

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0403111	<b>(X3) Date Survey Completed</b> 01/03/2020
<b>Name of Provider or Supplier</b> Arthritis And Rheumatology Consultants Pa	<b>Street Address, City, State</b> 7600 France Ave S, Suite 5100, Edina, MN	
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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to review and evaluate proficiency testing (PT) results from 1 of 10 PT events performed in 2019. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory on 01/03/20, at 10:10 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. Review and evaluation of API PT results was not performed by the laboratory for the 2019 event listed below. Specialty Event Hematology 2019-1 4. In an interview at 1:30 p.m. on 01/03/20, TP1 confirmed the above finding.</p>
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 9 of 10 reference intervals were consistent between a Hematology procedure and a patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1)</p>

during a tour of the laboratory at 10:10 a.m. on 01/03/20. 2. A Horiba Pentra 60 c+ hematology analyzer was observed as present and available for use during the tour. 3. Reference intervals listed in the Normal and Panic Ranges chart, effective date 06/05 /19, for the following analytes were not consistent with those included on a patient test report reviewed on date of survey as indicated below. White Blood Cells (WBC) Red Blood Cells (RBC) Hematocrit (HCT) Mean Corpuscular Volume (MCV) Mean Corpuscular Hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) Ed Cell Distribution Width (RDW) Platelets (PLT) Patient #851 - adult female tested on 09/12/19 Analyte\* Procedure Report WBC 3.5-10.8 4.0-10.0 RBC 3.8-5.2 3.80-5.80 HCT 36.0-49.0 37.0-47.0 MCV 81-100 80-100 MCH 27.0-35.0 27.0-32.0 MCHC 32.5-37.0 32.0-36.0 RDW 11.5-15.4 11.0-16.0 PLT 130-400 150-500 4. In an interview at 2:50 p.m. on 01/03/20, TP1 confirmed the above finding.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Laboratory Director (LD) failed to ensure 1 of 11 testing personnel in 2018 and 2 of 13 testing personnel in 2019 were evaluated for test procedure competency. Findings are as follows: 1. The laboratory was cited for non-performance of annual competency evaluations during the previous survey conducted on 02/09/18. 2. Annual competency evaluations were not found on date of current survey for 1 of 11 testing personnel in 2018 records and 2 of 13 testing personnel in 2019 records. See D6046. 3. In an interview at 11:45 a.m. and 12:20 p.m. on 01/03/20, TP1 confirmed the above finding.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure 1 of 11 testing personnel in 2018 and 2 of 13 testing personnel in 2019 were evaluated for test procedure competency. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m on 01/03/20. 2. Competency evaluations were required annually as established in the Employee

Training and Annual Competency for Testing Personnel procedure located in the Laboratory Policies and Procedures manual. 3. Annual competency evaluations were not found for testing personnel in 2018 and 2019 records as indicated below. 2018 Testing Personnel Missed evaluation MD9 Synovial crystal examination 2019 Testing Personnel Missed evaluation MD8 Synovial crystal examination TP4 Chemistry and Hematology 4. The laboratory was unable to provide the missing evaluations upon request. 5. In an interview at 11:45 a.m. and 12:20 p.m. on 01/03/20, TP1 confirmed the above finding. \*This is a repeat citation from the previous survey on 02/09/18. See D6030\*