

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0879836	(X3) Date Survey Completed 07/21/2022
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 review of the American Proficiency Institute (API) proficiency testing (PT) records, randomly chosen patient results' review, and interview with the general supervisor (GS) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the following Routine Chemistry analytes: CO2 and TIBC measured; for the second event 2020 (Q2-2020), Calcium Total and Sodium; for the third event 2020 (Q3-2020), and Bilirubin Total, Ferritin, and Folate for the first event of 2021 (Q1-2021). 1. Based on review of PT records, API reported the following unsatisfactory scores: Analyte Event Score CO2 Q2-2020 40% TIBC Q2-2020 40% Calcium Q3-2020 60% Sodium Q3-2020 40% Bilirubin Q1-2021 60% Ferritin Q1-2021 50% Folate Q1-2021 50% 2. Based on the laboratory testing declaration submitted at the time of the survey on May 5, 2022, the laboratory analyzed and reported approximately 15,437 Routine Chemistry tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The GS affirmed on 7/21/2022 2at approximately 1:30 p.m.. that the laboratory received the above unsatisfactory proficiency testing scores.</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>

This STANDARD is not met as evidenced by:
 Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, random patient sampling test results, and interview with the general supervisor (GS) 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 Parathyroid Hormone (PTH) and PSA analytes PT for the first event of 2021 (Q1-2021). The findings included: 1. Analyte Event Performance PTH Q1-2021 50% PSA Q1-2021 50% 2. For three (3) out of three (3) random patient sampling test results reviewed covering period from 12/30/2020 to 2/18/2021, the laboratory analyzed and reported approximately 700 PTH and PSA test results during the period the laboratory received the unsatisfactory proficiency testing score. 3. The GS and TP confirmed on July 21, 2022, at approximately 11:15 a.m. that the laboratory received the above unsatisfactory proficiency testing scores for PTH and PSA.

D3001

FACILITIES
 CFR(s): 493.1101(a)(1)

The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

This STANDARD is not met as evidenced by:
 Based on observation of the laboratory testing area and interview with the general supervisor (GS) and testing personnel (TP); it was determined that the laboratory testing area failed to be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the clinical testing process. The findings included: 1. The laboratory area consisted of three small rooms (approximately 1,500 square feet) which serves to house the automated testing instruments for the Chemistry and Endocrinology analyzers, Toxicology GC/MS instruments, two Biofire instruments, two Air Clean Biosafety cabinets, PCR processing and analyzing; testing personnel's office, as well as storage area for reagents, documents, and patients' results and data. 2. The space designated for the laboratory appears to be insufficient. The room is crowded, difficult to maintain, inappropriate for proper traffic flow, and fails to provide sample integrity and quality for testing, in addition to increase risk of contamination of paperwork and possible cross-contamination of samples. 3. The GS and TP affirmed on July 21, 2022, at approximately 1:00 p.m. that the laboratory failed to be constructed, arranged and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. 4. The laboratory's testing declaration form, signed by the laboratory director on July 7/20/2022, stated that the laboratory performs approximately 1,326,549 tests annually.

D3005

FACILITIES
 CFR(s): 493.1101(a)(3)

Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

This STANDARD is not met as evidenced by:
 Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR)

testing, and interviews with the laboratory's general supervisor (GS) and testing personnel (TP) on July 21, 2022 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using automated extraction and manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on July 21, 2022, at approximately 12:15 p.m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same room without unidirectional flow in the same room and Biosafety cabinet where samples were processed and tested for Toxicology. 3. The GS and TP confirmed by interview on 7/21/2022 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 186,300 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.

D6083

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:
 Based on the surveyor's direct observations of the laboratory's size for the testing volume, number of instruments, SARS-CoV-2 PCR testing processes, and interview with the laboratory's general supervisor and testing personnel on July 21, 2022; the laboratory director failed to ensure that the size of the physical plant and environmental conditions of the laboratory were appropriate for the number of personnel, volume of testing, and PCR testing performed. Findings include: See D3001 and D3005.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
 Based on interviews with the technical supervisor, general supervisor, and testing personnel, proficiency test reports documents for Routine Chemistry and Endocrinology and policies and procedures record review on July 21, 2022; the laboratory director failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. See D2087 and D2098.