

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0377479	(X3) Date Survey Completed 10/03/2019
Name of Provider or Supplier Northside Pediatrics Pc	Street Address, City, State 265 Fremont Street Suite 1, Battle Creek, 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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of hematology. Refer to D2123, and D2131.</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a</p>

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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined the laboratory failed to participate in the specialty of hematology testing event for 2 (the 3rd event of 2018 and the 1st event of 2019) of 3 testing events. Findings include: 1. A review of the CMS database and review of the API final proficiency testing reports revealed the laboratory attained the following for the specialty of hematology proficiency testing scores: PT Event Score 3rd of 2018 0% 2nd of 2019 0% 2. A review of API proficiency testing reports revealed the laboratory failed to participate in proficiency testing for the specialty of hematology.

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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined the laboratory failed to successfully participate in the specialty of hematology proficiency testing event for 2 (the 3rd event of 2018 and the 1st event of 2019) of 3 testing events. Findings include: 1. A review of the CMS database and review of the API final proficiency testing reports revealed the laboratory attained the following for the specialty of hematology proficiency testing scores: PT Event Score 3rd of 2018 0% 2nd of 2019 0% **This is a repeat deficiency from 12/29/16.**

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 review of the CMS database and review of the American Proficiency Institute (API) proficiency testing reports, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. Failure to ensure that the proficiency testing samples were tested as required under subpart H. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and review of the American Proficiency Institute (API) proficiency testing reports, the director failed to ensure the laboratory successfully participated in a proficiency testing program as required under subpart H. Findings include: 1. A review of the CMS database and review of the API final proficiency testing reports revealed the laboratory attained the following for the specialty of hematology proficiency testing scores: PT Event Score 3rd of 2018 0% 2nd of 2019 0% **This is a repeat deficiency from 12/29/16.**