

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1010383	<b>(X3) Date Survey Completed</b>  06/20/2021
<b>Name of Provider or Supplier</b>  Arthritis Clinic Pllc	<b>Street Address, City, State</b>  371 N Parkway, Ste 400, Jackson, TN	
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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the Complement C3 analyte and the specialty of immunology for 2020 event three and 2021 event one, resulting in the first unsuccessful PT performance for the Complement C3 analyte and the immunology specialty. (Refer to D2084 and D2085)</p>
<b>D2084</b>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing 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 Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and the laboratory's proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the Complement C3 analyte in two consecutive PT events, resulting in the first unsuccessful PT occurrence for the Complement C3 analyte. The finding include: 1. Review of the CMS 155 report revealed the following for the Complement C3 analyte: 2020 event three scored as 40% 2021 event one scored as 40% 2. Review of the laboratory's proficiency testing records for 2020 event three revealed sample numbers IMP-12, IMP-13, and IMP-14 scored as unacceptable for the Complement C3 analyte, resulting in an overall score of 40%. 3. Review of the laboratory's proficiency testing records for 2021 event one revealed sample numbers IMP-02, IMP-03, and IMP-05 scored as unacceptable for the Complement C3 analyte, resulting in an overall score of 40%, and the first unsuccessful PT occurrence for the Complement C3 analyte.

**D2085**

**GENERAL IMMUNOLOGY**

CFR(s): 493.837(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.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and the laboratory's proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the immunology specialty in two consecutive PT events, resulting in the first unsuccessful PT occurrence for the immunology specialty. The findings include: 1. Review of the CMS 155 report revealed the following for the immunology specialty: 2020 event three scored as 70% 2021 event one scored as 70% 2. Review of the laboratory's proficiency testing records for 2020 event three revealed a score of 40% for the Complement C3 analyte, resulting in an overall event score of 70% for the immunology specialty. 3. Review of the laboratory's proficiency testing records for 2021 event one revealed a score of 40% for the Complement C3 analyte, resulting in an overall event score of 70%, and the first unsuccessful PT occurrence for the immunology specialty.