

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2229976	(X3) Date Survey Completed 09/07/2022
Name of Provider or Supplier Sunshine Pediatrics Llc	Street Address, City, State 197 E University Drive Suite 2, Auburn, AL	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the Sight Olo Hematology quality control (QC) records, the laboratory policy and procedure, and an interview with the Testing Personnel, the laboratory failed to perform three levels of QC in duplicate as per procedure on one of nine days reviewed. The findings include: 1. A review of the policy and procedure manual, signed by the Laboratory Director on 11/2/2021, under "Quality Control" revealed three levels (Low, Normal and High) of QC should be run in duplicate on the Sight Olo Hematology analyzer every 30 days. (The laboratory had implemented an Individualized Quality Control Plan [IQCP] to allow for decreased frequency of QC testing.) 2. A review of the January through September 2022 Sight Olo QC records revealed the laboratory performed monthly QC as per procedure all months except August 2022. On 8/5/2022 the QC was performed only once, not in duplicate. 3. During an interview on 9/7/2022 at 2:25 PM, the Testing Personnel stated she had misunderstood the procedures and "validated" lot number OPT2206 by comparing the August QC to the previous month's results. The surveyor confirmed QC was only run once, and not in duplicate as per procedure. SURVEYOR ID #32558 Licensure and Certification Surveyor</p>