Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0273114	06/24/2022
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 June 17, 2022 to June 24, 2022. CFP Physicians Group clinical laboratory 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 testing of proficiency testing (PT) samples for 5 (2020 2nd & 3rd; 2021 2nd & 3rd; 2022 1st) of 6 events (2020 2nd & 3rd; 2021 1st, 2nd & 3rd; 2022 1st) in the specialty of Hematology. The laboratory also failed to have all testing personnel rotate through the testing of proficiency testing (PT) samples for 6 (2020 3rd; 2021 1st, 2nd & 3rd, 2022 1st & 2nd) of 7 events (2020 2nd & 3rd; 2021 1st, 2nd & 3rd, 2022 1st & 2nd) in the subspecialties of Routine Chemistry and Endocrinology. This is a repeat deficiency from the recertification survey of 02/05 /2022. Findings: Review of the American Proficiency Institute (API) PT attestation forms showed Testing Personnel A performed the PT for Hematology for 2020 2nd & 3rd events; 2021 2nd & 3rd events; and 2022 1st event. Review of the API PT records for Hematology testing listed the following submission deadlines: 2020 2nd event 07 /24/2020 2020 3rd event 11/20/2020 2021 1st event 03/31/2021 2021 2nd event 08/04 /2021 2021 3rd event 11/23/2021 2022 1st event 03/30/2022 Review of the API PT attestation forms showed Testing Personnel A performed PT for Chemistry Core (Routine Chemistry and Endocrinology) for the 2020 3rd event; 2021 1st, 2nd & 3rd; 2022 1st & 2nd. Review of the API PT records for Chemistry Core testing listed the following submission deadlines: 2020 2nd event 06/05/2020 2020 3rd event 09/11

	/2020 2021 1st event 02/03/2021 2021 2nd event 06/09/2021 2021 3rd event 09/15 /2021 2022 1st event 02/02/2022 2022 2nd event 06/08/2022 Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 06/17 /2022 listed three Testing Personnel (A, B, C). Testing Personnel A had competency evaluations performed on 01/13/2020, 01/14/2021, and 12/20/2021. Testing Personnel B had competency evaluations performed on 01/04/2021 and 01/19/2022. Testing Personnel C had competency evaluations performed on 01/13/2020, 01/14/2021, and 12/20/2021. Testing Personnel D was no longer employed by the laboratory and had competency evaluations performed on 12/19/19. The laboratory was unable to locate Personnel D's 2020 competency evaluation. Testing Personnel E was no longer employed by the laboratory and had competency evaluations performed on 01/13/20. On 06/17/2022 at 10:30 AM, the Technical Consultant stated Testing Personnel A did most of the PT. On 06/17/2022 at 3:00 PM, Testing Personnel A stated Testing Personnel B started working in the laboratory in 10/2020 and Testing Personnel C started working in the laboratory in 2/2022. Testing Personnel A also stated Testing Personnel D's last day of work in the laboratory was 07/20/2021 and Testing Personnel E's last day working in the laboratory was 06/20/2021.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain copies of the testing results (instrument printouts) from the proficiency testing (PT) for 2 (2020 2nd & 3rd) of 6 events (2020 2nd & 3rd; 2021 1st, 2nd & 3rd; 2022 1st) in the specialty of Hematology. The laboratory failed to maintain copies of testing results (instrument printouts) from proficiency testing (PT) for 2 (2020 2nd & 3rd) of 6 events (2020 2nd & 3rd; 2021 1st, 2nd & 3rd; 2022 1st) in the subspecialties of Routine Chemistry and Endocrinology (Chemistry Core). Findings: Review of the American Proficiency Institute (API) PT records showed instrument printouts for the 2020 2nd and 3rd events in Hematology and the 2020 2nd and 3rd events in Chemistry Core were missing On 06/17/2022 at 1:55 PM, the Technical Consultant stated they were unable to locate the instrument printouts.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During

