Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0677979	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Clearfield Professional Group Ltd	820 Turnpike Ave, Clearfield, PA	

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	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 review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the Testing Personnel (TP)#1, the laboratory failed to attain a score of at least 80% for 15 of 18 analytes in the MLE PT Routine Chemistry in 2020 and 2021. Findings Include: 1. On the day of survey, 04/28/2022, review of the MLE PT records revealed the following analytes had less than 80% score in 2020 for routine chemistry: - 2020 Event 2: - Alanine Aminotransferase (ALT): 40% - Albumin: 40% - Alkaline Phosphate: 60% - Total Bilirubin: 20% - Calcium: 60% - Total Cholesterol: 20% - high-density lipoprotein (HDL) Cholesterol: 60% - Creatine: 20% - Glucose: 20% -Total Iron: 20% - Potassium: 40% - Sodium: 20% - Total Protein: 40% - Blood urea nitrogen (BUN): 20% - Uric Acid: 20%. - 2020 Event 3: - Chloride: 40% -2021 Event 2: - Blood urea nitrogen (BUN): 60%. 2. The TP 1 confirmed the findings above on 04/28/2022 at 12:30 pm.
D2122	HEMATOLOGY CFR(s): 493.851(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 the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the Testing Personnel (TP)#1, the laboratory failed to

	attain a score of at least 80% for 2 of 6 analytes in the MLE PT Hematology in 2021. Findings Include: 1. On the day of survey, 04/28/2022, review of the MLE PT records revealed the following analytes had less than 80% score in 2021 for Hematology: - 2021 Event 1: - Hematocrit: 40 % - 2021 Event 2: - Hemoglobin: 0% - White Blood Cell (WBC): 40%. 2. The TP 1 confirmed the findings above on 04/28/2022 at 12:30 pm.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and interview with the Testing Personnel (TP) #1, the laboratory failed to perform two control materials of different concentrations each day of patient testing for 4 of 4 endocrinology analytes and 2 of 2 urine chemistry analytes from 04/28/2020 to the day of survey. Findings include: 1. On the day of survey, 04/28/2022, review of The Qualigen Fastpack (TSH, Free T4, PSA, and Vitamin D) and the Afinion Urine ACR (creatinine and albumin) records revealed, the laboratory did not perform two levels of control material each day of patient testing form 04/28/2020 to 04/28/2022. 2. The TS #1 confirmed the findings above on 09/25/2020 ay 10:45 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of Medical Laboratory Evaluations (MLE) proficiency testing (PT) records and interview with Testing Personnel (TP) #1, the laboratory director failed to identify problems that required a corrective action for 2 of 3 Hematology PT events in 2020 and 2021. Findings Include: 1. On the date of survey, 04/28/2022, the laboratory could not provide documentation of corrective action assessment for Hematology: -2020 Event #1: Lymphocytes, Granulocytes, and Monocytes Score 80% -2020 Event #2: Ganulocytes Score 80% -2021 Event #2: White Blood Cell (WBC) count score 40% Hemoglobin (HBG) score 0% -2021 Event #3: Hemoglobin Score 80% 2. TP #1 confirmed the findings above on 04/28/2022 at 12:30 pm.