Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1089622	02/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Genex Labobatories	1301 N San Fernando Blvd, Burbank, CA	

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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interviews with the technical consultant (TC), and laboratory director (LD), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Antinuclear antibody (ANA) analyte. The findings include: 1. The laboratory participated in the AAB-MLE PT program and obtained an unsatisfactory score of 60% for the ANA analyte during the third event of 2024 (Q3-2024). The results are as followed: Specimen Reported Expected 11 Negative Negative 12 Positive Positive *13 Negative Positive *14 Positive Negative 15 Negative Positive Legend: * = unsatisfactory score 2. The TC and LD affirmed by interviews on February 26, 2026, at approximately 10:20 a.m. that the laboratory received the unsatisfactory PT scores for the ANA analyte as mentioned in statement#1. 3. The quality and reliability of patient results reported cannot be assured. 4. According to the testing declaration form submitted at the time of survey, the laboratory tested and reported approximately 3,100 ANA test patient samples annually including the time when unsatisfactory scores were obtained. .
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing

	event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interviews with the technical consultant (TC) and laboratory director, it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Chloride (Cl), Hemoglobin A1C, Prostate-Specific Antigen (PSA), and Ferritin analytes. The findings include: 1. The surveyor reviewed the PT records wherein AAB-MLE reported an unsatisfactory score of the following: a. 40% Cl in the second event of 2024; b. 60% Hemoglobin A1C in the first event of 2025; c. 0% PSA analyte in the first event of 2025, and d. 60% Ferritin analyte in the second event of 2025 2. The TC and LD affirmed by interviews on February 26, 2026, at approximately 10:20 a.m. that the laboratory obtained the unsatisfactory PT scores for the Cl, Hemoglobin A1C, PSA and Ferritin analytes as mentioned in statement #1. 3. The accuracy and reliability of patient test reported cannot be determined. 4. According to the laboratory's testing declaration form (Lab-144) submitted on the day of the survey, the laboratory performed approximately 4,334 Cl, 2,811 Hemoglobin A1C, 1,804 PSA, and 3,557 Ferritin patient test samples annually including the time when the laboratory received the unsatisfactory proficiency testing score. .
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 the review of the laboratory's policy and procedure, proficiency testing (PT) records and interviews technical consultant (TC) and testing personnel (TP) on February 26, 2026, it was determined that the laboratory failed to perform and document a corrective action for any analyte that achieved an unsatisfactory score of less than 100 percent. The findings include: 1. The laboratory failed to follow their established and approved policy and procedure for PT that indicated, a corrective action must be performed for any unsatisfactory scores received. 2. The laboratory was enrolled with the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) PT program and obtained an unsatisfactory score of 60% for the Ferritin analyte. Further review of the documentation revealed that no corrective action was performed and documented for the second event of 2025 (Q2-2025). 3. The TC and TP affirmed by interviews on February 26, 2026, at approximately 10:20 a.m., that the corrective action documentation was missed for the unsatisfactory proficiency testing score of 60% for the Ferritin analyte in the Q2-2025 event. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 3,557 Ferritin patient samples annually, including the time when unsatisfactory PT scores were received and a corrective action was missed to be performed and documented. Thus, the quality and reliability of patient tests reported cannot be assured.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this

	part; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing documentation and interviews with the technical consultant and testing personnel on February 26, 2026, this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. The findings include: 1. The laboratory obtained an unsatisfactory score for General Immunology. See D2075. 2. The laboratory obtained unsatisfactory scores for several analytes in different testing events for Routine Chemistry. See D2087.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing documentation and interviews with the technical consultant and testing personnel on February 26, 2026, the laboratory director is herein cited for failing to ensure that the laboratory followed an established policy and followed an approved corrective action plan when any proficiency testing result received are found to be unacceptable or unsatisfactory. See D5221.