

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2032976	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier Sedona Medical Center Laboratory	Street Address, City, State 3700 West State Route 89a, Sedona, AZ	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2021 and 2022 and an interview with the facility personnel, the lab failed to enroll in an HHS approved PT program for regulated testing performed in the specialty of Chemistry, that is included in subpart I. Findings include: 1. No documentation was presented for review during the survey conducted on August 24, 2023 to indicate the laboratory was enrolled in a CMS-approved PT program for the regulated analytes pH, PCO2 and PO2, for Arterial Blood Gas (ABG) testing during the 3rd event of 2021 and the 1st, 2nd and 3rd events of 2022. 2. The facility personnel interviewed on 8/24/23 at 2:30 PM confirmed the laboratory was not enrolled in a CMS-approved PT program during the 3rd event of 2021 and all 3 events of 2022 for the regulated analytes listed above. 3. The annual reported test volume in the specialty of Chemistry is 87,478.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in</p>

accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6041 - failure to ensure that the laboratory was enrolled and participated in an HHS approved Proficiency Testing program commensurate with the services offered.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on lack of Proficiency Testing (PT) records from the 3rd testing event of 2021 and the 1st, 2nd and 3rd events of 2022, and interview with the facility personnel, it was determined that the technical consultant failed to ensure that the laboratory was enrolled and participated in an HHS approved PT program for pH, PCO₂ and PO₂, for Arterial Blood Gas (ABG) testing. See D2000 for findings.