

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1078114	(X3) Date Survey Completed 02/11/2019
Name of Provider or Supplier St Lukes Allentown Cancer Center Lab	Street Address, City, State 240 Cetronia Road Suite 100, Allentown, PA	
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
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on the review of American Association of Bioanalysts (AAB) 2018 proficiency testing (PT) records and interview with Technical Supervisor (TS), the laboratory director failed to identify problems that required a corrective action for the Hematology PT result for RBC and HCT in 2018. Findings Include: 1. On the day of survey, 02/11/2019, review of AAB PT records reveled the labortaory did not perform a corrective action for AAB 2018 Event #3: a. Hematology 80% for RBC. b. Hematology 80% for HCT. 2. The Labortaory director acknowledged the score of 80% for with their signature, but no assessment was made. 3. The TS confirmed the findings above on 02/11/2019 around 11:15 am. **** HCT = Hematocrit ****RBC = Red Blood Cells</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the Technical Supervisor (TS), the Technical Supervisor failed to evaluate the performance of the</p>

testing personnel (TP) #1, responsible for Hematology testing of CBC's and Manual differentials at least semi-annually during the first year. Findings include: 1. On the time of survey, 2/11/2019, the laboratory was unable to provide documentation of the assessed competency of TP#1 for Hematology testing of CBC's and Manual differentials at least semi-annually during the first year. - TP#1's initial training was performed 09/12/2017. - There 1st competency should have been performed by March 3rd, 2018. It was not assessed until April 20th, 2018. - There Competency was not assessed again in 2018. 2. In 2018: 20,000 Hematology tests were performed. 3 The TS confirmed the findings above on 02/11/2019 around 10:45 am.