Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0928967	08/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Core Analytics Laboratory, Inc	14735 Califa St, 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
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for LD /LDH and LDL cholesterol, The finding included: 1. Based on review of PT records for Q2-2020, API reported an unsatisfactory score of 0% for LD/LDH and 20% for LDL cholesterol. LD/LDH (U/L) Sample # Reported Intended range Performance 6 336 364-548 Unacceptable 7 258 278-419 Unacceptable 8 434 453-681 Unacceptable 9 205 217-322 Unacceptable 10 304 321-483 Unacceptable LDL cholesterol (mg/dL) Sample # Reported Intended range Performance 6 54 41-53 Unacceptable 7 43 32-42 Unacceptable 8 65 49-63 Unacceptable 9 34 27-35 Acceptable 10 48 37-47 Unacceptable 2. Based on the laboratory testing declaration submitted at the time of the survey on 08/03/2021 the laboratory analyzed and reported approximately 3,304,698 routine chemistry tests including LD/LDH and LDL Cholesterol during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 08/03/2021 at approximately 4:15 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 Proficience Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor (TS) and laboratory testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Free T3, PSA, and Free Thyroxine. The findings included: 1. Analyte Event Performance Free T3 Q2-2019 60% PSA Q-2 2019 67% Free Thyroxine Q1-2020 40% 2. For four (4) out of four (4) random patient sampling test results reviewed covering period from 5/14/2019 to 08/10/2020, the laboratory analyzed and reported 37, 867 endocrinology quantitative tests including Free T3, PSA and Thyroxine during the period the laboratory received the unsatisfactory proficiency testing score. 3. The TS and TP confirmed on 08/03/2021at approximately 4:00 p.m. that the laboratory received the above unsatisfactory proficiency testing scores for Free T3, PSA, and Free Thyroxine.
D2109	TOXICOLOGY CFR(s): 493.845(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 second quarter event in 2019 (Q2-2019) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in the Digoxin. The findings included: 1. The API reported for Q2-2019, an unsatisfactory proficiency testing score of 40% for Digoxin analyte. 2. For two (2) out of two (2) random patient sampling test results reviewed covering period from 3/15 /2019 to 5/14/2019, the laboratory analyzed and reported Digoxin analyte during the time the laboratory received an unsatisfactory proficiency testing score. 3. The TS affirmed on August 3, 2021 at approximately 1:30 p.m. that the laboratory received the above unsatisfactory proficiency test score.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the microbiology laboratory lacks a biosafety cabinet (BSC) for processing samples for microbiology pathogens and positive blood cultures. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey 08/03 /2021 at approximately 1:30 p.m. the surveyor observed that the microbiology section lacked a BSC to work with infectious pathogens. 2. The TS and TP affirmed the lack of a BSC to process microbiology samples and work with isolated infectious

	pathogens. 3. Based on the laboratory's annual testing volume declaration submitted on august 3, 2021, the laboratory processes and reports 330,293 microbiology tests.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation on the lack of calibrated thermometers in all refrigerators and incubators to verify digital temperature readings and interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to monitor the temperature of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, August 3, 2021 based on observation and interview with the TS and TP the laboratory failed to have calibrated thermometers on refrigerators, freezers, and incubators that verify accurate digital thermometers readings which affect proficiency and patients' samples testing. 2. The TS and GS confirmed on 08/03 /2021, at approximately 11:30 a.m. that the laboratory has no calibrated thermometers in refrigerators, freezers, and incubators. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 18,043 samples daily
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 surveyors' observation, examination of laboratory reagents, and interview with the technical supervisor (TS) and testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, August 3, 2021 at approximately 1:00 p.m.the surveyor found the Gram stain iodine reagent being used beyond its expiration date: Reagent Lot # Expiration Date Gram stain iodine 153601 04/30/2021 2. The TP affirmed on 08/03/2021 at approximately 1:15 p. m.using Gram stain iodine reagent beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 328,213 Bacteriolo tests annually including gram stains.
D5815	TEST REPORT CFR(s): 493.1291(h)

	When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, patient test records review from March 15, 2019 to July 20, 2021, and interview with the technical supervisor (TS); it was determined that the laboratory failed to have a policy for turn-around time (TAT) for all tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for ten (10) out of ten (10) randomly chosen patients at the time of the survey (August 3, 2021). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory TS on August 3, 2021 at approximately 12:00 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the ordering physicians. 3. The laboratory's testing declaration form, signed by the laboratory director on 08/03/2021, stated that the laboratory performs 6,585,798 test annually.
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 review of the laboratory's records for policies and procedures, proficiency testing results, expiration date of reagents in use, lack of a biosafet cabinet, and interview with the technical supervisor and laboratory staff on August 3, 2021; it was determined that the laboratory director failed to ensure that several aspects of the preanalytical and analytical phases of laboratory testing were monitored. See D3011, D5413, D5415, D5417, D2098, D2109, and D2088 .