Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0677979	02/21/2018
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of Select medical products operation manual, and interview with the Testing Personnel (TP) # 1 and #2, the laboratory failed to perform manufacture specified calibrations on the Select Medical Products PSS 868 HX 6 Place Horizontal Spin Centrifuge since the initial installment of the centrifuge to 2017. Findings include: 1. Select Medical Products PSS 868 HX 6 Place Horizontal Spin Centrifuge Operations Manual's Calibration section states "According to Code of Federal

	Regulations Title 21, centrifuge requires verification or calibration as follows: 1) Before initial use; 2) after repair or adjustments; 3) 6 months after use. The centrifuge timer timer however should be checked at least every 3 months." 2. On the date of survey, 02/21/2018, review of the Select medical products operation manual, revealed that the centrifuge calibration was not performed per manufactures instructions. 3. In the past 12 month period 34,976 Hematology specimen have been tested. 4. TP #1 and #2 confirmed the findings above on 02/21/2018 around 02:15 PM.
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) 2016 and 2017 proficiency testing (PT) scores and interview with laboratory personnel (TP) #1 and #2, the laboratory director failed to identify problems that required a corrective action for routine Chemistry PT results. Findings Include: 1. On the date of survey, 02/21 /2018, the laboratory could not provide documentation of corrective action assessment for: -2016 Event #2 Magnesium (MG) Score 80% -2016 Event #2 Triglycerides (TRIGL) Score 80% -2017 Event #1 Total Cholesterol Score 80% -2017 Event #2 Sodium (NA) Score 80% 2. TP #1 and #2 confirmed the findings above on 02/21 /2018 around 01:45 PM.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of Procedure Manuals and interview with the Testing Personnel (TP) #1 and #2, the Laboratory Director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process from 2016 to the date of survey. Finding Include: 1. On the date of survey, 02/21 /2018, review of the 6 of 6 procedure manuals revealed that the laboratory director did not approve procedures in use. 2. TP #1 and #2 confirmed the finding above on 02/21 /2018 around 02:45 PM.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with Testing personnel (TP) #2. The Technical consultant (TC) (Laboratory Director) failed to evaluate the competency of all TP as required from 2016 and 2017. Findings Include: 1. On the date of survey 02/21/2018, review of TP #1 competency assessment revealed that their 2016 and 2017 assessment were performed and signed by the director on 01/18. 2. TP #2 could not provide documentation of their competency assessment for 2016 and 2017. 3. In the past 12 month period 55,091 specimen were tested. 4. TP #1 and #2 confirmed the findings above on 02/21/2018 around 01:30 PM.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on, the review of proficiency testing records and interview with Testing personnel (TP) #1 and #2, the Technical Consultant failed to evaluate the assessment of 1 of 2 testing personnel through external proficiency testing samples or internal blind testing samples from 2016 to the date of survey. Findings Include: 1. On the date of survey, 02/21/2018, review of proficiency testing attestation forms, revealed 1 of 2 testing personnel performed in the Medical laboratory evaluation (MLE) proficiency testing for 2016 and 2017. 2. TP #1 and #2 confirmed the finds above on 02/21/2018 around 14:00 PM.