

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2009748	(X3) Date Survey Completed 04/09/2025
Name of Provider or Supplier South Texas Spinal Clinic Pa	Street Address, City, State 9150 Huebner Road, Suite 290, San Antonio, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's procedure manual, and staff interview, the laboratory failed to have procedures for two of twelve assays performed. The findings included: 1. A review of the laboratory's test menu identified twelve assays performed on the Siemens Viva-E instrument. Two of twelve assays were introduced by the laboratory in 2023. They were: a) EDDP performed: 10/2023 to 3/2024 b) Tramadol performed: 12/7/2023 to current 2. A review of the laboratory's procedures determined the laboratory failed to have documentation of procedures for EDDP and Tramadol. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 04/09/2025 at 1230 hours in the conference room. Key EDDP: 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control records from July, August, and September 2024, review of patient test records from July, August and September 2024, and staff interview, the laboratory failed to have documentation of remediating patients tested since the previous successful quality control run on eight of eight days. The findings included: 1. A review of the laboratory's quality control records from July, August and September 2024 identified the following days when quality control testing failed and the resolution was to recalibrate the system and rerun quality control. Thus, remediation of patients since the last successful quality control run was required. The days and assays were: a) July 5, 2024 assay: 6AM b) July 12, 2024 assay: Tramadol c) July 15, 2024 assay: 6AM d) July 18, 2024 assay: 6AM e) July 24, 2024 assay: Tramadol f) August 13, 2024 assay: Oxycodone g) August 29, 2024 assay: 6AM September 18, 2024 assay: 6AM 2. A review of patient test records from July, August and September 2024 identified the following patients requiring remediation due to quality control failures (date listed is previous successful quality control date): a) July 2, 2024 Patient IDs: 182951 250232 211140 168686 195784 246535 204023 206767 168249 242083 85423 130465 197112 158587 220405 250248 101323 158482 59048 225505 206797 239703 239776 249949 250341 248842 153378 165579 248539 239142 b) July 10, 2024 Patient IDs: 52132 229839 250381 187242 223335 238878 247530 163642 250076 92814 233934 172091 183881 246728 173977 251073 184702 208495 37924 249569 236725 181881 223733 199977 243360 118771 245647 c) July 11, 2024 Patient IDs: 169058 181261 181831 249045 236709 236078 189141 148148 195849 250463 21083 171980 250245 193182 18259 d) July 16, 2024 Patient IDs: 230329 250049 248638 170119 58718 175375 214450 250688 249611 195758 249739 40330 185545 102061 245377 202392 245178 191429 186848 223974 68661 142720 111130 151534 125075 168552 195366 189408 247227 220793 e) July 23, 2024 Patient IDs: 196800 227810 209044 250195 248522 208731 251413 240724 239236 250949 250455 250636 f) August 12, 2024 Patient IDs: 136533 219624 242086 227253 201844 g) August 27, 2024 Patient IDs: 57528 251640 197244 207199 248657 213571 172654 233061 229233 192946 98040 170747 230314 251156 251391 250616 193021 151714 239317 250416 134361 245114 252214 251527 236903 214155 h) September 17, 2024 Patient IDs: 98653 176425 216070 30313 202492 250952 252505 182577 224327 252174 191721 252015 178911 252374 191539 20052329 182181 195373 214113 231272 119169 251428 194951 251615 215174 238916 138622 178610 214614 210739 180827 182553 187108 250527 221245 251059 244956 198115 155855 190262 181528 252568 28859 65850 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 04/09/2025 at 1230 hours in the conference room. Key: 6AM: 6-acetylmorphine

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's verification studies performed in 2023 and staff interview, the laboratory director failed to review two of two studies to ensure the results met the laboratory's criteria for acceptability. The findings included: 1. A

review of the laboratory's verification studies identified two studies were performed in 2023. They were: a) EDDP performed: 10/2023 b) Tramadol performed: 12/2023 2. Further review of the verification studies determined: a) EDDP results not evaluated or approved by the laboratory director b) Tramadol results not approved by the laboratory director 3. The laboratory director confirmed the findings by phone on 04/09/2025 at 1230 hours. Key EDDP: 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine