Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2310314	06/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cortex Lab Inc	14435 Hamlin St Ste 2004, Van Nuys, 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) (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 the surveyor's review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the technical consultant (TC), testing personnel (TP), and owner; it was determined that the laboratory failed to attain at least 80 percent of the acceptable scores in Routine Chemistry for the second event of 2025 (Q2-2025). The findings include: 1. The surveyor reviewed the PT records for Q2-2025 wherein API reported unsatisfactory scores for Alkaline Phosphatase (ALP), Phosphorus, Potassium, and Uric Acid analytes. The results as follows: a. ALP PT analyte, Overall score: 0% Specimen Reported Expected CH-06 *16 20 - 31 CH-07 *206 242 - 365 CH-08 *88 103 - 155 CH-09 *155 182 - 274 CH-10 *271 331 - 497 b. Phosphorus PT analyte, Overall score: 20% Specimen Reported Expected CH-06 1.4 1.3 - 1.9 CH-07 *3.8 4.0 - 5.0 CH-08 *2.2 2.3 - 3.0 CH-09 *3.1 3.3 - 4.1 CH-10 *4.8 5.1 - 6.3 c. Potassium PT analyte, Overall score: 20% Specimen Reported Expected CH-06 2.3 2.3 - 3.0 CH-07 *5.5 5.6 - 6.3 CH-08 *3.4 3.5 - 4.2 CH-09 *4.5 4.6 - 5.3 CH-10 *6.9 7.0 - 7.7 d. Uric Acid PT analyte, Overall score: 0% Specimen Reported Expected CH-06 *2.1 1.5 - 2.0 CH-07 *10.0 7.5 - 9.3 CH-08 *4.9 3.6 - 4.6 CH-09 *7.7 5.8 - 7.2 CH-10 *13.3 10.0 - 12.4 Legend: * = unsatisfactory score reported 2. The TC, TP and owner affirmed by interviews on June 19, 2025, at approximately 9:30 a.m. that the laboratory obtained the PT unsatisfactory scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 35,000 patient test samples for Routine Chemistry including the ALP, Phosphorus, Potassium, and Uric Acid analytes during

	the time the laboratory received unsatisfactory proficiency testing scores. Thus, the quality and reliability of patient test reported cannot be determined.
D2127	HEMATOLOGY CFR(s): 493.851(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) reports and an interview with the technical consultant (TC); it was determined that the laboratory failed to return the proficiency testing results for Hematology for the third quarter event of 2024 (Q3-2024) within the time frame specified resulting to an unsatisfactory performance score of zero percent (0%). The findings include: 1. The laboratory received an unsatisfactory score of 0% for the Q3-2024 event after failure to submit results within the time frame as mandated by the API PT program. 2. The TC affirmed on June 19, 2025 at approximately 9:40 a.m. that the laboratory received the unsatisfactory score as mentioned in statement #1. 3. The laboratory analyzed and reported approximately 24,000 Hematology patient test samples during the time when an unsatisfactory score was obtained. Thus, the accuracy and reliability of patient results reported cannot be assured.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the surveyor's review of five (5) patient records, lack of personnel competency documentation, and interviews with the technical consultant (TC); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessments for the testing personnel (TP) prior to the start of patient testing. The findings include: 1. Surveyor's review of 5 patient records showed that competency assessment for all TP were missed to be performed for 2025 prior to the start of patient testing. 2. The TC affirmed by interview on June 19, 2025, at approximately 1:00 p.m. that no competency records were available for review for all TP hired for the year 2025. Thus, the quality and reliability of patient reports could not be assured. 3. According to the testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 71,575 patient samples annually including the time when patient testing were performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i)

	Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the lack of a complete verification of performance specifications for Hematology, Chemistry, and Endocrinology and interviews with the technical consultant (TC), testing personnel (TP), administrator, and owner on June 19, 2025, it was determined that the laboratory failed to provide a complete documentation for verification of performance specifications when new instruments were obtained. The findings include: 1. Surveyor's review of the verification of performance specifications for Alinity analyzer used for Chemistry and Endocrinology, and Pentra 60C analyzer used for Hematology showed that all the documentation lacked the accuracy studies. 2. All binders presented at the time of survey containing the verification of performance specifications were not reviewed nor signed by the laboratory director. 3. The TC, TP, administrator, and owner affirmed on an interview on June 19, 2025, at approximately 10:40 a.m., that the validation documentation missed the accuracy portion of the study as mentioned in the statements above. 4. According to the testing declaration submitted at the time of survey, the laboratory performed and reported approximately 71,575 tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's validation studies for the Alinity and Horiba analyzers, the laboratory director is herein cited for failure to ensure that the verification of performance specifications were complete and valid prior to patient testing. See D5421.
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 laboratorys 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 the years 2024 and 2025, policy /procedure, and interviews with the technical consultant, testing personnel, administrator, and owner on June 19, 2025; the laboratory director is herein cited for failing 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. 1. PT scores less than 80% for Chemistry. See D2087. 2. PT failure to participate in Hematology. See D2127.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack of the laboratory personnel competency evaluations for the year 2025 and interviews with the technical consultant, testing personnel, administrator, and owner, the laboratory director is herein cited for failure to ensure that policies and procedures established were followed to monitor individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens and perform test procedures promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209.