Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2061345	05/21/2021
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a Chemistry and a Hematology procedure (performance verification) was approved, signed, and dated by the laboratory director prior to use. Findings are as follows: A. Chemistry 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 05/21 /21, at 9:05 a.m. 2. A Horriba Pentra c400 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities for the analyzer were acceptable and the laboratory began patient specimen testing on 03/25/21 as indicated in laboratory records. 4. The laboratory Director did not approve, sign, or date the Precision and Accuracy performance verification documents prior to use of the analyzer. 5. In an interview on 05/21/21, at 12:30 p.m., TP1 confirmed the above findings. B. Hematology 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 05/21/21, at 9:05 a.m. 2. A Horriba Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities for the analyzer were acceptable and the laboratory began patient specimen testing on 02/26/21 as indicated in laboratory records. 4. The laboratory Director did not approve, sign, or date the Precision and Accuracy performance verification documents prior to use of the analyzer. 5. In an interview on 05/21/21, at 12:45 p.m., TP1 confirmed the above findings. .
D5807	TEST REPORT CFR(s): 493.1291(d)

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.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 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) during a tour of the laboratory on 05/21/21, at 9:05 a.m. 2. A Horriba Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities were completed and the laboratory began testing patient specimens using the analyzer on 02/06/21 as confirmed by TP1. 4. Reference intervals listed in the Quality Assurance - Patient Test Management: Panic / Critical Values, Attachment I: Normal & Panic Values table found in the Maple Grove Policy & Procedure Manual were not consistent with that included on a patient test report reviewed on date of survey as indicated below. Date of Service: 03/09/21 Patient: Female, 32 years Analyte Procedure Report WBC* 3.5 - 10.8 4.0 - 10.0 RBC* 3.80 - 5.20 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 Platelet Count 130 - 400 150 - 500 Lymphocyte, 0.9 - 5.2 1.0 - 4.0 Absolute Lymphocyte, 15.1 - 43.0 25.00 - 50.00 Percent 5. In an interview at 12:45 p.m., on 05/21/21, TP1 confirmed the above finding. WBC* White Blood Cell Count RBC* Red Blood Cell Count HCT* Hematocrit MCV* Mean Corpuscular Volume MCH* Mean Corpuscular Hemoglobin MCHC* Mean Corpuscular Hemoglobin Concentration RDW* Red Cell Distribution Width .