

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D0663728	<b>(X3) Date Survey Completed</b> 02/01/2021
<b>Name of Provider or Supplier</b> Bhadresh Nayak Md Plc	<b>Street Address, City, State</b> 43243 Schoenherr Road, Sterling Heights, MI	
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 record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the analyte: Platelets. Findings include: Review of the CMS database and the API proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the analyte: Platelets. Refer to D2123 and D2130.</p>
<b>D2123</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:  
. Based on record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to participate in proficiency testing for the analyte: Platelets for 1 (3rd event of 2020) of 2 testing events reviewed. Findings include: 1. A record review of the American Proficiency Institute (API) proficiency testing records revealed final reports were not submitted to API for the 3rd event of 2020. 2. A record review of the CMS database revealed the laboratory failed to participate for one out of two consecutive PT events for the analyte: Platelets. Platelets PT Event Score 2nd event 2020 60% 3rd event 2020 0%

**D2130**

**HEMATOLOGY**  
CFR(s): 493.851(f)

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 record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte: Platelets for 2 (2nd and 3rd events of 2020) of 2 consecutive testing events reviewed. Findings include: 1. A record review of the American Proficiency Institute (API) proficiency testing records revealed final reports were not submitted to API for the 3rd event of 2020. 2. A record review of the CMS database revealed the laboratory failed to achieve satisfactory performance for two consecutive PT events: Platelets PT Event Score 2nd event 2020 60% 3rd event 2020 0%