

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1009515	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier J Lee Md Medical Corporation	Street Address, City, State 1010 W Laveta Ave, Ste 360, Orange, 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	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the first quarter (Q1-2020) event of the College of American Pathologists (CAP) proficiency testing records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Rheumatoid Factor (RF). The findings included: 1. For Q1-2020, CAP reported score of 20% for RF analyte. 2. Based on the laboratory's annual testing declaration for 2018-2020 the laboratory analyzed and reported 150 RF tests during the time the laboratory had unsatisfactory proficiency testing results. c. The TP affirmed (09/29/2020) the laboratory received the above unsatisfactory proficiency testing score.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the first quarter (Q1-2019) event of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Alkaline Phosphatase. The finding included: 1 For Q1-2019, AAB reported an unsatisfactory score of 40% for the Alkaline</p>

Phosphatase test. The laboratory failed to report an acceptable test value for three (3) out of five (5) tested samples: Sample # Reported Acceptable Range 1 77 82-152 2 26 71-132 5 20 23-42 2. Based on the laboratory testing declaration submitted at the time of the survey on 09/29/2020 for 2018-2020 the laboratory analyzed and reported approximately 600 Alkaline Phosphatase tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TP affirmed 09/29/2020 at approximately 11:00 a.m. that the laboratory received the above unsatisfactory proficiency testing score.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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 examining specimens.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory written policies and procedures and interview with the laboratory director (LD) and testing personnel (TP), it was determined that the laboratory failed to establish and follow written procedures for Hematology and Chemistry. The findings included: 1. On the day of the survey 09/29/2020 at approximately 1:30 p.m. the laboratory failed to provide written policies and procedures for Hematology and Chemistry. 2. For eight (8) out of eight (8) random patient test results reviewed covering period from January 01/11/2019 to 09/21/2020, four (4) patients had Hematology and Chemistry tests ordered, analyzed, and reported for which the laboratory had no policies and procedures written. 3. The LD and TP confirmed on 09/29/2020 at approximately 2:00 p.m. that the laboratory lacked established written policies and procedures for Hematology and Chemistry.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on the lack of documentation of critical values, critical or life threatening test reporting protocol, and interview with the testing personnel (TP); it was determined that the laboratory failed to document, establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: 1. On the day of the survey 09/29/2020 at approximately 11:00 a.m. based on document review; the surveyor found that the laboratory had no policy available or procedure established as to what were the laboratory's critical values for both Chemistry and Hematology. 2. The laboratory had no policy and procedure established as to when to inform provider and documentation of follow up of a critical or life threatening result. 3. For one (1) out of eight (8) random patient test results reviewed covering period from 01/11/10 to 09/14/2020 critical values results reporting for CBC were not documented. 4. The TP

affirmed (09/29/2020) that the laboratory has not established policy or written procedure for critical values and the steps to take to inform the providers.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory documentation records and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5791

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must 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 interview with the laboratory director and testing personnel on September 29, 2020 at approximately 2:00 p.m., the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings include: 1. The laboratory did not have a policy or procedure covering reporting of critical values/abnormal test results. See D5791. 2. The laboratory fail to find written policies and procedures for Chemistry and Hematology. See D 5401.