Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0879836	01/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Corona Pathology Cps Inc	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
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(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 Q1-2017 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) the laboratory failed to attain an overall General Immunology testing event score of at least 80 percent, constituting unsatisfactory performance. Findings include: a. The laboratory performed four tests in the specialty Immunology. b. CMS reported scores of 100% for ANA (Anti-nuclear Antiboday) and ASO (Anti-Streptolysin O Titer); and scores of 0% for HBsA (Hepatitis B Surface Antigen) and Anti-HBc (Hepatitis B Core Antibody). And thus, the laboratory had the overall score of 52% for General Immunology. b. See D2077. .
D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

	This STANDARD is not met as evidenced by: Based on review of Q1-2017 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), the lack of laboratory proficiency testing documents, and interviews with laboratory personnel and AAB personnel, the laboratory failed to participate in Non-chemistry/ Immunology proficiency testing for HBsAg (Hepatitis B Surface Antigen) and Anti-HBc (Hepatitis B Core Antibody). Findings include: a. CMS and AAB reported scores of 0% for hepatitis testing: HBsA and Anti-HBc. b. The laboratory was unable to provide for review proficiency testing documents for Q1-2017 Non-chemistry. c. The Technical Consultant affirmed (12/15/17) that the laboratory failed to participate in hepatitis proficiency testing for Q1-2017. d. The reliability and quality of HBsA and Anti-HBc results reported during the timeframe January to April, 2017, could not be assured. Based on the stated estimate of 137 tests per year, the laboratory reported approximately 11 results each month for these two tests. .
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 reviews of proficiency testing reports from CMS (report 155D, Individual laboratory profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing documents, and patients test records; and interview with laboratory personnel, the laboratory failed to attain a score of at least 80% for Magnesium for Q3-2016, constituting unsatisfactory analyte performance. Findings include: a. CMS reported the score of 20% for Magnesium. b. AAB reported the score of 20% for Magnesium, mg/dL, with the comments "Reagent code not reported. Instrument code not reported"; and the score of 100% for Magnesium MEq/L using Roche Cobas Integra. c. The Technical Consultant affirmed (12/15/17) the root cause for the score of 20% was due to data entry error in reporting to AAB. d. The reliability and quality of results reported for Magnesium during the timeframe September to December 2016 could not be assured. A few examples are as follows: Date Accession ---------- ---------- 9/21/16 16001135 10/19/16 16001195 11/03/16 16001221 12/03/16 16001292
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by:

	Based on review of 2017 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), the lack of laboratory proficiency testing documents, and interviews with laboratory personnel and AAB personnel, the laboratory failed to participate in proficiency testing for Chemistry for Q2-2017. Findings include: a. The laboratory was unable to provide for review proficiency testing documents for Q2-2017 Chemistry. b. AAB proficiency testing reports for Q2-2017 Chemistry revealed "No data received" for all of the analytes. AAB personnel affirmed (1/12/18) no results were received from the laboratory, and that the scores were reported as "100% Er (Exclusion requested)". c. The CMS reporting system didn't recognize "100% Er", and thus reported false scores of 100% for individual chemistry tests: ALT (SGPT) Glucose Albumin Iron Alkaline phosphatase LDH Amylase Magnesium AST (SGOT) Potassium Total Bilirubin Sodium Calcium Total protein Chloride Triglycerides Total Cholesterol BUN HDL (cholesterol) Uric acid Creatine kinase d. The Technical Consultant affirmed (12/15 /17) that the laboratory failed to participate in proficiency testing for Q2-2017 Chemistry. e. The reliability and quality of results reported during the timeframe May to August, 2017, could not be assured. Based on the stated estimated total annual chemistry test volume of 26,000; the laboratory reported approximately 2,166 results each month.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of 2017 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), the lack of laboratory proficiency testing documents, and interviews with laboratory personnel and AAB personnel, the laboratory failed to participate in proficiency testing for Endocrinology for Q2 -2017. Findings include: a. The laboratory was unable to provide for review proficiency testing documents for Q2-2017 Endocrinology. b. AAB proficiency testing reports for Q2-2017 Endocrinology revealed "No data received" for all of the analytes. AAB personnel affirmed (1/12/18) no results were received from the laboratory, and that the scores were reported as "100% Er (Exclusion requested)". c. The CMS reporting system didn't recognize "100% Er", and thus reported false scores of 100% for individual tests in endocrinology: Free T4 (Thyroxine) hCG (pregnancy hormone) Total T3 (Triiodothyronine) TSH (Thyroid Stimulating Hormone) Total T4 (Thyroxine) d. The Technical Consultant affirmed (12/15/17) that the laboratory failed to participate in proficiency testing for Q2-2017 Endocrinology. e. The reliability and quality of results reported during the timeframe May to August, 2017, could not be assured. Based on the stated estimated total annual endocrinology test volume of 2,830; the laboratory reported approximately 235 results each month.

