

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0928131	(X3) Date Survey Completed 10/18/2021
Name of Provider or Supplier Galen North Pediatrics	Street Address, City, State 1039 Executive Dr Ste #101, Hixson, TN	
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: ===== Hematology: The laboratory failed to maintain satisfactory participation in two consecutive events for the Hemoglobin (HGB) and White Blood Cell (WBC) analytes resulting in the initial unsuccessful proficiency testing (PT) occurrence for HGB and WBC. (Refer to D2130) =====</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

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 the CMS CASPER Report 0155D and the laboratory's 2021 Proficiency Testing (PT) performance summary records from the American Proficiency Institute (API) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the Hemoglobin (HGB) and White Blood Cell (WBC) analytes in the 1st event 2021 and 2nd event 2021, resulting in the initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed an unsatisfactory HGB analyte score of 40% and unsatisfactory WBC analyte score of 60% for the 1st event of 2021 and unsatisfactory HGB and WBC analyte scores of 0% for the 2nd event of 2021. 2. A review of the laboratory's API Proficiency Testing records revealed an unsatisfactory HGB analyte score of 40% and unsatisfactory WBC analyte score of 60% for the 1st event of 2021 and unsatisfactory HGB and WBC analyte scores of 0% for the 2nd event of 2021.

=====