

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2010850	(X3) Date Survey Completed 10/11/2023
Name of Provider or Supplier Arthritis & Osteoporosis Clinic Of Brazos Valley	Street Address, City, State 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	<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: Review of proficiency testing records and interview of facility personnel found the laboratory failed to review and evaluate results obtained in two of four Special Immunology proficiency testing events in 2022 and 2023. THIS IS A REPEAT DEFICIENCY The findings included: 1. Review of the College of American Pathologists (CAP) proficiency testing records for Special Immunology (two events per year) found the laboratory failed to evaluate the results and document corrective actions when analytes were not graded by the proficiency testing agency as follows: a. Review of the Original Evaluation for the S2-B 2022 Special Immunology Proficiency event found five of five results were not graded with the Exception Reason Code [33]=Specimen determined to be unsatisfactory after contacting CAP. The laboratory director signed the "Reviewed by" on 9/6/2022. There was no documentation of corrective actions taken available for review. b. Review of the Original Evaluation for the S2-B 2023 Special Immunology Proficiency event found one of two results for Anti-SSB- qual were not graded by the proficiency agency and the results included Exception Reason Code[27] Lack of participant or referee consensus. The laboratory director signed the "Reviewed by" on 8/23/2023. There was no documentation of corrective actions taken available for review. c. Review of the Actions Laboratories Should Take when a PT Result is Not Graded (page 29 of the participant summary) 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 acceptability of performance as outlined below and retain documentation of</p>

review for at least 2 years. The actions laboratories should take include but are not limited to: Exception Reason Code 33 - Specimen determined to be unsatisfactory after contacting the CAP: Action Required: Document that the laboratory has contacted the CAP and no replacements were available. Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested. Exception Reason Code 27 - Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested. 3. During interview of the Technical Supervisor conducted October 11, 2023 at 9:47 AM, she confirmed that there was no documentation of review, assessment and corrective actions taken when results were not graded by the proficiency testing agency.

D6116

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(3)

The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.

This STANDARD is not met as evidenced by:
Review of proficiency testing records and interview of facility personnel found the laboratory director failed to review and evaluate results obtained in two of four Special Immunology proficiency testing events in 2022 and 2023.