

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1105031	(X3) Date Survey Completed 08/20/2021
Name of Provider or Supplier Coastal Pain & Spinal Diagnostics	Street Address, City, State 6221 Metropolitan St, Ste 201, Carlsbad, CA	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the proficiency testing (PT) results during the laboratory inspection, and an interview with the General Supervisor (GS), it was determined that the laboratory failed to enroll in Toxicology proficiency testing) for Cycle 1 of 2019 and Cycle 2 of 2020 for PT specimens not processed by the College of American Pathology (CAP) program. The laboratory inspection occurred on 8/20/21 between 1:30 p.m. and 4:00 p.m. Findings include: 1. The PT process and the associated PT reports were reviewed 2. The laboratory normally participates in the CAP Toxicology testing program for approximately 25 toxicology analytes. Approximately 14 other analytes from their requisition form are split-tested and sent to another CLIA-certified</p>

laboratory- Integra Lab Solutions in Jupiter, Florida for 2019 and Equaltox in Tustin, CA for 2020. 3. For each patient specimen (approximately 500 per year), the laboratory does a screening test using a Thermo Indiko device, and a Sciex chromatography/spectroscopy device for specific analyte measurement using LC/MS (liquid chromatography/mass spectroscopy) 4. PT specimen testing is normally done twice per year for both CAP and the specimens sent to the Integra or Equaltox laboratories. 5. Five split specimens are normally sent to Integra and Equaltox. 6. The analytes (identified by the GS) normally sent to Integra or Equaltox are: - Cyclobenzapine - Desipramine - Doxepin - Imipramine - MDEA - Midazolam - Methylphenidate - Naloxone - Norketamine - Nortriptyline - Naltrexone - Sulfentanil - Ventalfaxine - Zolpidem 7. The GS normally receives the data in spreadsheet format and prepares a correlation report to evaluate the PT acceptance 8. The spreadsheet correlation reports were only available for one cycle for 2019 and one for 2020- two PT report cycles are required per CLIA requirements 9. The GS affirmed on 8/20/21 at 2:20 p.m. that PT submissions for split testing for 2019 and 2020 were only done for 1 cycle and that the second cycle was skipped.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a review of the proficiency testing (PT) results during the laboratory inspection, and an interview with the General Supervisor (GS), it was determined that the laboratory failed to enroll in Toxicology proficiency testing) for Cycle 1 of 2019 and Cycle 2 of 2020 for PT specimens not processed by the College of American Pathology (CAP) program. 1. The laboratory director did not ensure that the laboratory participated in two PT events annually for the split specimens. 2. See D 2016.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) 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.

This STANDARD is not met as evidenced by:
Based on a review of the procedure documentation, and an interview with the GS, it was determined that the laboratory director failed to complete competency reports for

the GS for 2019 and 2020. The laboratory inspection occurred on 8/20/21 between 1:30 p.m. and 4:00 p.m. Findings include: 1. The GS was asked to produce competency reports for his performance for 2019 and 2020. 2. The GS indicated on 8/20/21 at 2:45 p.m. that the competency reports were not done for 2019 and 2020.