

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0561185	<b>(X3) Date Survey Completed</b>  09/25/2020
<b>Name of Provider or Supplier</b>  Klein Khaw Abrams And Raiman	<b>Street Address, City, State</b>  16101 Ventura Blvd, Ste 340, Encino, 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>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, proficiency testing (PT) records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant on September 25, 2020 at 1:15 pm, the laboratory failed to test PT samples the same number of times that it routinely tests patient samples for 1 event out of 3 events, reviewed. The findings include: 1. The laboratory tested AAB CHEM 8 PT samples on 5/16/2020 which was documented by the instrument printout. However, on the same printout there were many handwritten numbers which indicates that the testing person might had tested the PT sample at least 4 times. This was confirmed by the fact that the laboratory reported one of the handwritten test results for Sodium, Potassium, Chloride and CO2 to the PT agency. The laboratory's policy and procedure stated to test patient sample a maximum of 3 times if any critical values obtained and the repeat results exceeds 15%. 2. The laboratory TC on September 25, 2020 at 1:15 pm, affirmed that the laboratory testing person #1 tested the AAB CHEM 8 PT sample 4 times. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/24/2020, stated that the laboratory performs 24,000 routine chemistry tests, annually.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient and quality control (QC) testing records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant (TC) on September 25, 2020 at 12:30 pm, the laboratory failed to retain QC records for 4 events out of 4 events, reviewed. The findings include: 1. The laboratory tested QC samples repeatedly however, it failed to retain all test records. a. On 9/21/2020, the laboratory tested LDL QC sample twice however, it kept records for only run and discarded the other run result. b. On 9/24/2020, the laboratory tested QC samples for CREAT thrice, ALT twice and LDHifcc thrice however, it kept records for only one run and discarded other run results for all the QC samples. 2. The laboratory TC on September 25, 2020 at 12:30 pm, affirmed that the laboratory did not keep all the QC run results. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/24/2020, stated that the laboratory performs 24,000 routine chemistry tests, annually.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's proficiency testing (PT) records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant on September 25, 2020 at 1:10 pm, the laboratory failed to retain its PT test records for 1 event out of 3 events, reviewed. The findings include: 1. The laboratory tested AAB CHEM 8 PT samples 4 times, on 5/16/2020 however, it failed to retain all printout from the Abx Pentra-400 instrument. On one printout, all the repeat test results were handwritten. 2. The laboratory TC on September 25, 2020 at 1:10 pm, affirmed that the laboratory did not keep all the PT run results. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/24/2020, stated that the laboratory performs 24,000 routine chemistry tests, annually.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient, QC and PT testing records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant (TC) on September 25, 2020 at 12:30 pm, it was

determined that the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D2010, D3031, D3037 and D6016.

**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 review of laboratory's policy and procedure, PT records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant on September 25, 2020 at 1:15 pm, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required. The findings include: See D2010.