Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2010850	12/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Osteoporosis Clinic Of Brazos Valley	1725 Birmingham Rd, Ste 200, College Station, TX	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Review of Immunology proficiency testing records , Proficiency testing agency instructions and interview of facility personnel found the laboratory failed to evaluate results not scored by the proficiency testing agency in five of five testing events in 2020 and 2021. The findings included: 1. Review of the College of American Pathologists (CAP) Diagnostic Immunology proficiency testing records for 2020 and 2021 (three events per year) found the laboratory failed to evaluate results not graded by the proficiency testing agency in the following events: a. S-A 2020 Diagnostic Immunology - The laboratory was given a score of 100% with five of five results not graded by the proficiency testing agency with an Exception Reason Code [20]= Response was not formally graded due to the insufficient peer group data. Please see the participant summary for additional information. b. S-B 2020 Diagnostic Immunology - The laboratory was given a score of 100% with five of five results not graded by the proficiency testing agency with an Exception Reason Code [20]= Response was not formally graded due to the insufficient peer group data. Please see the participant summary for additional information. c. S-C 2020 Diagnostic Immunology - The laboratory was given a score of 100% with five of five results not graded by the proficiency testing agency with an Exception Reason Code [20]= Response was not formally graded due to the insufficient peer group data. Please see the participant summary for additional information. d. S-A 2021 Diagnostic Immunology - The laboratory was given a score of 100% with five of five results not graded by the proficiency testing agency with an Exception Reason Code [20]= Response was not formally graded due to the insufficient peer group data. Please see the participant summary for additional information. e. S-B 2021 Diagnostic

	Immunology - The laboratory was given a score of 100% with five of five results not graded by the proficiency testing agency with an Exception Reason Code [20]= Response was not formally graded due to the insufficient peer group data. Please see the participant summary for additional information. 2. Review of the Proficiency testing agency instructions to laboratories found "The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain documentation of review at least two years. The actions laboratories should take include, but are not limited to: [20] Applies to a response that is not formally evaluated when a peer group is not established due to fewer than 10 laboratories reporting. Document that the laboratory performed a self evaluation using the data presented in the participant data summary and compared its results to a similar method, all methods, all participant statistics or data tables for groups of 3-9 laboratories, if provided. Perform and document corrective actions of any unacceptable results. If self-evaluation is not possible, it is up to the laboratory director /designee to determine an alternative performance assessment." 3. Interview of the Technical Supervisor on December 22, 2021 at 9:32 AM confirmed the laboratory did not evaluate results that were not graded by the proficiency testing agency in the five event.
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: Review of policies and procedures, and interview of facility personnel found that the laboratory director failed to approve, sign and date five of five procedures used by testing personnel for patient testing, prior to use. Findings included: 1. Review of policies and procedures found the following procedures available to testing personnel without the laboratory director's signature and date of approval: a. Antinuclear Antibodies b. 25- OH Vitamin D c. Anti-cyclic Citrullinated Peptide Antibodies d. Quantiferon-TB Gold e. Rheumatoid Factor IgM and RF/3 2. Interview of the technical supervisor conducted December 22, 2021 at 9:05 AM confirmed that the laboratory procedures had not been signed as approved by the laboratory director prior to use by testing personnel in patient testing.