

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2051483	(X3) Date Survey Completed 07/25/2023
Name of Provider or Supplier Tiehh Bioterrorism Response Laboratory	Street Address, City, State 1207 S Gilbert Drive, Building 555, Lubbock, 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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. 493. 801 Condition: Proficiency Testing; Enrollment
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based upon review of proficiency testing records and interview of facility personnel, the laboratory failed to enroll in a proficiency testing program for Virology pathogens tested using the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel for the calendar year 2023. The findings included: 1. Review of proficiency testing records found no evidence of the laboratory participating in a proficiency testing program in 2023 for Influenza A and B . 2. During interview of the Technical Supervisor listed on the CMS report 209 Laboratory Personnel Report conducted July 25,2023 at 11:33 AM, she confirmed that she had not enrolled in a proficiency testing program for Influenza A and B for 2023.</p>
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologists(CAP) proficiency testing records from 2022, and staff interview, the laboratory failed to document the review and corrective actions for proficiency testing results not graded by the proficiency testing agency for two of three ID3 Nucleic Acid Amp, Respiratory Ltd testing events. The findings included: 1. Review of CAP proficiency testing records from 2022 (3 testing events annually) found no documentation of review for analytes not graded by the proficiency testing agency as follows: a. ID3-A 2022 Nucleic Acid Amp, Respiratory Ltd I. Influenza A virus Subtype - Five of five results for the Influenza A virus Subtype submitted by the laboratory were not graded by the proficiency testing agency and noted an exception Reason Code [26] = Educational challenge. II. RSV (Respiratory Syncytial Virus)- Five of five results submitted by the laboratory were not graded by the proficiency testing agency and noted an exception Reason Code [11] Unable to analyze (documentation to be provided by laboratory). b. ID3-C 2022 Nucleic Acid Amp, Respiratory Ltd I. Influenza A virus Subtype - Five of five results for the Influenza A virus Subtype submitted by the laboratory were not graded by the proficiency testing agency and noted an exception Reason Code [26] = Educational challenge. II. RSV (Respiratory Syncytial Virus)- Five of five results submitted by the laboratory were not graded by the proficiency testing agency and noted an exception Reason Code [11] Unable to analyze (documentation to be provided by laboratory). c. Review of the Actions Laboratories Should Take when a PT Result is Not Graded as provided by the CAP Proficiency testing agency in the participants Data summary found that the laboratory should take the following actions for the Exception Reason Codes cited: "[26] - Educational Challenge - Response to the CAP is not required. Laboratory should document its review. [11] - Document why the specimens were not analyzed (eg, instrument not functioning or reagents not 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." d. There was no other documentation of assessment of proficiency testing results available for review. 2. During interview of the Technical Supervisor listed on the CMS report 209 Laboratory Personnel report conducted July 25, 2023 at 1:51 PM, she confirmed that there was no evaluation of results not graded by the proficiency testing agency.