

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1012189	(X3) Date Survey Completed 04/18/2018
Name of Provider or Supplier Novant Health Twin City Pediatrics	Street Address, City, State 2821 Maplewood Avenue, Winston-Salem, NC	
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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2016, 2017, and 2018 hematology quality control records, review of 2016, 2017, and 2018 quality assessment records, and interview with the TC (technical consultant) 4/18/18, the laboratory failed to ensure that corrective action was taken and documented when Coulter AcT diff 2 quality control results were outside acceptable limits. Findings: The laboratory's "Coulter AcT Diff 2" procedure states on page 4 "... If 1 level of control is outside the acceptable ranges, perform the following: ... 3. Re-mix the out-of-range control and repeat testing. 4. If control results are within range, document on the daily log sheet Corrective Action taken. ... If 2 levels of control material are outside of acceptable range, perform the following: ... 3. Re-mix the out-of-range control and repeat testing. 4. If control results are within range, document on the daily log sheet Corrective Action taken. 5. If results of the repeat testing are out of range, follow the bleach bath procedure... 6. Re-mix the control material and repeat testing. ... 8. If results continue to be out of range call Beckman Coulter Service and your Technical Consultant. 9. Do not report patient results until acceptable quality control has been obtained. ..." Review of 2016, 2017, and 2018 hematology quality control records revealed: 1. The laboratory reported patient CBC (complete blood count) hematology test results when two levels of control were outside acceptable limits on 3</p>

days in 2016: a. 8/9/16 - 2 patients tested and results reported; b. 10/17/16 - 7 patients tested and results reported; c. 12/12/16 - 7 patients tested and results reported. 2. The laboratory failed to repeat controls that were outside acceptable limits. Two of three levels of control were outside acceptable limits on the following dates with no corrective action documented: a. 10/29/16; b. 10/30/16; c. 5/13/17; d. 5/14/17. Review of 2016, 2017, and 2018 quality assessment records revealed a "QUALITY ASSESSMENT / INCIDENT MANAGEMENT FORM" completed by the TC 1/6/17. The form stated "8/9, 10/17, 10/29, 10/30, 12/12/16 - 2 out of 3 Coulter controls not acceptable. ... Identify any patients tested, determine if any results were questionable. ..." There was no documentation available to indicate that patients tested on those dates were identified and their results reviewed to determine whether they were adversely affected. During interview at approximately 1:45 p.m., the TC stated that the laboratory and the provider(s) should have reviewed patient records to ensure results were not adversely affected. She confirmed that the laboratory failed to follow-up as directed in the procedure when quality control results are unacceptable.