

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0310064	<b>(X3) Date Survey Completed</b> 01/03/2020
<b>Name of Provider or Supplier</b> Indravadan K Shah Md	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 &amp; 155 (CMS 153 &amp; 155) and American Proficiency Testing (API) evaluation reports, the laboratory failed to maintain satisfactory performance in White Blood Cell Differential (WBC) for the 3rd event of 2018 and 2nd and 3rd events of 2019 resulting in the second unsuccessful performance occurrence. (Refer to D2130).</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> 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 proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 & 155) and American Proficiency Testing (API) performance summary, the laboratory failed to maintain satisfactory performance in White Blood Cell Differential (WBC) for the 3rd event of 2018 and 2nd and 3rd events of 2019 resulting in the second unsuccessful performance occurrence. The findings include: 1. Review of the CMS 153 & 155 report revealed a score of 0% for the 3rd event 2018, 73% for the 2nd event 2019 and a 20% for the 3rd event 2019. 2. Review of API performance summary revealed a score of 0% for the 3rd event 2018, 73% for the 2nd event 2019 and a 20% for the 3rd event 2019.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's unsatisfactory performance of proficiency testing (PT) second unsuccessful performance, the laboratory director failed to maintain satisfactory performance White Blood Cell Differential (WBC) for the 3rd event of 2018 and 2nd and 3rd events of 2019 resulting in the second unsuccessful performance occurrence. (Refer to D6004).

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 & 155) and American Proficiency Testing (API) performance summary, the laboratory director failed to maintain satisfactory performance in White Blood Cell Differential (WBC) for the 3rd event of 2018 and 2nd and 3rd events of 2019 resulting in the second unsuccessful performance occurrence. The findings include: 1. Review of the CMS 153 & 155

report revealed a score of 0% for the 3rd event 2018, 73% for the 2nd event 2019 and a 20% for the 3rd event 2019. 2. Review of API performance summary revealed a score of 0% for the 3rd event 2018, 73% for the 2nd event 2019 and a 20% for the 3rd event 2019.