

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2009599	(X3) Date Survey Completed 05/08/2022
Name of Provider or Supplier Norton Children's Medical Group-Nulu	Street Address, City, State 1050 East Market Street, Louisville, 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
D0000	An Off-Site desk review of Proficiency Testing was conducted, on 05/08/2022, with deficiencies cited. Based on the findings, it was determined the Condition of Participation (CoP) was not met for Successful Participation 42 CFR 493.803 with associated Standard Level deficiency at D-2130, Hematology, 42 CFR 493.851(f).
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 an Off-Site desk review of Hematology proficiency testing results from the American Proficiency Institute (API) and the American Academy of Family</p>

Physicians (AAFP) on 05/08/2022, it was determined the laboratory failed to successfully participate in the Cell ID or White Blood Cell (WBC) Differential analyte in two (2) consecutive testing events. Refer to: D-2130

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 the Off-Site desk review of Hematology proficiency testing results from the American Proficiency Institute (API) and the American Academy of Family Physicians (AAFP), on 05/08/2022, it was determined the laboratory failed to achieve satisfactory scores for two (2) consecutive testing events for the analyte Cell ID or White Blood Cell (WBC) Differential. Findings include: 1. Record review of proficiency test results from API revealed the laboratory failed to achieve a satisfactory score for the analyte Cell ID or White Blood Cell (WBC) Differential with a score of zero (0) percent for the third proficiency testing event of 2021. 2. Record review of proficiency test results from AAFP revealed the laboratory failed to achieve a satisfactory score of the analyte Cell ID or White Blood Cell (WBC) Differential with a score of thirteen (13) percent for the first proficiency testing event of 2022.