

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0929322	(X3) Date Survey Completed 10/01/2025
Name of Provider or Supplier Rheumatology Associates Of Balto Llc	Street Address, City, State 1220b East Joppa Rd #310, Baltimore, MD	
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing provider. The facility was found to be out of compliance with the following conditions of the CLIA program: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting 0155D report and American Proficiency</p>

	<p>Institute, the laboratory failed to successfully participate in an approved PT program for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of hematology for hematocrit and red blood cell count. Refer to D2130 and D2131.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and the proficiency testing (PT) comparative evaluation report from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the same hematology analytes in two out of three consecutive PT events. Findings: 1. Review of the CASPER 0155D report revealed the following results. a. Red blood cell count i. 40% in the 2024 3rd event ii. 60% in the 2025 2nd event b. Hematocrit i. 40% in the 2024 3rd event ii. 0% in the 2025 2nd event 2. Review of the API comparative evaluation report confirmed the CASPER 0155D report results.</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>(g) 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.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and the proficiency testing (PT) comparative evaluation report from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for hematology in two out of three consecutive PT events. Findings: 1. Review of the CASPER 0155D report showed that the laboratory received an overall hematology score of 61% in the 2024 3rd event and 76% in the 2025 2nd event. 2. Review of the API comparative evaluation report confirmed the CASPER 0155D report results.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on desk review of proficiency testing (PT) records from the Certification and</p>

Survey Provider Enhanced Reporting 0155D report and American Proficiency Institute, the laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting 0155D report and American Proficiency Institute, the laboratory director failed to ensure proficiency testing (PT) samples were tested as required. The laboratory director failed to ensure successful participation in an approved PT program. Cross-refer to D2130 and D2131.