Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2061345	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Rheumatology Consultants Maple Grove	12000 Elm Creek Blvd #150, Maple Grove, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain Hematology patient testing records for at least 2 years. Findings are as follows: 1. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing as confirmed by Testing Personnel 2 (TP2) during a tour of the laboratory at 10:15 a.m. on 04/23/19. 2. A Sedimat 15 Plus ESR analyzer was observed as present and available for use during the tour of the laboratory. 3. Testing record retention was required for a minimum of 2 years as established in the Quality Assurance - Log/Record Maintenance procedure found in the Maple Grove Policy and Procedure Manual. 4. The September 2017 through March 2019 ESR patient testing logs were not present in laboratory records on date of survey. The laboratory was unable to provide the missing documents upon request. 5. In an interview at 12:25 p. m. on 04/23/19, TP2 indicated the patient testing logs were discarded at the end of each month.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to include a procedure in the procedure manual for all tests performed by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 2 (TP2) during a tour of the laboratory at 10:15 a. m. on 04/23/19. 2. A written procedure for Synovial Fluid microscopic examination was not found during review of laboratory policies and procedures. The laboratory was unable to provide this procedure upon request. 3. In an interview at 1:44 p.m. on 04/23/19, TP2 confirmed a written procedure for Synovial Fluid microscopic examinations was not present in laboratory manuals.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain the original test result information when a corrected report was generated Findings are as follows: 1. The laboratory performed Immunology, Chemistry, and Hematology testing as confirmed by Testing Personnel 2 (TP2) during a tour of the laboratory at 10:15 a.m. on 04/23/19. 2. The Correction of Laboratory Reports procedure found in the Maple Grove Policy and Procedure Manual indicated the original test result was replaced in the electronic medical record by the corrected test result. The procedure did not indicate the original result was retained. 3. A corrected electronic report for patient 39116 from 06/15/18 did not include the original test result value. The Communication Log entry associated with this event did not include the original test result information. 4. In an interview at 2:21 p.m. on 04/23 /19, TP2 confirmed the original test result was not retained when a corrected report was generated.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical supervisor failed to assess the competency of 2 of 4 providers at least annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Synovial Fluid Microscopic examinations as confirmed by Testing Personnel 2 (TP2) during a tour of

	the laboratory at 10:15 a.m. on 04/23/19. 2. Synovial Fluid competency assessments for all providers were not found in laboratory records. The Worklist: Provider Competency for Synovial Fluid Microscopy forms found in the Provider Competency for Synovial Fluid Microscopy manual did not include assessments for 2 of 4 providers in 2017 and 2018. See below where x indicates competency completion. Provider 2017 2018 1 x 2 x x 3 x 4 The laboratory was unable to provide the missing competency assessments for Providers 1, 3, and 4 upon request. 3. In an interview at 12:15 p.m. on 04/23/19, TP2 confirmed the above finding.