

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2190912	(X3) Date Survey Completed 09/23/2022
Name of Provider or Supplier Spine And Wellnes Centers Of America	Street Address, City, State 405 S 21st Ave, Hollywood, FL	
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	A recertification survey conducted on 09/13/2022 found the SPINE AND WELLNESS CENTERS OF AMERICA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have documentation that proved if samples received after 2 days of collection were stored at 4 C for up to two days or frozen -20 for long term storage at the collection site before sending them to the laboratory for four out of six samples reviewed from 03/01/2021 to 07/01/2022. Findings include: -Review of procedure manual signed by the laboratory director on 09/12/2022 revealed that in the policy SPE 100.0 Laboratory Sample Collection Policy in section "Retrieval of specimens from facilities and transport of specimens to laboratory" stated that "The samples can be stored post collection at room temperature, 20-25C for up to 24 hours. Specimens can be stored at 4 C (refrigerator) for up to two days before being sent via courier to laboratory as defined above. Specimens can be stored long term (1 week) at -20 (freezer) before being sent to the laboratory as defined above." -Review of method validation signed by the laboratory director on 03/21/2022 revealed that the stability study for samples stored at room temperature was performed for up to five days. -Review of six sample requisition/tests reports revealed the following: a) Sample # 1: collected on 03/01/2021, received on 03</p>

/11/2022. Transit time of ten days. No documentation found if the sample was stored at 4 C for up to two days or frozen in the collection site or not. b) Sample # 2: collected on 10/01/2021, received on 10/06/2021. Transit time of five days. No documentation found if the sample was stored at 4 C for up to two days or frozen in the collection site or not. c) Sample # 3: collected on 11/01/2021 received 11/03/2021. Transit time of two days. Acceptable d) Sample # 4: collected on 04/01/2022 received on 04/07/2022, Transit time of six days. No documentation found if the sample was stored at 4 C for up to two days or frozen in the collection site or not. e) Sample # 5: collected on 05/02/2022, received on 05/03/2022. Transit time of one day. Acceptable f) Sample # 6: collected on 07/01/2022, received 07/07/2022. Transit time of six days. No documentation found if the sample was stored at 4 C for up to two days or frozen in the collection site or not. During an interview on 09/13/202 at 2:10 PM, the Technical Supervisor confirmed that the laboratory failed to have documentation if the samples were stored at 4 C for up to two days or frozen in the collection site or not for the samples of reference.