Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2229525	09/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
L&L Diagnostics, Llc	908 N Citrus Ave, Covina, 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) 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 review of the American Proficiency Institute (API) proficiency testing (PT) records, six (6) randomly selected patients records, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for Sodium analyte in 2023. The findings include: 1. Based on review of PT records for the third event of 2023 (Q3-2023), API reported an unsatisfactory score report as follows: Sodium PT Q3-2023 Overall score: 20% Specimen Reported Expected CHM-11 *145 148-157 CHM-12 *126 129-138 CHM-13 *141 143-152 CHM-14 140 140-149 CHM-15 *135 136-145 * Unacceptable result 2. The TC affirmed by interview on September 19, 2024, at approximately 110:30 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 8,5000 Routine Chemistry test samples, including Sodium analyte, during the time the laboratory had unsatisfactory proficiency testing results.
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 review of the laboratory's validation documentation, policies and procedures manual, and interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to provide validation documentation of the laboratory director approval, signature, and date of new procedures established by the laboratory as indicated in the policies and procedures. The findings included: 1. On the day of the survey September 19, 2024, at approximately 11:30 a.m. the validation documentation for new tests (endocrinology, cortisol, prolactin, microalbumin, testosterone, nail fungus, wound panel, etc.) was not approved, signed, and dated by the laboratory director before sample testing was performed. Policies and procedure manual in place included a validation of new tests policy signed and dated by the laboratory director stating his approval before sample testing. 2. The TC and TP affirmed on September 19, 2024; that the laboratory failed to follow the validation policy in place indicating a step-by-step validation protocol and approvals of new laboratory tests. 4. The laboratory's testing declaration form stated that the laboratory processes and reports approximately 38,500 microbiology and chemistry test samples for which validation of new tests was not approved, signed, and dated by the laboratory director.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, examination of laboratory reagents, and interviews with the laboratory's technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed in using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's observations during the laboratory tour, the laboratory stored 2 bottles of absolute ethanol expired 3/15/2021. 2. The TC and TP affirmed on September 19, 2024, at approximately 12:15 p.m. that the laboratory was not using the reagent listed on #1. However, the laboratory could not confirm that the reagent was not used currently. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory tested and reported approximately 73,500 total tests samples where expired absolute alcohol reagent may have been used.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, proficiency testing records, validation of new tests established in the laboratory, six (6) randomly selected patients test records, and interviews with the technical consultant and testing personnel on September 19, 2024; it was determined that the

	laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic and analytical phases of the laboratory testing were monitored. See D2087, D5407, and D5417.