

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2150401	(X3) Date Survey Completed 12/17/2018
Name of Provider or Supplier Redmed Of Arlington, Llc	Street Address, City, State 5389 Airline Rd, Arlington, TN	
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 observation of the laboratory, review of the 2018 complete blood count (CBC) quality control (QC) records, the CBC QC manufacturer instructions and interview with the laboratory director, the laboratory failed to identify and correct that the new lot number platelet QC mean was entered incorrectly into the instrument on August 16, 2018. The findings include: 1) Observation of the laboratory on December 17, 2018 at 1:15 p.m. revealed the Beckman Coulter AcTdiff CBC instrument (serial number BB12022) in use for patient testing. 2) Review of the 2018 CBC QC records revealed on August 16, 2018 a new lot number (088000) low CBC QC was entered with incorrect platelet mean value of 80. 3) Review of the November 2018 CBC QC summary report revealed on December 1, 2018 technical consultant numbers one, two and three performed quality assessment review but failed to identify the platelet mean for lot 088000 was incorrect. 4) Review of the CBC QC manufacturer package inserts for acceptable means and limits revealed lot number 77700 platelet mean of 75 was since in use with the 088000 platelet mean, from August 16, 2018 to November 4, 2018. 5) Interview on December 17, 2018 at 3:30 p.m. confirmed on August 16, 2018, technical consultant number two changed the lot number 088000 low QC but the platelet mean was not changed from the previous lot number and that the December 1, 2018 quality assessment review did not identify and correct the error.</p>