Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0273114	02/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cfp Physicians Group	985 Sr 436, Casselberry, FL	

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
D0000	A Recertification survey was conducted on February 5, 2020. CFP Physicians Group was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all testing personnel rotate through the testing of proficiency testing (PT) samples for 6 out of 6 events in Hematology (2018 1st, 2nd & 3rd; 2019 1st, 2nd & 3rd), 3 out of 6 events in Chemistry Core (2018 1st, 2nd & 3rd) (2018 1st, 2nd, and 3rd, 2019 1st, 2nd & 3rd), and 2 out of 4 events in Chemistry Miscellaneous (2018 1st & 2nd) (2018 1st & 2nd, 2019 1st & 2nd). Findings: Review of the American Proficiency Institute (API) PT attestation forms showed that Testing Personnel A performed the PT for: Hematology - 6 out of 6: 2018 1st, 2nd & 3rd, and 2019 1st, 2nd & 3rd Chemistry Core -3 out of 6: 2018 1st, 2nd & 3rd Chemistry Miscellaneous 2 out of 4: 2018 1st & 2nd. Review of the CMS-209 form "Laboratory Personnel Report (CLIA)" that was signed and dated by the Laboratory Director on 10/30/20 listed 3 testing personnel. During an interview on 2/5/20 at 3:40 PM, the Testing Personnel confirmed that she had performed all the proficiency testing for 2018 and 2019 in Hematology, and 2018 in Chemistry Core and Chemistry Miscellaneous.
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 record review and interview, the laboratory failed to receive at least 80% score for two analytes for the second testing event of 2019 for the specialty of Chemistry. Findings: Review of the American Proficiency Institute (API) proficiency testing records revealed that the laboratory received a score of 0% for the analyte Glucose and 60% for the analyte Calcium for the second event of 2019. During an interview on 2/5/20 at 3:41 PM, Testing Personnel A confirmed the laboratory the proficiency testing results.
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 record review and interview, the laboratory failed to receive at least 80% score for two analytes for the third testing event of 2018 for the specialty of Hematology. Findings: Review of the American Proficiency Institute (API) proficiency testing records revealed that the laboratory received a score of 0% for the analyte Erythrocyte Count and 60% for the analyte Hemoglobin for the third event of 2018. During an interview on 2/5/20 at 3:41 PM, Testing Personnel A confirmed the laboratory the proficiency testing results.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to properly label quality control and calibrator bottles currently in use in Hematology, Chemistry and Endocrinology testing. Findings: 1. A tour of the laboratory on 2/5/20 at 9:25 AM revealed that the low, normal, and high Cell-Dyn 18 Plus Controls (lot #L9350, N9350 & H9350) for the Cell-Dyn Emerald Hematology analyzer did not have the new expiration date on the opened vials. Review of the Assay Sheet for the Cell-Dyn 18 Plus Controls noted that the controls are stable for 8 consecutive days once opened. 2. A tour of the laboratory on 2/5/20 at 9:30 AM revealed that the A Pointe Scientific Level 1 Cont Serum (lot #926301-323 & 929001-022), Level 2 Cont Serum (lot #920501-323 & 920501-022), and Chemistry Calibrator (lot #930103-325) for the Mindray BS-200 Chemistry analyzer did not have the new expiration date on the opened vials. Review of the package inserts for the A Pointe Scientific controls and calibrators noted that the reconstituted controls and calibrators are stable for seven days. 3. A tour of the laboratory on 2/5/20 at 9:40 AM revealed that the Access

	Calibrator bottles for the Beckman Coulter Access 2 Immunoassay Endocrinology analyzer did not have an open date on the bottles. The Access Hybritech PSA Calibrators (lot #921357) were labeled "recd 11/15/19" on the box. The Access TSH (3rd IS) Calibrators (lot #920910) had no date on the box or bottles. The Access Vitamin B12 Calibrators (lot #921025) were labeled as "11/21" on the box. During an interview on 2/5/20 at 10:25 PM, Testing Personnel A acknowledged she did not write the new expiration dates on the Hematology controls and Chemistry controls and calibrator, and that the open dates for Endocrinology calibrators were not recorded on the bottles.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the daily background check for the Cell-Dyn Emerald Hematology analyzer from 2/5/18 to 2/5 /20. Findings: Review of the quality control records showed that there were no records to show the results of the daily background check on the Cell-Dyn Emerald Hematology analyzer. During an interview on 2/5/20 at 4:00 PM, Testing Personnel A confirmed that the laboratory performed background counts on the Cell-Dyn Emerald Hematology analyzer, that they didn't printouts the background check results, and she didn't know how to retrieve the results from the analyzer.