

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0320482	(X3) Date Survey Completed 11/09/2018
Name of Provider or Supplier Norton Children's Medical Group - Prospect	Street Address, City, State 9217 Us Highway 42, Prospect, KY	
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 desk review of Bacteriology proficiency testing results from the American Proficiency Institute on 11/09/2018, the laboratory failed to successfully participate in the Throat Culture certified analyte in three consecutive testing events. This is the second unsuccessful proficiency failure. See the first unsuccessful failure dated 12/18 /2017. See D2020 and D2028</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p>

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on desk review of Bacteriology proficiency testing results from American Proficiency Institute on 11/09/2018, the laboratory failed to attain an overall testing score of 80 percent in three of five testing events. Findings include: The laboratory scored 33 percent in the second testing event of 2017, scored 67 percent in the third testing testing event of 2017, and scored 60 percent in the third testing event of 2018 for unsatisfactory performances.

D2028

BACTERIOLOGY
CFR(s): 493.823(e)

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 desk review of Bacteriology proficiency testing results from American Proficiency Testing agency on 11/09/2018, the laboratory failed to achieve satisfactory performance for three of five testing events for a second unsuccessful performance in the specialty of Bacteriology. Findings include: Unsatisfactory performances were obtained in the second and third testing events of 2017 with scores of 33 percent and 67 percent respectively and a score of 60 percent in the third testing of 2018.

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 Bacteriology proficiency testing results from the American Proficiency Institute on 11/09/2018, the laboratory director failed to fulfill the responsibility of evaluating the laboratory's performance of Throat cultures. Findings include: The corrective action taken for the first unsuccessful proficiency failure dated 12/18/2017, failed to correct the performance for Throat Cultures which is evidenced by the second unsuccessful proficiency failure occurring in the third testing event of 2018.