

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1077328	(X3) Date Survey Completed 01/13/2026
Name of Provider or Supplier Robert Klein Md Inc	Street Address, City, State 18350 Roscoe Blvd, Ste 701, Northridge, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the proficiency testing (PT) records and interviews with the office manager (OM) and medical assistant (MA) on January 13, 2026, 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 was enrolled with the American Proficiency Institute (API) for the Prostate-Specific Antigen (PSA) analyte and obtained an unsatisfactory score of 80% for both the first and second events of 2025. 2. During the interview with the OM and MA on January 13, 2026, at approximately 9:30 a.m., both stated that no corrective action were performed nor documented for the first and second event in 2025 for the PSA analyte when a 80% unsatisfactory score was received. 3. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 800 PSA tests annually, including the time when unsatisfactory PT scores were received and corrective action was missed to be documented.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
 Based on the lack of the laboratory's policy and procedure for quality assessment and interviews with the office manager (OM) and medical assistant (MA), it was determined that the laboratory failed to establish a written policy and procedure for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. The findings include: 1. The laboratory failed to establish a written and approved policy and procedure for quality assessment that outlined an ongoing mechanism to monitor, assess, and, when necessary, correct problems within the general laboratory systems. Consequently, proficiency testing scores that obtained less than 100 percent were missed to be documented and corrected. 2. The OM and MA affirmed by interviews on January 13, 2026, at approximately 9:30 a.m., that the laboratory lacked any specific policy and procedure for quality assessment and did not have a corrective action documentation system to manage any errors that occurred. 3. According to the testing declaration submitted on the day of the survey, the laboratory performed and reported approximately 800 tests for Prostate-specific antigen analyte annually including the period when the laboratory lack a quality assessment policy and system to monitor, assess, and when indicated, correct problems identified.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's proficiency testing (PT) records from the American Proficiency Institute for 2025 and interviews with the office manager and medical assistant on January 13, 2026, the laboratory director failed to ensure that all graded proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. See D5221.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:
 Based on the lack of a written and approved policy and procedure for quality assessment, review of proficiency testing results and interviews with the office manager and medical assistant, the laboratory director is herein cited for failure to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. See D5291.