

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2117969	<b>(X3) Date Survey Completed</b>  01/25/2022
<b>Name of Provider or Supplier</b>  Arthritis & Rheumatology Center Pc	<b>Street Address, City, State</b>  11731 Pointe Place, Roswell, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on January 25, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) for the year 2020 and 2021, as well as staff interview, the laboratory did not perform testing of the PT samples in the same manner as patient samples. Findings: 1. Review of CAP documents for 2020 and 2021, for specialties Hematology, Chemistry, Microbiology, and Diagnostic Immunology, the laboratory performed PT testing of samples in duplicate and testing performed by two different Testing Personnel. 2. Interview with staff #2, and #3 (reference CMS 209 form), on January 25, 2022, at approximately 2pm, in the Laboratory Office, confirmed the aforementioned statement.</p>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p>

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) for the years 2020 and 2021, as well as staff interview, the laboratory did not test PT specimens by personnel who routinely perform the testing in the laboratory.

Findings: 1. Review of the CAP documents for 2020 and 2021 for the Specialties of Hematology, Chemistry, Microbiology, and Diagnostic Immunology, PT test samples were not rotated to all personnel who routinely perform clinical testing in the laboratory. Staff # 4 (reference CMS 209 form), did not complete any PT testing. 2. Interview with staff # 2 and 3 (reference CMS 209 form) on January 25, 2022, at approximately 2:30 pm in the laboratory office, confirmed the aforementioned statement.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) provider for the year 2020 and 2021, and staff interview, the laboratory was not performing testing of the PT samples in the same manner as they test their patient samples. Findings: 1. Review of the CAP PT documents for 2020, and 2021 for Specialty Hematology, Chemistry, Microbiology, and Diagnostic Immunology, the laboratory was performing testing of all samples in duplicate, with testing being performed by two different Testing Personnel. 2. Review of the Attestation Statement forms for all events in 2020, and 2021, revealed that two different testing personnel were performing the PT samples in duplicate and not the same as patient samples were tested. The Laboratory Director was signing the Attestation Statements confirming that the PT samples were being tested in the same manner as patient samples. 3. Interview with staff #two and three (CMS 209 form), on January 25, 2022, at approximately 2 pm, confirmed the above aforementioned statements.