Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2246783	06/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nura Diagnostic Inc	900 Valley View Ave Ste 9, Pasadena, 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 the surveyors' review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, CASPER 0155D report, corrective actions, and an interview with the technical consultant (TC) on June 8, 2026, 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 in the General Immunology subspecialty for the third event of 2024 (Q3-2024). The findings include: 1. The laboratory participated in the AAB-MLE PT program and obtained an unsatisfactory score of 60% for the ANA analyte in the General Immunology subspecialty during the Q3-2024 event. This was verified through review of the CASPER 0155D report and the corrective action documentation that was provided at the time of the survey. 2. The TC confirmed by an interview on June 8, 2026, at approximately 2:00 p.m. that the laboratory received the unsatisfactory PT scores for the ANA analyte as mentioned in statement#1. 3. According to the testing declaration form submitted at the time of survey, the laboratory tested and reported approximately 1,527 ANA test patient samples annually including the time when unsatisfactory scores were obtained during the Q3-2024 event. .
D2121	HEMATOLOGY CFR(s): 493.851(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 surveyors' review of the proficiency testing documentation from the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE), CASPER 0155D report, test tally documentation, and an interview with the technical consultant (TC) on June 8, 2026, it was determined that the laboratory failed to attain at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the first event of 2026 (Q1-2026) testing event. The findings include: 1. Review of the laboratory's AAB-MLE PT documentation showed that the laboratory received an unsatisfactory score of 60 percent for the Q1-2026 testing event. 2. During the interview on June 8, 2026, at approximately 2:00 p. m., the TC confirmed that the laboratory obtained the unsatisfactory score as mentioned in statement #1. 3. According to the test tally documentation reviewed at the time of the survey, the laboratory performed and reported approximately 2,378 tests annually including the period when the unsatisfactory score was obtained for Q1-2026.
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, lack of corrective action documentation, test tally documentation, and an interview with the technical consultant (TC) on June 8, 2026, it was determined that the laboratory failed to perform and document a corrective action for the Iron analyte during the second event of 2023 (Q2-2023) and for the Uric Acid during the first event of 2026 (Q1-2026) both of which received an unsatisfactory score of less than 100 percent. The findings include: 1. The laboratory's PT policy stated that corrective action documentation is required for all PT activities received. 2. Review of the proficiency testing records and CASPER 0155D report showed that the laboratory obtained an 80% score for the Iron analyte during the Q2-2023 event and for the Uric Acid analyte for the Q1-2026 event. 3. The surveyors' reviewed the PT documentation and found that the laboratory lacked a corrective action report for the Iron and Uric Acid analytes. 4. The TC confirmed by an interview on June 8, 2026, at approximately 2:00 p.m., that the corrective action documentation was not performed for the Iron analyte during the Q2-2023 event and the Uric Acid analyte during the Q1-2026 event, despite both having received 80% scores. 5. According to the test tally documentation submitted at the time of the survey, the laboratory performed and reported approximately 2,454 Iron and 2,568 Uric Acid tests annually, including the time when unsatisfactory PT scores were received and no corrective action was performed.
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 surveyors' review of the laboratory's policy and procedure, proficiency testing documentation and interviews with the technical consultant and laboratory assistant on June 8, 2026, the laboratory director is herein cited for failure to ensure that the proficiency testing samples were tested as required in this subpart. The findings include: 1. The laboratory obtained an unsatisfactory score of 60% for the ANA analyte for the General Immunology subspecialty during the third event of 2024. See D2075 2. The laboratory obtained a score of 60% for the Hematocrit analyte in the Hematology specialty during the first event of 2026. See D2121
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, lack of corrective action documentation, and an interview with the technical consultant on June 8, 2026, it was determined that the laboratory director failed to ensure that the laboratory's established policies and procedures for evaluating and performing corrective actions were followed when proficiency testing results were found to attain less than 100%. See D5221.