

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0530354	(X3) Date Survey Completed 03/13/2020
Name of Provider or Supplier Scottsdale Pediatric Center Pc	Street Address, City, State 10752 N 89th Place Ste 126, Scottsdale, 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 2019 and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for regulated testing performed in the specialty of Microbiology, which are included in subpart I . Findings include: 1. No documentation was presented for review during the survey conducted on March 13, 2020 to indicate the laboratory was enrolled during 2019 in a CMS-approved PT program for regulated testing listed in subpart I, Throat Culture, for which the laboratory performed patient testing. 2. The facility personnel confirmed that the laboratory was not enrolled in a CMS-approved PT program during 2019 for Throat Culture testing. 3. The approximate annual test volume during 2019 was 423.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p>

This CONDITION is not met as evidenced by:
The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6088 - ensuring that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on lack of proficiency testing enrollment documentation presented for review, the laboratory director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program during 2019 for testing performed under the specialty of Microbiology. See D2000 for findings.