

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2117969	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Arthritis & Rheumatology Center Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 17, 2019. 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:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to evaluate and verify PT activities as required. Findings include: 1. College of American Pathologists (CAP) PT document review revealed corrective action was not performed for the following General Chemistry PT events: 2018 -- Event #2 (Uric Acid - 60 percent); 2019 -- Event 1 (Uric Acid - 80 percent). 2. An interview with Staff #2 (CMS 209) in the laboratory on 7/17/2019 at approximately 2:30 p.m. confirmed corrective action was not performed for the aforementioned PT events.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system</p>

performance and environmental conditions, and variance in operator performance. (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required
Findings include: 1. Horiba Micros 60 (Hematology analyzer) document review revealed there were no Levey-Jennings charts for 2018 and 2019 thus far. 2. An interview with Staff #2 (CMS 209) in the laboratory at approximately 2:30 p.m. confirmed there were no Levey-Jennings charts for 2018 and 2019 thus far.