

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1087627	(X3) Date Survey Completed 07/31/2025
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
D0000	An announced survey of the laboratory was conducted on 07/31/2025. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D6076 - 42 C. F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's submitted form CMS-209, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure testing personnel had documentation of education sufficient to qualify them to perform high complexity testing on patient specimens. Refer to D6102.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the laboratory's submitted form CMS-209, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure one of four testing personnel had documentation of education to qualify them to perform high complexity testing on patient specimens in 2024 and 2025. Refer to D6171.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on a review of the laboratory's submitted form CMS-209, personnel records, and staff interview, the laboratory failed to ensure one of four testing personnel met the requirements to perform high complexity testing in 2024 and 2025. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an

accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted form CMS-209, laboratory's personnel records, and staff interview, the laboratory failed to ensure one of four testing personnel met the requirements to perform high complexity testing in 2024 and 2025. Findings included: 1. Review of the laboratory's submitted form CMS-209 revealed four listed testing personnel performing high complexity testing. 2. Review of the laboratory's personnel records revealed testing person number four (TP4) was hired in February 2024 through August 2024 and again in June 2025. 3. Further review of the laboratory's personnel records revealed TP4 had documentation of Master of Science degree. There was no other diploma or transcripts specifying field of study or course hours to verify TP4's qualifications for high complexity testing. 4. In an interview on 07/31/2025 at 0945 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS-209) confirmed the findings.