Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0928967	01/07/2019
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
D2020	BACTERIOLOGY CFR(s): 493.823(a) 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 second quarter (Q2-2017) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte. The findings included: a. Q2-2017, API reported 53% for Susceptibility testing. b. For seven (7) out of seven (7) random patient sampling test results reviewed covering period from 5/6/2017 to 3/15/2018, the laboratory analyzed and reported susceptibility tests for both gram positive and gram negative organisms during the time the laboratory received an unsatisfactory proficiency testing score for susceptibility tests. c. The technical consultant confirmed (1/7/2019, 1530), that the laboratory received the above unsatisfactory proficiency test score.
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 third quarter (Q3-2017), first quarter (Q1-2018) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined

	that the laboratory failed 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. The findings included: a. API Reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year Calcium 20% Q3-2017 LDH 0% Q1-2018 b. For thirteen (13) out of thirteen (13) random patient sampling test results reviewed covering period from 3/5/2017 to 2/5/2018, the laboratory analyzed and reported Calcium analyte during the time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (1/7/2019, 1530), that the laboratory received the above unsatisfactory proficiency test 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 second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte. The findings included: a. Q2-2018, API reported 40% for Triiodothyronine (T3) analyte. b. For two (2) out of two (2) random patient sampling test results reviewed covering period from 10/15/2018 to 10/21/2018 the laboratory analyzed and reported T3 during the approximate time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (1/7/2019, 1530), that the laboratory received the above unsatisfactory proficiency test score.
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 third quarter (Q3-2018) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte. The findings included: a. Q3-2018, API reported the unsatisfactory proficiency testing score of 60% for Theophylline. b. For two (2) out of two(2) random patient sampling test results reviewed covering period from 2/3/2017 and 10/16/2018, the laboratory analyzed and reported Theophylline analyte during the time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (1/7 /2019, 1530), that the laboratory received the above unsatisfactory proficiency test score.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to at least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. API reported the following unsatisfactory proficiency testing scores. Routine Chemistry Analyte: Score: Event /Year: Ammonia 33% Q1-2017 UMicro Alb 0% Q2-2017 Troponin I 50% Q2-2017 LDL Chol 40% Q3-2017 UMicro Alb 0% Q1-2018 25-OH Vit D 0% Q1-2018 LDL Chol (measured) 40% Q1-2018 LDL Chol (calculated) 20% Q2-2018 Ferritin 67% Q1-2018 UIBC 0% Q2-2018 UIBC 20% Q3-2018 Toxicology Analyte: Score: Event /Year: Amikacin 60% Q1-2017 Amikacin 60% Q2-2017 Urinalysis Analyte: Score: Event/Year: Urine Bili 50% Q2-2017 Ketones 0% Q3-2018 Leuk Est 0% Q3-208 Nitrite 0% Q3-2018 Ammonia For one (1) out of one (1) random patient sampling test result reviewed for Ammonia test analyzed and reported 1/9/2018. Amikacin For two (2) out of two (2) random patient sampling test result reviewed for Amikacin test analyzed and reported 1/20/2017 and 1/15/2018. Urinalysis For five (5) out of five (5) random patient sampling test result reviewed for Urinalysis test analyzed and reported 5/6/2017 to 3/5/2018. b. Based on the laboratory's annual testing declaration submitted for 2017-2018, the laboratory analyzed and reported approximately 1,349,220 tests which included the above analytes that have received an unsatisfactory proficiency testing scores. c. The technical supervisor confirmed (1/7/2019, 1530), that the laboratory received the above unsatisfactory proficiency test scores.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of random patient sampling test results, and interview with the technical consultant, and the laboratory staff, it was determined that the laboratory failed to assess and evaluate patient test results for inconsistencies. The findings included: a. For three (3) out of five (5) random patient sampling test results reviewed covering period from 5/6/2017 503/15/2018, three (3) patient test results do not correlate with the urinalysis macroscopic against the microscopic results: Patient #1: Macro Results: Micro Results: Leuko Est. Neg 22/HPF Blood Neg 5/HPF Patient #2: Macro Results: Micro Results: Leuko Est. Neg 2/HPF Blood Neg 3/HPF Nitrite Neg Moderate Patient #3: Macro Results: Micro Results: Nitrite Neg Many b. The technical consultant, and the laboratory staff confirmed (1/28.2019, 11:30) that the laboratory has not established a system to identify and assess patient test results that appear inconsistent.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records, CMS Casper Report 0096D, and interview with the technical supervisor, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2020, D 2087, D 2098, D 2109, and D5217.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's Microbiology Gram stain Weekly Quality Control (QC) log, request for the laboratory's Gram Stain policy and procedure, and interview with the testing personnel and technical supervisor, it was determined that laboratory director failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. See D 6178.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's Microbiology Gram stain Weekly Quality Control (QC) log, request for the laboratory's Gram Stain policy and procedure, and interview with the testing personnel and technical supervisor, it was determined that the testing personnel performing high complexity testing did not follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. The findings included: a. Based on review of the laboratory's Microbiology Gram Stain Weekly QC logs covering period from 3/4/2017 to 7/24/2018, the laboratory documented Gram negative (GM-) as positive (+). b. Based on review of the above Gram Stain QC log it

	stated on the log the following: "Reaction: Control Organisms: Expected Results: Positive Staph Aureus ATCC 2593 Purple Negative E Coli AYCC 25922 Red" c. Based on the review of the laboratory's Manual Gram Stain Procedure, on page 4 of 7, it stated: "Results Gram-positive bacteria will stain purple. Gram-negative bacteria will stain pink." d. Based on the laboratory's annual volume testing declaration submitted for 2017-2018, the laboratory analyzed and reported 15,000 Bacteriology tests which included Gram stain procedures. e. The testing personnel, technical supervisor confirmed (1/28/2019, 11:30) that the laboratory has not followed its own policy and procedure in documenting the gram stain positive and negative results.