

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0928131	(X3) Date Survey Completed 04/09/2019
Name of Provider or Supplier Galen North Pediatrics	Street Address, City, State 1039 Executive Dr Ste #101, Hixson, TN	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p> <p>===== Based on review of Complete Blood Count (CBC) quality control (QC) on 4/13/18, patient reports and interview with Technical Consultant, the laboratory failed to meet QC criteria prior to reporting patients. The findings include: 1. Review of CBC quality controls on 4/13/18 revealed normal and high controls (lot#'s: 079200 and 089200) for platelets failed to meet acceptable QC criteria. 2. Review of patient CBC's on 4/13/18 revealed 11 patients reported. 3. Interview with the Technical Consultant at 12:30 p.m. April 9, 2019 confirmed that 2 levels of CBC quality controls failed to meet acceptable criteria for platelets and 11 patients were reported.</p> <p>=====</p>