

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0663728	(X3) Date Survey Completed 12/09/2020
Name of Provider or Supplier Bhadresh Nayak Md Plc	Street Address, City, State 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.		

(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 record review of the CMS database and the American Association of Bioanalysis (AAB) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the specialty of chemistry. Findings include: Review of the CMS database and the AAB proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the specialty of chemistry. Refer to D2089 and D2097.</p>
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 Association of Bioanalysis (AAB) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing event for the specialty of chemistry for 2 (2020 events 2 and 3) of 2 consecutive testing events resulting in a score of 0. Findings include: 1. A review of the CMS database and the AAB proficiency testing reports revealed unsatisfactory performance, resulting in a score of 0 for two consecutive proficiency testing events for routine chemistry: Routine Chemistry PT event Score 2nd event 2020 0% 3rd event 2020 0%

D2097

ROUTINE CHEMISTRY
CFR(s): 493.841(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 record review of the CMS database and the American Association of Bioanalysis (AAB) proficiency testing reports, it was determined the laboratory failed to achieve an overall testing event score of satisfactory performance in routine chemistry for 2 (2020 events 2 and 3) of 2 consecutive testing events. Findings include: 1. A review of the CMS database and the AAB proficiency testing reports revealed unsatisfactory performance for two consecutive proficiency testing events for routine chemistry: Routine Chemistry PT event Score 2nd event 2020 0% 3rd event 2020 0%