D2121	HEMATOLOGY CFR(s): 493.851(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 2016 - 2017 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing documents, and patients test records; and interview with laboratory personnel, the laboratory failed to attain scores of at least 80% for PTT (Partial Thromboplastin Time for coagulation) in Q2-2016; and for Cell ID (White Blood Cell Identification, microscopic hematology) in Q3-2017, constituting unsatisfactory analyte performances. Findings include: a. PTT 1) CMS reported the score of 60% for Q2-2016; and AAB reported the score of 60% based on the laboratory's reporting of 2 unacceptable results out of 5. 2) The Technical Consultant affirmed (12/15/17) the aforementioned unsatisfactory score, and thus, unsatisfactory analyte performance in testing for PTT. 3) The reliability and quality of results reported for PTT during the timeframe May to August 2016 could not be assured. A few examples are as follows: Date Accession ---------- ---------- 6/30/16 16000947 7/27/16 16000990 8/10 /16 16001016 b. Cell ID 1) CMS reported the score of 40% for Q3-2017; and AAB reported the score of 40% based on the laboratory's reporting of 3 unacceptable identifications out of 5. 2) The Technical Consultant affirmed (12/15/17) the aforementioned unsatisfactory score, and thus, unsatisfactory analyte performance in microscopic examination of Cell Identification. 3) The reliability and quality of results reported for Manual Differentials during the timeframe October to December 2017 could not be assured. Based on the stated estimated annual test volume of 200, approximately 16 Manual Differentials with Cell Identification were reported each month. A few examples are as follows: Date Accession ---------- ---------- 10/04 /17 22019 11/03/17 29446 12/04/17 37600
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of 2017 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), the lack of laboratory proficiency testing documents, and interviews with laboratory personnel and AAB personnel, the laboratory failed to participate in proficiency testing for hematology coagulation tests PTT (Partial Thromboplastin Time) and PT (Prothrombin Time). Findings include: a. CMS reported 2017 scores for PTT and PT

	as follows [NR*, No results reported]: Event 1 Event 2 Event 3 ---------- ---------- ---------- PTT 0% No score 0% NR* PT 0% 100% 0% NR* b. AAB proficiency testing reports revealed "No data received" for PTT for Q1 and Q2 of 2017; as well as for PT for Q1-2017. AAB personnel affirmed (1/12/18) no results were received from the laboratory. c. The Technical Consultant affirmed (12/15/17) the aforementioned scores and lack of participation. d. The reliability and quality of PTT and PT results reported in 2017 could not be assured. .
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 2016- 2017 proficiency testing reports from AAB (American Association of Bioanalysts), and interview with laboratory personnel, the laboratory failed to verify the accuracy of H. pylori Antibody, Hepatitis C virus Antibody, Hepatitis A Antibody, CO2, PTH (Parathyroid Antibody), and Urinalysis, microscopic examination of sediment. Findings include: a. The laboratory chose to participate in AAB's proficiency testing programs as the means to satisfy the requirement to verify the accuracy of testing. b. AAB reported unsatisfactory scores as follows based on the laboratory's unacceptable results: Event / year Test Score ---------- ---------- ---------- Q2- 2016 H pylori 50% Q2- 2017 Anti-HCV 40% Q3- 2017 Anti-HAV 60% Q3- 2017 CO2 40% Q3- 2017 PTH 50% Q3- 2017 Urinalysis, sediment 50% c. The Technical Supervisor affirmed (12/15/17) the aforementioned unsatisfactory scores; and thus, accuracy of testing failed to be verified. d. The reliability and quality of results reported during the timeframes of unsatisfactory testing could not be assured. Based on the stated estimates of annual test volumes, the laboratory reported approximate monthly volumes as follows: H pylori ..... 13 Anti-HCV..... 5 Anti-HAV..... 5 CO2.....not provided PTH.....16 Urinalysis, microscopic.....8 e. A few examples of results reported are as follows: Date Accession Test ---------- ---------- ---------- 5/25/16 16000746 H pylori 7/27/16 16000990 " 8/10/16 16001016 " 5/26/17 1356 Anti-HCV 6/15/17 1647 " 7/26/17 4982 " 8/02/17 5705 " 10/24/17 26602 Anti-HAV 11/07/17 30285 " 9/19/17 18144 CO2 10/04/17 22019 " 11/03/17 29446 " 12/04 /17 37600 " 9/05/17 14264 PTH 10/02/17 21304 " 11/06/17 29929 " 12/13/17 39969 " 9/11/17 15753 Urinalysis 10/09/17 22727 " 11/14/17 32064 " 12/08/17 38700 "
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of six BioFire FilmArray muliplex PCR instruments in the

