Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2181116	11/16/2021
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 out of compliance with the following CONDITION LEVEL DEFICIENCIES: D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant. D6063 - 42 C.F.R. 493.1412 Condition: Laboratories performing moderate complexity testing; testing personnel. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 and 2021, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 1 of 3 attestation statements. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 (Chemistry - Miscellaneous event 2) and 2021 (Chemistry- Miscellaneous events 1 and 2) revealed the laboratory failed to have documentation of the laboratory director signing 1 of 3

	attestation statements. The missing laboratory director signature was on 2021 Chemistry-Miscellaneous event 2. 2. The laboratory was asked to provide documentation of the laboratory director signing the identified attestation statement. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/16//2/21 at 1200 hours in the laboratory confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's test systems, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification every six months. The findings include: 1. A review of the laboratory's policy titled "Calibration Verifications (AMP) and Assay Correlations Policy" (approved by the laboratory director on 6/5/2020) under the section "I. Purpose" revealed: "These procedure are required to maintain on-going evaluation of both quantitative and qualitative test systems..." and"The Analytical Measurable Range AMR must be revalidated at least every six months..." 2. A review of the laboratory's test system revealed the following assays tested utilized 2 or fewer calibrators and quality control was performed once daily, therefore calibration verification was required: Ethanol THC Hydrocodone Methadone Oxycodone Creatinine pH Amphetamine Benzodiazapines Cocaine EDDP Opiates 3. The laboratory was asked to provide documentation of performing calibration verification on the identified analytes. No documentation was provided. 4. An interview with testing personnel number 1 on 11/16/2021 at 1230 hours in the laboratory confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient reports from November 1, 2021 to November 10, 2021 and confirmed in interview of facility personnel, the laboratory failed to include the correct facility address on 8 of 8 patient reports. The findings were: 1. A review of patient reports from November 1, 2021 to November 10, 2021 found the laboratory failed to include the correct testing facility address on 8 of 8 patient test reports. 2. The laboratory was asked to provide documentation of patient reports which included the laboratory's correct address. No documentation was provided. 3. An interview with the office manager on November 16, 2021 at 12:30 hours in the break room confirmed the findings. She agreed the address was not correct on the reports.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification studies performed on the Thermo Scientific Indiko Plus chemistry analyzer in February 2020, and staff interview, it was revealed the laboratory director failed to document his review of the studies to assess their acceptability. The findings include: 1. A review of the laboratory's verification studies performed the Therm Scientific Indiko Plus chemistry analyzer in February 2020 revealed the laboratory director failed to document his review of the studies to assess their acceptability. The analytes tested as part of the studies were: Ethanol THC Hydrocodone Methadone Oxycodone Creatinine pH Amphetamine Benzodiazapines Cocaine EDDP Opiates 3. The laboratory was asked to provide documentation of the review of the studies for the identified analytes. No documentation was provided. 4. An interview with testing personnel number 1 on 11/16/2021 at 1230 hours in the laboratory confirmed the findings.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 and 2021, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director review of the results for 1 of 2 events. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 (Chemistry - Miscellaneous event 2) and 2021 (Chemistry- Miscellaneous event 1) revealed the laboratory failed to have documentation of the laboratory director reviewing the results for 1 of 2 events. The missing review was on 2021 Chemistry-Miscellaneous event 1. 2. The laboratory was asked to provide documentation of the laboratory director reviewing the identified results. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/16//2/21 at 1200 hours in the laboratory confirmed the findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 personnel records and confirmed in interview of facility personnel, the laboratory failed to provide documentation that one of one technical consultants met the qualifications to be a TC over a moderate complexity laboratory (refer to D6034).
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of personnel records and confirmed in interview of facility personnel, the laboratory failed to provide documentation that one of one technical consultants met the qualifications for a moderate complexity laboratory. The findings included: 1. Review of the laboratory's submitted Form CMS-209 found one of one technical consultants listed. 2. Review of personnel records available for review did not provide documentation that the technical consultant was an M.D. certified in anatomic or clinical pathology or both or had at least one year training or experience in the designated specialty of

	toxicology. 3. The laboratory was asked to provide documentation of additional records that could qualify the technical consultant to be a TC over a moderate complexity laboratory. No documentation was provided. 4. An interview with the office manager on November 16, 2021 at 15:30 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services M.D. - medical doctor TC - technical consultant
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 it was determined that two of three testing personnel failed to have documentation of education required to perform moderate complexity testing (refer to D6065).
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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's personnel records and confirmed in interview of facility personnel found that two of three testing personnel failed to have documentation of education required to perform moderate complexity testing. The findings included: 1. Review of the laboratory's policy titled "Personnel Qualifications and Standards Policy - High Complexity" found the policy provided procedures based on the laboratory performing high complexity testing. However, from when the laboratory began testing in June 2020, the laboratory has only performed moderate complexity testing. The laboratory's policy failed to include procedures for testing personnel for moderate complexity testing. 2. Review of the laboratory's personnel records found Testing Person number 1 and 2 (as listed on Form CMS-209) did not have documentation of education required for moderate complexity testing. 3. The laboratory was asked to provide education documents qualifying Testing Person number 1 and 2 to perform moderate complexity testing. No documentation was provided. 4. An interview with the office manager on 10/16 /2021 at 15:30 hours in the break room confirmed the findings.

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's personnel records and confirmed in interview of facility personnel found that three of three testing personnel failed to have documentation of training required to perform moderate complexity testing. The findings included: 1. Review of the laboratory's policy titled "New Employee Training Procedure Policy" stated: "I. Purpose: The orientation of new employees and its documentation is an important step in establishing performance expectations in regards to training and performance standards. II. Procedures: New employees will have a standards packet of orientation and training information. These packets should NOT be a stack of loose leaf papers, but a notebook of documents. All documents for lab specific orientation, training, 6-month, and annual competency should be included." The policy went on to say, "New employees will not be cleared to perform tasks independently until their training checklist for this tasks is complete." 2. Review of the laboratory's personnel records found Testing Person number 1, 2, and 3 (as listed on Form CMS-209) did not have documentation of training required for moderate complexity testing. 3. The laboratory was asked to provide training records for Testing Person number 1, 2, and 3 to perform moderate complexity testing. No documentation was provided. 4. An interview with the office manager on 10/16/2021 at 15:30 hours in the break room confirmed the findings.