Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2181116	04/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Clinic For Pain Management Pa	4101 S Shary Road, Ste 101-A, Mission, 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	The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories following a survey completed on 04/28/2026. The following conditions were not met: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Quidel Triage Tox Drug Screen test devices, and staff interview, the laboratory failed to have documentation of monitoring room and refrigerator temperatures to ensure they met manufacturer's requirements 6 of 6 months. The findings included: 1. The manufacturer's instructions for the Quidel Triage Tox Drug Screen test devices under the section titled "Storage and Handling Requirements" stated: "Store the Test Devices in a refrigerator at 2 to 8C (36 to 46F).”" And, "Once removed from refrigeration, the pouched Test Device is stable for up to 14 days when stored at 18C to 28C (64F to 82F)." 2. A review of the laboratory's records determined the laboratory failed to have documentation of

	monitoring room and refrigerator temperatures from October 2025 to March 2026. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings on 04/28/2026 at 1400 hours in the laboratory.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the laboratory's test records from March 2026, review of the laboratory's quality control records from March 2026, and staff interview, the laboratory failed to have documentation of performing quality control testing on 1 of 2 test dates. The findings included: 1. A review of the laboratory's test records from March 2026 identified that testing was performed on March 6, 2026 and March 13, 2026. 2. A review of the laboratory's quality control records from March 2026 determined the laboratory failed to have documentation of performing quality control testing on March 13, 2026. 3. The laboratory did not have documentation of performing an Individualized Quality Control Plan to modify the frequency of the control testing. 4. Further review of the laboratory's testing records from March 2026 identified 40 patient tests were performed on March 13, 2026 (see patient alias list). 5. Testing personnel number 1 confirmed the findings in an interview conducted on 04 /28/2026 at 1400 hours in the laboratory.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from November 2025, review of patient test records from November 2025 and staff interview, the laboratory failed to ensure quality control testing results were acceptable prior to reporting patient results. The findings included: 1. A review of the laboratory's quality control records from November 2025 determined quality control results were not acceptable on November 19, 2025. a) Serial number: 103022 Negative Control: Amp Positive mAMP Positive BAR Positive BZO Positive COC Positive EDDP Positive OPI Positive TCA Positive THC Positive Positive Control: Amp Positive mAMP Positive BAR Positive BZO Positive COC Positive EDDP Positive OPI Positive TCA Positive THC Positive b) Serial number 102998 Negative control Amp Positive mAMP Positive BAR Positive BZO Positive COC Positive EDDP Positive OPI Positive TCA Positive THC Positive Positive control Amp Positive mAMP Positive BAR Positive BZO Positive COC Positive EDDP Positive OPI Positive TCA Positive THC Positive 2. A review of patient test records from November 19, 2025 identified the following patients were tested: Patient ID: 61479 Patient ID: 61451 Patient ID: 61488 Patient ID: 61477 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 04/28/2026 at 1335 hours in the laboratory. Key Amp Amphetamine mAMP Methamphetamine BAR Barbiturates BZO Benzodiazepines COC Cocaine EDDP 2-ethylidene-1,5-dimethyl-3,3-

	diphenylpyrrolidine OPI Opiates TCA Tricyclic antidepressants THC tetrahydrocannabinol
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrument printouts, and staff interview, the laboratory failed to have a quality assurance plan that could identified problems in analytic systems. The findings included: 1. A review of the laboratory's instrument printouts from the Quidel Triage Meter Pro identified the date and time on the instrument printouts did not reflect the actual date and time the test was performed. Examples are: a) Instrument serial number: 00102998 test date/time: 04/28/2026 at 1: 15 pm printout date/time: 03/04/2026 at 11:43 pm b) Instrument serial number: 0013022 test date/time: 04/28/2026 at 1:15 pm printout date/time: 03/01/2026 at 12: 40 am 2. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 04/28/2026 at 1330 hours at the front desk.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, the laboratory director failed to provide management and oversight for the laboratory. The findings included: 1. The laboratory director failed to ensure verification studies were reviewed and approved prior to testing being performed (refer to D6013). 2. The laboratory director failed to ensure quality control plans and quality assurance plans were developed and followed (refer to D6020). 3. The laboratory director failed to ensure testing personnel had documentation of education and training prior to performing patient testing (refer to D6029). 4. The laboratory director failed to ensure a procedure manual was available (refer to D6031).
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 for the Quidel Triage Meter Pro analyzers and staff interview, the laboratory director failed to document his review and acceptance of the studies for 2 of 2 analyzers. The findings included: 1. A

	review of the laboratory's verification studies for the Quidel Triage Meter Pro analyzers performed in September 2025 determined there was no documentation of the review or acceptance of the studies by the laboratory director (who was also identified as the technical consultant). Instrument studies were performed on the following analyzers: a) Serial number: 00102998 b) Serial number: 00103022 2. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 04/28/2026 at 1145 hours in the laboratory.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, the laboratory director failed to ensure quality control and quality assurance programs were developed and followed. The findings included: 1. The laboratory director failed to ensure quality control testing was performed each day of patient testing (refer to D5449), 2. The laboratory director failed to ensure quality control results were acceptable prior to reporting patient results (refer to D5481). 3. The laboratory director failed to ensure a quality assurance plan identified time and date of testing did not match the actual date and time of occurrence (refer to D5791).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 review of the laboratory's personnel records and staff interview, the laboratory director failed to ensure testing personnel had the required education and training to perform moderate complexity testing (refer to D6065 and D6066).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by:
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification

	requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of qualify 1 of 1 technical consultants (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) 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; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of qualify 1 of 1 technical consultants. The findings included: 1. A review of the laboratory's personnel records determined the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records determine the technical consultant listed on Form CMS 209 failed to meet the required qualifications. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 04/28/2026 at 1145 hours in the laboratory.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of education to qualify 3 of 4 testing personnel (see D6065) and documentation of training for 4 of 4 testing personnel (refer to D6066).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209, review of the laboratory's records and staff interview, the laboratory failed to have documentation of education for 3 of 4 testing personnel. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 4 personnel who performed testing since the laboratory starting performing testing on 09/29/2025. 2. Further review of the laboratory's personnel records determined the laboratory failed to have documentation of education for 3 of the testing personnel. They were (as listed on Form CMS 209): a) Testing person #2 b) Testing person #3 c) Testing person #4 3. Testing personnel number 1 confirmed the findings in an interview conducted on 04/28/2026 at 1130 hours in the laboratory.

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) (b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209, review of the laboratory's records and staff interview, the laboratory failed to have documentation of training prior to performing patient testing for 4 of 4 testing personnel. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 4 personnel who performed testing since the laboratory starting performing testing on 09/29/2025. 2. Further review of the laboratory's personnel records determined the laboratory failed to have documentation of training for the 4 testing personnel prior to them performing patient testing. a) Testing person #1 Started testing: February 2026 Trained: April 2026 b) Testing person #2 Started testing: August 2025 Trained: April 2026 c) Testing person #3 Started testing: August 2025 Trained: no documentation d) Testing person #4 Started testing: October 2025 Trained: no documentation 3. Testing personnel number 1 confirmed the findings in an interview conducted on 04/28/2026 at 1130 hours in the laboratory.