

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2028285	(X3) Date Survey Completed 01/27/2022
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CASPER Report 155 report and graded results from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for the analytes Cell ID, Red Blood Cell (RBC), Hematocrit Hemoglobin, White Blood Cell (WBC), Platelets . Refer to D2130, D2131.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a review of the CASPER 155 report and graded results from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for the analyte: Cell Identification (Cell ID), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), Platelets (PLT). The laboratory had unsatisfactory scores for the 2nd event of 2021, and 3rd event 2021. Findings include: Analyte Year Event Score Cell ID 2021 2 0% Cell ID 2021 3 0% RBC 2021 2 0% RBC 2021 3 0% HCT 2021 2 0% HCT 2021 3 0% HGB 2021 2 0% HGB 2021 3 0% WBC 2021 2 0% WBC 2021 3 0% PLT 2021 2 0% PLT 2021 3 0%

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a review of the CASPER Report 155 report and graded results from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to achieve an overall testing score of satisfactory performance in the Specialty Hematology. The laboratory had unsatisfactory scores for the 2nd event of 2021, and 3rd event of 2021. Findings include: Specialty Year Event Score Hematology 2021 2 0% Hematology 2021 3 0%