

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2147461	(X3) Date Survey Completed 03/24/2025
Name of Provider or Supplier Pain & Spine Associates Of Tx	Street Address, City, State 2743 Smith Ranch Road, Ste 404, Pearland, 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	A validation survey was completed on 03/24/2025. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 116 application, the QC records from February 2024 to September 2024, patient results, and confirmed in an interview, the laboratory failed to obtain a positive qualitative quality control material prior to patient testing for 1 of 5 analytes for 1 of 5 days reviewed for moderate complexity tests on Medica easyRA chemistry analyzer. The findings were: 1. Review of the laboratory's CMS 116 application form, signed by the laboratory director on 03/24/2025, revealed the laboratory performed 5 analytes on Medica easyRA chemistry analyzer (SN:20818010316). Benzodiazepine Caanobinoid (THC) Opiates Oxycodone Cocaine 2. Random review the laboratory's QC records from February 2024 to September 2024 revealed the laboratory failed to obtain a positive qualitative quality control material prior to patient testing for 1 of 5 analytes performed on Medica easyRA chemistry analyzer for 1 of 5 days reviewed. 02/29/2024 Cocaine 3. Review the laboratory's patient results from 02/29/2024 revealed 34 patients testing performed on Medica easyRA chemistry analyzer. 02/29/2024 Patient ID: 10732 Cocaine Result: Negative 02/29/2024 Patient ID: 13501 Cocaine Result: Negative 02/29/2024 Patient ID: 12015 Cocaine Result: Negative 02/29/2024 Patient ID: 13308 Cocaine Result: Negative 02/29/2024 Patient ID: 13494 Cocaine Result: Negative 02/29/2024 Patient ID: 11533 Cocaine Result: Negative 02/29/2024 Patient ID: 9175 Cocaine Result: Negative 02/29/2024 Patient ID: 11910 Cocaine Result: Negative 02</p>

/29/2024 Patient ID: 9260 Cocaine Result: Negative 02/29/2024 Patient ID: 13457
Cocaine Result: Negative 02/29/2024 Patient ID: 13451 Cocaine Result: Negative 02
/29/2024 Patient ID: 10804 Cocaine Result: Negative 02/29/2024 Patient ID: 10628
Cocaine Result: Negative 02/29/2024 Patient ID: 9212 Cocaine Result: Negative 02/29
/2024 Patient ID: 13029 Cocaine Result: Negative 02/29/2024 Patient ID: 13168
Cocaine Result: Negative 02/29/2024 Patient ID: 10620 Cocaine Result: Negative 02
/29/2024 Patient ID: 10564 Cocaine Result: Negative 02/29/2024 Patient ID: 13499
Cocaine Result: Negative 02/29/2024 Patient ID: 13502 Cocaine Result: Negative 02
/29/2024 Patient ID: 11714 Cocaine Result: Negative 02/29/2024 Patient ID: 12020
Cocaine Result: Negative 02/29/2024 Patient ID: 9182 Cocaine Result: Negative 02/29
/2024 Patient ID: 13392 Cocaine Result: Negative 02/29/2024 Patient ID: 13260
Cocaine Result: Negative 02/29/2024 Patient ID: 13500 Cocaine Result: Negative 02
/29/2024 Patient ID: 13242 Cocaine Result: Negative 02/29/2024 Patient ID: 13354
Cocaine Result: Negative 02/29/2024 Patient ID: 11221 Cocaine Result: Negative 02
/29/2024 Patient ID: 9151 Cocaine Result: Negative 02/29/2024 Patient ID: 13420
Cocaine Result: Negative 02/29/2024 Patient ID: 10574 Cocaine Result: Negative 02
/29/2024 Patient ID: 9156 Cocaine Result: Negative 02/29/2024 Patient ID: 11197
Cocaine Result: Negative 4. An interview on 03/24/2025 at 12:20 pm in a conference
room, the technical consultant (indicated on the CMS 209 form) confirmed the above
findings. Key: CMS=Center of Medicare and Medicaid Services QC=Quality Control