

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D1077328	<b>(X3) Date Survey Completed</b> 08/03/2021
<b>Name of Provider or Supplier</b> Robert Klein Md Inc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory's proficiency testing (PT) papers from American Proficiency Institute (API), and an interview with the laboratory testing person on August 3, 2021 at 11:40 am, it was determined that PT was not performed with regular patient workload by the laboratory personnel who routinely perform testing. Only one (TP1) out of 5 testing persons performed all PT in last 2 years resulting doubt on patient test results accuracy reported by other testing persons. Findings include: 1. The laboratory participated in the API PT program for the years of 2019, 2020 and 2021. Review of laboratory's PT records for the above years, it was found that only TP1 performed and signed all PT documents. However, the laboratory has 5 testing persons who routinely performed patients testing. 2. The laboratory testing person, on August 3, 2021 at 11:40 am, affirmed that the laboratory did not include PT sample in the regular patient workload during routine testing by other testing personnel and waited for the only one specific testing person, instead. 3. The laboratory testing declaration form signed by the laboratory director attests to test volumes of 700 PSA and 100 Testosterone performed, annually.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or</p>

examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory policy & procedure, testing records, and interview with the testing personnel, it was determined that the laboratory failed to provide a written procedures manual to testing personnel for testing performed might cause deviation from the procedure and erroneous results. The findings include: 1. The laboratory was unable to produce a procedure manual for PSA and Testosterone tests when requested by surveyor. 2. Based on interview with laboratory staff on August 3, 2021 at 11:00 am, the staff affirmed that a written procedure manual for all tests was not available. 3. The laboratory testing declaration form signed by the laboratory director attests to test volumes of 700 PSA and 100 Testosterone performed, annually.

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory policy & procedure, and interview with the testing personnel, it was determined that the laboratory failed to have a procedures manual for Testosterone and PSA approved and signed by the current laboratory director. Findings include: 1. During survey on August 3, 2021 when asked for the laboratory procedure manual, laboratory staff provided two signed documents which described Testosterone and PSA ranges. The signature was illegible, and the papers were not dated. 2. When interviewed on August 3, 2021, at 11:10 am, the laboratory staff affirmed that they could not identify if the signature was from the current lab director and the date. 3. The laboratory testing declaration form signed by the laboratory director attests to test volumes of 700 PSA and 100 Testosterone performed, annually.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor's review of laboratory's proficiency testing (PT) papers from American Proficiency Institute (API), and an interview with the laboratory testing person on August 3, 2021 at 11:40 am, the laboratory director failed to assure that PT was performed with regular patient workload by the laboratory personnel who routinely perform testing as required under Subpart H. Findings include: See D2007. The laboratory director is responsible for the employment of personnel who are

competent to perform test procedures and testing of PT samples is one way to assure the competency of the testing personnel. Therefore, failure to adhere with the regulation might have caused inaccurate patient test results reported by the testing personnel.

**D6031**

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

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:  
Based on surveyor review of the laboratory policy & procedure, testing records, and interview with the testing personnel, it was determined that the laboratory director failed to establish and ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings include: See D5401. Availability and adherence to an approved procedure manual by testing personnel could prevent any deviation from the established procedure and reduce mistake in testing and reporting wrong results.