

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0303225	(X3) Date Survey Completed 07/09/2019
Name of Provider or Supplier Rheumatology Associates Of N A	Street Address, City, State 4606 Bellewood Drive, Huntsville, AL	
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 a review of the CASPER reports (#153/#155) for proficiency testing participation and a telephone interview with the laboratory director, the surveyor determined the laboratory scored forty percent (40 %) and zero percent (0 %) for the WBC (White Blood Cell) Differential for testing Events #1 and #2 of 2019, respectfully. The failing scores of two consecutive testing events resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. The laboratory scored 40 % for the WBC Differential for Event #1, 2019 and 0 % for the WBC Differential for Event #2, 2019, two consecutive testing events. 2. In a telephone interview on 7/08/2019 at 3:37 PM, the Laboratory Director stated</p>

an investigation was underway, including speaking with the manufacturer of the Hematology instrument.

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 review of the CASPER reports (#153/#155) for proficiency testing participation and a telephone interview with the laboratory director, the surveyor determined the laboratory scored forty percent (40 %) and zero percent (0 %) for the WBC (White Blood Cell) Differential for testing Events #1 and #2 of 2019, respectfully. The unsatisfactory (failing) scores for two consecutive testing events for the same analyte resulted in unsuccessful performance for the laboratory. 1. Refer to D2016.