

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403111	(X3) Date Survey Completed 02/09/2018
Name of Provider or Supplier Arthritis And Rheumatology Consultants Pa	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the technical consultant (TC) failed to assess all required elements in a 2017 competency evaluation for 1 of 3 testing personnel. Required competency evaluation elements per 493.1413(b)(8) include the following: 1) Direct observation of test performance, 2) Monitoring the recording and reporting of test results, 3) Review of intermediate test results or worksheets and testing records, 4) Direct observation of instrument maintenance, 5) Assessment of test performance with previously analyzed specimens, and 6) Assessment of problem solving skills. Findings are as follows: 1. The laboratory performed Diagnostic Immunology, Chemistry and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/09/18 at 9:30 a.m. 2. Testing Personnel 3 (TP3) was included on the Laboratory Personnel Report (CLIA) Form CMS-209 as a part-time employee who performed testing in the Specialties listed above. 3. Requirements to assess testing personnel in all areas of testing annually were established in the Employee Training and Annual Competency for Testing Personnel procedure. 4. An evaluation in the Specialties of Diagnostic Immunology, Chemistry and Hematology for the elements listed below was not found in the 2017 competency assessment records for TP3. 2) Monitoring the recording and reporting of test results 3) Review of intermediate test results or worksheets and testing records 5) Assessment of test performance with previously analyzed specimens The laboratory was unable to provide the missing evaluations upon request. 5. In an interview on 02/09/18 at 11:13 a.m., TP1 confirmed the above finding.</p>