

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0879836	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Corona Pathology Cps Inc	Street Address, City, State 4444 W Riverside Dr Ste 308, Burbank, 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	<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 reviews of analyte performance of the American Proficiency Institute (API) proficiency testing performance summary records, seven (7) randomly selected patients' test requisitions from 02/05/2018 to 02/18/2020 and test results (medical records), quality control reviewed, proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Q3/2018 for the phosphorus (P) analyte. The findings included: a. API reported Proficiency Testing scores 60%: Event Analyte Sample Results Exp. Results Q3 2018 P CH-14 2.4 3.0-3.8 Q3 2018 P CH-15 3.4 4.1-5.3 b. Patient test results reviewed covering the period of Q3, 2018, the laboratory analyzed and reported phosphorus testing during this time. c. The laboratory personnel confirmed (03/10/2020, 12:30 PM) that the laboratory received the above unsatisfactory proficiency testing score. d. The laboratory annual testing declaration (03/09/2020) for routine chemistry (phosphorus included) estimated that a total test volume of 1,397,368.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(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:</p>

Based on reviews of analyte performance of the American Proficiency Institute (API) proficiency testing performance summary records, seven (7) randomly selected patients' test requisitions from 02/05/2018 to 02/18/2020 and test results (medical records), quality control reviewed, proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Q2/2018 Free T3 (FT3). The findings included: a. API reported Proficiency Testing scores 20%: Event Analyte Sample Results Exp. Results Q2 2018 FT3 CH-06 7.0 3.8-6.6 Q2 2018 FT3 CH-07 6.6 3.6-5.1 Q2 2018 FT3 CH-09 6.2 3.3-4.7 Q2 2018 FT3 CH-10 7.4 4.3-7.2 b. Patient test results reviewed covering the period of Q2, 2018, the laboratory analyzed and reported Free T3 tests during this time. c. The laboratory personnel confirmed (03/10/2020, 12:30 PM) that the laboratory received the above unsatisfactory proficiency testing score. d. The laboratory annual testing declaration (03/09/2020) for Endocrinology (Free T3 included) estimated that a total test volume of 1,397,368.