Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0543719	12/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Privilege Dx Medical Laboratories, Inc	10133 Riverside Dr, Toluca Lake, 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
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 supervisor (TS) and technical consultant (TC), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Urinalysis for the urine Glucose analyte. The findings include: 1. The surveyor reviewed the PT records wherein AAB-MLE reported an unsatisfactory score of 0% for the Glucose analyte in Urinalysis. 2. The TS and TC affirmed by interviews on December 9, 2025, at approximately 9:40 a.m. that the laboratory obtained the unsatisfactory PT scores for urine Glucose analyte 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 4,805 patient test samples annually for Urinalysis including the Glucose analyte during the time the laboratory received an unsatisfactory proficiency testing scores.
D2098	ENDOCRINOLOGY CFR(s): 493.843(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, Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, PT documentation, and interviews with the laboratory's technical supervisor (TS) and technical consultant (TC); the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the serum pregnancy (hCG) analyte for the third event of 2022 (Q3-2022). The findings include: 1. The surveyor reviewed the CASPER report and AAB-MLE PT documentation and found that the laboratory obtained an unsatisfactory score of 0% for serum hCG for the Q3-2022 event. 2. The TS and TC affirmed by interviews on December 9, 2025, at approximately 9:40 a.m. that the laboratory obtained the unsatisfactory PT scores for serum hCG for Q3-2022 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 41 patient test samples for serum hCG analytes annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined.
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 surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interviews with the technical supervisor (TS) and technical consultant (TC) on December 9, 2025, at 9:40 a.m., it was determined that the laboratory failed to attain a score of at least 80% of acceptable responses for White Blood Cell (WBC) count which is an unsatisfactory analyte performance for the testing event. The findings include: 1. The surveyor's review of the PT documentation indicated that the laboratory participated in the AAB-MLE PT program for the first event of 2025 (Q1-2025) and obtained a score of 60% for WBC count. Therefore, the accuracy of the patient test results for WBC count reported by the laboratory during the failed proficiency testing period cannot be assured and might have caused potential patient harm. 2. The TS and TC on December 9, 2025, at 9:40 a.m., affirmed that the laboratory received less than 80% score at the Q1-2025 PT event for the WBC count in Hematology specialty. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/05/2025 stated that the laboratory performed approximately 15,227 tests in WBC count annually.
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 with the technical supervisor (TS) and technical consultant (TC) on December 9, 2025; it was determined that the laboratory failed to perform and document a corrective action for analytes 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 stated a corrective action must be performed for any unsatisfactory scores received. 2. The laboratory obtained an unsatisfactory score for the following analytes and events that lacked a corrective action documentation: a. A score of 80% for the HIV analyte for the first event of 2023. b. A score of 60% for the Antinuclear antibodies (ANA) analyte for the first event of 2025. 3. The TS and TC affirmed by interviews on December 9, 2025, at approximately 9:40 a.m., that the corrective action documentation was missed for the unsatisfactory proficiency testing scores received by the laboratory as mentioned in statement #1 and #2. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 368 for the HIV analyte and 1,959 for ANA analyte annually, including the time when unsatisfactory PT scores were received and corrective action was missed to be documented.
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 proficiency testing documentation for all events from the years 2022, 2023, 2024, and 2025, and interviews with the technical supervisor and technical consultant on December 9, 2025; 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 Routine Chemistry. See D2087. 2. The laboratory obtained an unsatisfactory score for Endocrinology. See D2098. 3. The laboratory obtained an unsatisfactory score Hematology. 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 and interviews with the technical supervisor and technical consultant on December 9, 2025, the laboratory director is herein cited for failing to ensure that the laboratory followed an established policy and an approved corrective action plan when any proficiency testing result received are found to be unacceptable or unsatisfactory. See D5221.