

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310064	(X3) Date Survey Completed 10/14/2019
Name of Provider or Supplier Indravadan K Shah Md	Street Address, City, State 2341 McCallie Ave Suite 201, Chattanooga, TN	
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 desk review of the Centers for Medicare and Medicaid Services CASPER report 155 & 153 (CMS 153&155) and the proficiency testing agency, American Proficiency Institute (API) performance summary determined the laboratory failed to maintain satisfactory performance for the specialty of Hematology in event 3 in 2018 and event 1 in 2019 resulting in the first unsuccessful occurrence.</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:

1. Review of the CMS Casper 155 report revealed the following: 3rd event 2018 Cell I. D. or White Blood Cell (WBC) Diff, Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB, White Blood Cell (WBC) and Platelets (PLT) with a score of 0%. 2nd event 2019 Cell I. D. or White Blood Cell (WBC) Diff score of 73% Red Blood Cell (RBC) with a score of 60% Hematocrit (HCT) with a score of 60% Hemoglobin (HGB) with a score of 60% Platelets (PLT) with a score of 60% 2. Review of API performance summary revealed the following: 3rd event 2018 Cell I. D. or White Blood Cell (WBC) Diff, Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB, White Blood Cell (WBC) and Platelets (PLT) with a score of 0%. 2nd event 2019 Cell I. D. or White Blood Cell (WBC) Diff score of 73% Red Blood Cell (RBC) with a score of 60% Hematocrit (HCT) with a score of 60% Hemoglobin (HGB) with a score of 60% Platelets (PLT) with a score of 60%