboratory failed to test two levels of quality control material each day bilirubin testing was performed. Findings include: Review of the policy and procedure manual on 03/05/2018, revealed that the laboratory's quality control plan was not followed. Review of patient test reports revealed that quality control was not performed on May 22, 2017, June 16, 2017, July 22, 2017, and September 27, 2017. Testing personnel acknowledged in an interview at 10:30 am on 03/05/2018 that the laboratory failed to test at least two levels of quality control material each day of patient testing.</p>