

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2231440	(X3) Date Survey Completed 08/01/2023
Name of Provider or Supplier Cvi Ambulatory Surgery Center	Street Address, City, State 6547 Sw State Road 200, Ocala, FL	
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
D0000	A recertification survey was conducted on August 1, 2023 at Cvi Ambulatory Surgery Center, a clinical laboratory located in Ocala, Florida. Cvi Ambulatory Center was found to NOT be in compliance with 42 CFR 493, requirements for clinical laboratories.
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 staff interview, it was determined that the laboratory's quality assessment (QA) process failed to monitor and correct issues with failed proficiency testing scores for a non regulated analyte for two of three Hematology testing events in 2022. The findings include: Record review of the American Proficiency Institute (API) test events for 2022 showed the following: *2022 1st Event Hematology for the unregulated analyte Activated Clotting Time (ACT) failed with a score of 50% *2022 2nd Event Hematology for the unregulated analyte Activated Clotting Time (ACT) failed with a score of 50% There was no documentation of corrective action performed by the laboratory. The interview with Testing Person A on 8/1/23 at 11:15am confirmed the multiple failures of ACT proficiency testing. She was unaware of the failures and confirmed no corrective action was documented.</p>