

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2028285	(X3) Date Survey Completed 12/18/2019
Name of Provider or Supplier Satish A Shah Md Pllc	Street Address, City, State 1 Presidential Blvd, Bala Cynwyd, PA	
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 a review of the laboratory records and an interview of laboratory testing personnel, the laboratory failed to enroll in a proficiency testing (PT) program that is approved by HHS, for Complete Blood Counts, for 2of 2 years from 2018 through 2019. Findings include: 1. At the time of the survey, the laboratory could not provide evidence of enrollment in an approved proficiency testing program for Complete Blood Counts for calendar years 2018 and 2019. Refer to D6015. 2. During the survey (14:30 12/18/2019), Laboratory Testing Personnel 1 confirmed the above finding.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p>

This STANDARD is not met as evidenced by:

Based on a review of the laboratory records and an interview of laboratory testing personnel, the Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing (PT) program that is approved by HHS, for Complete Blood Counts, for 2 of 2 years from 2018 through 2019. specimens. Findings include: 1. At the time of the survey, the laboratory could not provide evidence of enrollment in an approved proficiency testing program for Complete Blood Counts for calendar years 2018 and 2019. 2. During the survey (14:30 12/18/2019), Laboratory Testing Personnel 1 confirmed the above finding.