	the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to report all SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) test results as required to Florida Department of Health (FDOH) since testing began on 12/08/2020. Findings: Cross Reference D3009. Based on observation and interviews, the laboratory failed to report their negative Corona Virus Disease 2019 (COVID-19) test results and failed to provide documentation of reporting positive test results as required by the Florida Department of Health from 12/08/2021 to 06/17/2022.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to report negative Corona Virus Disease 2019 (COVID-19) test results and failed to provide documentation of reporting positive test results as required by the Florida Department of Health (FDOH) from 12/08/2021 to 06/17/2022. Findings: The mandatory reporting requirements outlined by FDOH Executive Order 20-013, section 381.0031, Florida Statutes, and Florida Administrative Code Chapter 64D-3, noted laboratories must report both negative and positive COVID-19 test results. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 06/17/2022, the laboratory listed they performed COVID-19 testing using the Abbott Diagnostics ID instrument. A tour of the laboratory on 6/17/20 at 9:40 AM, revealed the laboratory had Abbott Diagnostics ID NOW Instrument, a box containing Package #1, the test base, and a box containing Package #2, the transfer cartridge. On 06/17/2022 at 3:25 PM, the Office Manager stated they faxed the positive COVID-19 test results to FDOH and they had not reported the negative COVID-19 results. On 06/17/2022 at 3:27 PM, the Office Manager stated that she kept records showing the positive results were faxed for a while, then stopped and threw all the records out. On 06/21/2022 at 8:31 AM, Testing Personnel A reported in an email the first day of COVID-19 testing was 12/18/2020. On 06/24/2022 at 3:27 PM, the Office Manager reported in an email the laboratory had performed 636 COVID-19 tests.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in

	493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, observation, and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and identify problems. Findings: Cross Reference D5415. Based on observation and interview, the laboratory failed to properly label quality control and calibrator bottles currently in use in Hematology and Chemistry testing from 06/13 /2022 to 06/17/2022. This is a repeat deficiency from the 02/05/2020 recertification survey.
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 and Chemistry testing from 06/13/2022 to 06/17/2022. This is a repeat deficiency from the 02/05/2020 recertification survey. Findings: According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 06/17/2022, the laboratory had a total estimated annual test volume of 68,433 tests per year. 1. A tour of the laboratory on 6/17/20 at 9:40 AM, revealed the low, normal, and high Cell-Dyn 18 Plus Controls (lot #L2094, N2094 & H2094) 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 the controls had a "8 Consecutive Day Open - Tube Stability." 2. A tour of the laboratory on 6/17/20 at 9:40 AM revealed the Beckman Coulter Lyophilized Chemistry Calibrator - Level 1 (lot #9610101) and Level 2 (lot #9610101) for the Beckman Coulter AU 480 Chemistry analyzer did not have the new expiration date on the opened vials. Review of the package inserts for the Beckman Coulter Lyophilized Chemistry Calibrator noted "Reconstituted calibrator materials are stable for 7 days from the date of reconstitution . . . ." On 6/17/20 at 9:45 AM, Testing Personnel A stated they only wrote the opened date on the reagents.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review, and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference

	D6016. Based on record review and interview, the Laboratory Director failed to ensure proficiency testing was performed for all testing personnel in the laboratory as required by Subpart H from 06/2020 to 06/17/2022.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review, and interview, the Laboratory Director failed to ensure proficiency testing was performed by all testing personnel in the laboratory as required by Subpart H from 06/2020 to 06/17/2022. Findings The Laboratory Director failed to ensure all testing personnel rotated through testing of proficiency testing (PT) samples for 5 (2020 2nd & 3rd; 2021 2nd & 3rd; 2022 1st) of 6 events (2020 2nd & 3rd; 2021 1st, 2nd & 3rd; 2022 1st) in the specialty of Hematology. The laboratory failed to have all testing personnel rotate through the testing of proficiency testing (PT) samples for 6 (2020 3rd; 2021 1st, 2nd & 3rd, 2022 1st & 2nd) of 7 events (2020 2nd & 3rd; 2021 1st, 2nd & 3rd, 2022 1st & 2nd) in the subspecialties of Routine Chemistry and Endocrinology. This is a repeat deficiency form the recertification survey on 02/05/2022. (See D2007)