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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D1087627 | (X3) Date Survey Completed 12/13/2023 |
| Name of Provider or Supplier Coastal Spine And Pain Institute Pllc | Street Address, City, State 16922 Telge Rd, Suite 2a, Cypress, TX | |
| 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 |
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| D0000 | An announced survey of the laboratory was conducted on 12/13/2023. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories. STANDARD LEVEL DEFICIENCIES were cited. |
| D2009 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document laboratory director's and testing personnel's attestation to the routine integration of the samples into the patient workload for two of two PT events reviewed. Findings included: 1. Review of laboratory's PT records for 2023 revealed the laboratory used CAP (College of American Pathologists) as laboratory's PT provider, and performed testing of samples for Urine Toxicology 2023 Event B and Urine Toxicology 2023 Event C. 2. Further review of the above PT records revealed the laboratory did not document attestation to the routine integration of the samples into the patient workload for either of the two events. 3. In an interview on 12/13/2023 at 1035 hours in the laboratory, the facility's Technical Supervisor (as indicated on submitted Form CMS 209), after review of the data, confirmed the findings. Key: CMS = Centers for Medicare and Medicaid</p> |
| 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.</p> |

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 review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to retain required PT documentation for two of two PT events reviewed. Findings included: 1. Review of laboratory's PT records for 2023 revealed the laboratory used CAP (College of American Pathologists) as laboratory's PT provider, and performed testing of samples for Urine Toxicology 2023 Event B and Urine Toxicology 2023 Event C. 2. Further review of the above PT records revealed the laboratory only had retained CAP PT Participant Evaluation Summaries for the above events, and did not retain original mailing packets/instructions, testing records /results, attestation documents or Participant Evaluation packets. 3. In an interview on 12/13/2023 at 1035 hours in the laboratory, the facility's Technical Supervisor (as indicated on submitted Form CMS 209), after review of the data, confirmed the findings. Key: CMS = Centers for Medicare and Medicaid

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures for test establishment studies, test establishment records and staff interview, the laboratory failed to follow its own policy for establishment of interference for 33 of 33 analytes tested by the laboratory. Findings included: Review of laboratory's "Analytic Method Validation" policy for test establishment (approved by laboratory director on 07/14/2023) revealed: "Selectivity - Interferences ... Also, 6 separate lot numbers of blank urine will be tested to see if there are any endogenous interferences." 2. Review of test establishment study records for Interference revealed the laboratory performed only 1 blank urine sample per analyte. No blank urine lot number was documented. 3. In an interview on 12/13/2023 at 1220 hours in the laboratory, the facility's Technical Supervisor (as indicated on submitted Form CMS 209), after review of the data, confirmed the findings. Key: CMS = Centers for Medicare and Medicaid