

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1073896	(X3) Date Survey Completed 02/07/2018
Name of Provider or Supplier Texas Oncology Plano Preston Wood	Street Address, City, State 6957 West Plano Pkwy, Suite 2000a, Plano, TX	
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 quality control plan, review of the laboratory's quality control records from 2017, and 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when quality control results failed to meet the laboratory's criteria for acceptability. The findings were: 1. A review of the laboratory's quality control plan titled "Quantitative Quality Control" revealed: "Systemic Errors Systemic error is not acceptable, as it indicates some failure in the system that can and should be corrected. Examples of evidence of systematic error may include: - shift when the control is on the same side of the mean for more than five consecutive runs -trend when the control is moving in one direction, and appears to be heading toward an out-of-control value." 2. A review of the laboratory's quality control Sysmex e-check records for the Sysmex XS 1000 (hematology analyzer) from December 2017 through February 7, 2018 revealed the following shifts and trends for platelet quality control: a) February 7, 2018 Low control Trend Quality control showed the value for platelet 36 control range 40-72 (manufacture's) 40-72 Normal control Shift Quality control values showed a value for platelet 196 control range (manufacture's) 206-262 High control Shift Quality control values showed a value for platelet 491 control range (manufacture's) 490-598 3. The laboratory was asked to provide documentation of performing corrective actions to</p>

resolve the potential quality control issues identified. No documentation was provided. 4. An interview with testing person number 1 (as listed on Form CMS 209) on 02/07/2018 at 1415 hours in the break room - after her review of the records- confirmed the findings.