

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0683071	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Maryland Oncology Hematology Pa	Street Address, City, State 11886 Healing Way #701, Silver Spring, MD	
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant, the laboratory (lab) did not have procedures to identify hematology quality control problems when the hematology analyzer "rejected analysis" of quality control test results. Findings: 1. On August 16, 2019 and January 17, 2019 the hematology analyzer reported that it "rejected analysis" of the normal hematology quality control results; 2. There was no record showing that the lab investigated (during the monthly quality control review) why the analyzer rejected the analysis of the control results, even though the rejected results met the labs criteria for quality control acceptability; and 3. This was confirmed during interview with the technical consultant on the day of survey.</p>