	laboratory, review of patients test results, manufacturer's instructions for Respiratory Panel and GI (Gastrointestinal) Panel, and the laboratory written policy for quality control; the lack of quality control documents, and interviews with a BioFire technical representative and the Technical Consultant, the laboratory failed to include a Negative and a Positive control material each day of testing patients specimen. Findings include: a. The Respiratory Panel includes 20 tests for bacteria and virus as follows: Adenovirus Coronavirus: 229E; HKU1; NL63; OC43 Human Metapneumovirus Human Rhinovirus/ Enterovirus Influenza A; H1; H3, H1-2009 Influenza B Parainfluenza: 1, 2, 3, 4 Respiratory syncytial virus Bordetella pertussis Chlamydia pneumoniae Mycoplasma pneumoniae b. The GI Panel includes 22 tests for bacteria, parasites, and virus as follows: Enteroaggregative E. coli (EAEC) Enterpathogenic E. coli (EPEC) Enterotoxigenic E. coli (ETEC) It/st Shiga-like toxin-producing E. coli (STEC) E. coli O157 Shigella/Enterovinvasive E. coli (EIEC) Campylobacter (jejuni / coli / upsaliensis) Clostridium difficile Toxins A/B Plesiomonas shigelloides Salmonella Vibrio (parahaemolyticus / vulnificus / cholerae) Vibrio cholerae Yersinia enterocolitica Cryptosporidium Cyclospora cayetanensis Entamoeba histolytica Giardia lamblia Adenovirus F 40/41 Astrovirus Norovirus GI/ GII Rotavirus A Sapovirus (I, II, IV, V) c. The manufacturer's Instruction Booklets states the following: 1) Each test pouch includes two internal controls to monitor the testing process. A BioFire technical representative affirmed (1/18/18) that the pouch control named "RNA Process Control" is a yeast organism that undergoes lysis (extraction) and all phases of amplification, analysis, and detection; that the "PCR2 Control" is DNA, and that neither are specific to the organisms being tested in the panels. 2) The instructions recommend including "external positive and negative controls regularly", to use transport medium as the external Negative Control, and "previously characterized positive samples" or samples" spiked with well characterized organisms as external Positive Controls. External controls should be used in accordance with" (CLIA). d. The laboratory failed to provide for review documents for external Negative and Positive Controls each day of testing patients specimen. e. IQCP 1) The laboratory document titled "BioFire FilmArray Individualized Quality Control Plan (IQCP)", effective 5/28/17, stated that external controls were to be performed Monthly and limited to 2 out of 6 analyzers, on a rotating basis. 2) However, the laboratory failed to have documents for external QC data demonstrating the stability of the BioFire test systems to provide accurate and reproducible positive and negative results each day of testing for a Month (30 - 31 consecutive days), prior to implementing the practice of reduced frequency when testing patients specimen. f. The Technical Consultant affirmed (1/19/18) that historical QC data was limited to 20 days of testing. g. The reliability and quality of results reported for BioFire Respiratory and BioFire GI panels could not be assured. Based on the stated estimates of annual test volumes, the laboratory reported approximately 43,333 repiratory results and 18,200 GI results each month beginning in May 2017. A few examples of results reported without QC are as follows: Date Accession Test ---------- ---------- ---------- 6/07/17 1433 Respiratory 7 /25/17 4596 " 8/07/17 6311 " 9/08/17 15338 " 10/18/17 24433 " 11/30/17 35554 " 12 /27/17 43449 " 6/07/17 1434 GI 7/25/17 4622 " 8/04/17 6179 " 9/11/17 15290 " 10/18 /17 23753 " 11/29/17 35527 " 12/19/17 41580 "
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in ensuring the quality control program for molecular based assays is established to include positive and negative controls each day of testing to assure the quality of results obtained or that the Individualized Quality Control Plan included appropriate historical QC studies See D5449. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on survey findings and deficiency cited, the Technical Consultant is herein cited for deficient practice in establishing a quality control program appropriate for the molecular testing performed to include positive and negative controls each day of testing specimen or that the Individualized Quality Control Plan included appropriate historical QC studies. See D5449.