

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1061177	<b>(X3) Date Survey Completed</b> 07/18/2018
<b>Name of Provider or Supplier</b> Texas Children's Pediatrics Lone Star	<b>Street Address, City, State</b> 12120 Rr 620 North, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2123</b>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records for 2016, 2017 and 2018, and interview of facility personnel, the laboratory failed to participate in 1 of 6 proficiency testing events for the specialty of hematology. The findings include: 1. A review of the American Proficiency Institute (API) proficiency testing records found the laboratory failed to submit the results in the time frame specified by the program for the 2017 Hematology 3rd testing event. a. Review of the 2017 Hematology 3rd event proficiency testing instructions found that the Proficiency online and postmark due date as Friday, 12/1/2017 11:59 PM b. Review of the 2017 Hematology 3rd event Performance Summary found no scores for the analytes Erythrocytes, Hematocrit, Hemoglobin, Leukocyte Count, MCH, MCHC, MCV, Platelet count, RDW, and White Blood Cell Differential. c. Review of the 2017 Hematology 3rd event Performance Evaluation found a handwritten notation " deadline missed for online reporting. Spoke with API, recommended self grading of scores. 100% for all analytes." 2. Interview of the Technical Consultant conducted on July 18, 2018 at 10:06 AM confirmed that the laboratory failed to test specimens and submit results to the proficiency testing agency before the submission deadline. She confirmed that the</p>

specimens were not tested until December 19, 2017 and self graded on January 25, 2018.

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records from 2016, 2017 and 2018 and staff interview, found the laboratory director failed to ensure proficiency test results were returned prior to the submission deadline in one of six events. (refer toD2123).