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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0893127 | <b>(X3) Date Survey Completed</b><br><br>02/20/2018 |
| <b>Name of Provider or Supplier</b><br><br>Arthritis And Rheumatism Associates Pl                                          | <b>Street Address, City, State</b><br><br>612 Druid Rd E, Clearwater, FL   |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                            |                                                     |

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| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>D2016</b>              | <p>SUCCESSFUL PARTICIPATION<br/>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:<br/>Based on review of the laboratory's proficiency testing records for 2017, the laboratory did not have successful performance in proficiency testing for the specialty of general immunology. Refer to D2085. Findings include: Review of the American Proficiency Institute (API) proficiency testing records and the review of the Centers for Medicare &amp; Medicaid Services (CMS) 153 and 155 reports, on February 20, 2018, on or about 10:00 AM, showed that the laboratory had unsatisfactory testing scores for the analyte, anti-nuclear antibodies (ANA) for two consecutive testing events in 2017.</p> |
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| <p><b>D2085</b></p> | <p>GENERAL IMMUNOLOGY<br/>CFR(s): 493.837(g)</p> <p>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:<br/>Based on the review of the Centers for Medicare &amp; Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful participation in proficiency testing for the specialty of general immunology. Findings include: On February 20, 2018 on or about 10:00 AM the American Proficiency Institute (API) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the analyte, anti-nuclear antibodies, ANA, as shown below. Event #2, 2017 ANA-40% Event #3, 2017 ANA-0%</p>                                                                                                                                                                  |
| <p><b>D6076</b></p> | <p>LABORATORY DIRECTOR<br/>CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the specialty of general immunology. Findings include: On February 20, 2018, on or about 10:00 AM, the American Proficiency Institute (API) proficiency records and the Centers for Medicare &amp; Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for two consecutive testing events for the analyte, anti-nuclear antibodies (ANA), in the specialty of general immunology. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2085.</p> |
| <p><b>D6089</b></p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing in the specialty of general immunology. Findings Include: The review of the American proficiency Institute (API) proficiency testing records and the Centers for Medicare &amp;</p>                                                                                                                                                                                                                                                                                                                                                                                                                        |

Medicaid Services (CMS) 153 and 155 reports on February 20, 2018 on or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores as shown below. Event #2, 2017 ANA-40% Event #3, 2017 ANA-0%