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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>39D0677979 | <b>(X3) Date Survey Completed</b><br><br>04/23/2024 |
| <b>Name of Provider or Supplier</b><br><br>Clearfield Professional Group Ltd   | <b>Street Address, City, State</b><br><br>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. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D2015</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with testing personnel (TP) #1, the laboratory director (LD)/designee and testing personnel (TP) failed to sign 4 of 6 AAB-MLE PT attestation statement documents for chemistry and hematology testing performed in 2023. Findings include: 1. The AAB/MLE PT Program Guide general instructions for reporting results states, " The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to the analysts' signatures, the director or the director's designee must sign only once for each reporting form." 2. On the day of survey, 04/23/2024 at 9:48 am., review of AAB-MLE PT attestation records revealed the following 4 of 6 AAB-MLE PT attestation statement documents were not signed by the LD/designee or TP in 2023: - Chemistry: Events #1 &amp; #2 - Chemistry module (CH) M1 &amp; M2 - Urine Microalbumin/Creatinine (UM) - Prostate</p> |

Specific Antigen (PSA) - Endocrinology 2 (25-Hydroxyvitamin D) - Hematology: Events #1 & #2 - Nonchemistry M1 & M2 (Hematology with 5-Part Diff DxH 500 series) 3. TP #1 confirmed the findings above on 04/23/2024 at 10:30 am.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel competency records, the CLIA laboratory personnel report (CMS 209), and interview with Testing Personnel (TP) #1, the Technical Consultant (TC) (CMS 209 personnel #3) failed to evaluate the annual competency of 1 of 2 testing personnel (TP) who performed Chemistry and Hematology testing in 2022 and 2023. Findings include: 1. On the day of survey 04/23/2024 at 8:50 am, review of the laboratory's personnel competency records and CMS 209 form revealed the TC failed to evaluate the annual competency of TP #2 (CMS 209 personnel #2) who performed testing on the Envoy 500 + Chemistry analyzer and the Beckman DxH 520 Hematology analyzer in 2022 and 2023. 2. TP #1 (CMS 209 personnel #1) performed the annual competency assessment of TP #2 in 2022 and 2023. 3. Review of personnel credentials revealed TP #1 does not meet the education requirements under 493.1411 of TC for moderate complexity testing. 4. TP #1 confirmed the findings above on 04/23/2024 at 10:30 am.