

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0953865	<b>(X3) Date Survey Completed</b>  01/08/2019
<b>Name of Provider or Supplier</b>  North Jefferson Pediatrics	<b>Street Address, City, State</b>  934 Grubbs Ave, Gardendale, AL	
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>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 a desk review of proficiency testing evaluations from American Proficiency Institute (API) and CASPER reports (#153/#155), the surveyor determined the laboratory failed two consecutive testing events (Events #2 and #3, 2018) for the WBC Differential (White Blood Cell Differential). These failures resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. The laboratory did not submit results for Hematology testing Event #2, 2018 by the submission deadline (7/27/2018), due to instrument (Cell-Dyn Emerald) problems. The laboratory was graded a zero percent by API, due to the laboratory's "Failure to Participate." See the full report from Recertification Survey 10/16/2018. 2.</p>

A review of API proficiency testing evaluations and CASPER reports revealed the laboratory also scored 53 % (fifty-three percent) for the WBC Differential for Event #3, 2018. This score included 40 % for Granulocytes and 20 % for Lymphocytes. 3. The failures of the WBC Differential for two consecutive testing events resulted in the laboratory's initial unsuccessful proficiency testing participation.

**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 a desk review of proficiency testing evaluations from American Proficiency Institute (API) and CASPER reports (#153/#155), the surveyor determined the laboratory failed the WBC Differential (White Blood Cell Differential) for two consecutive testing events (Events #2 and #3, 2018). These failures were considered unsatisfactory performance and resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. The laboratory did not submit results for Hematology testing Event #2, 2018 by the submission deadline (7/27/2018), due to instrument (Cell-Dyn Emerald) problems. The laboratory was graded a zero percent by API, due to the laboratory's "Failure to Participate." See the full report from Recertification Survey 10/16/2018. 2. A review of API proficiency testing evaluations and CASPER reports revealed the laboratory also scored 53 % (fifty-three percent) for the WBC Differential for Event #3, 2018. This score included 40 % for Granulocytes and 20 % for Lymphocytes. 3. The failures of the WBC Differential for two consecutive testing events resulted in the laboratory's initial unsuccessful proficiency testing performance.