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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2070437 | (X3) Date Survey Completed 07/11/2023 |
| Name of Provider or Supplier Pennsylvania Pain And Spine | Street Address, City, State 1500 Horizon Cr Suite 102b, Chalfont, 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 |
|---------------------------|--|
| D2015 | <p>TESTING OF PROFICIENCY TESTING SAMPLES 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: Based on lack of documentation and interviews with the Laboratory Director (LD), Technical Supervisor (TS) and General Supervisor (GS), the laboratory failed to provide 4 of 6 Pennsylvania (PA) State Drugs of Abuse in Urine proficiency testing (PT) attestation statements for chemistry in 2021 and 2022. Findings include: 1. On the day of survey, 07/11/2023 at 10:38 am, the laboratory did not provide the following PA State Drugs of Abuse in Urine PT attestation statements in 2021 and 2022 PA State Drugs of Abuse in Urine: - 2021 Event #3 - 2022 Event #1, Event #2, Event #3 2. The LD, TS and GS confirmed the findings above on 07/11/2023 around 11:40 a.m.</p> |