

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2233755	(X3) Date Survey Completed 02/11/2026
Name of Provider or Supplier Texas Interventional Pain Specialists	Street Address, City, State 17314 St Hwy 249 Suite 100, Houston, 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 in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, LC/MS establishment studies, patient final reports, and confirmed in interview, the laboratory failed to perform all performance characteristics of an FDA modified test to include stability studies on saliva specimen types for 29 of 29 analytes performed in 2025 (October-December) and 2026 (January). Findings included: 1. During a tour of the facility at 09:40 AM, the surveyor observed one LC/MS analyzer available for patient testing (Serial Number: 21086587). In the specimen processing room freezer, the surveyor observed specimens labeled "saliva" on the freezer shelf. The surveyor inquired as to the nature of these specimens, and General Supervisor 1 (GS-1) confirmed these were saliva specimen types processed for toxicology on the LC/MS analyzer. 2. Review of laboratory policy, "Temperature Stability Study" (Approved by the Laboratory Director on 11/25/2025) revealed the following: "Policy CLIA regulation 42 CFR</p>

493.1242 (a) states that the laboratory must establish and follow written policies and procedures for each of the following, if applicable: (4) Specimen storage and preservation and (5) conditions for specimen transportationTesting Procedure: 1. Collect a minimum of 100 mL of negative human urine to prepare the samples listed in step 2. a. Medical Grade Polypropylene Specimen Cups SKU: ERK-SC1400ST" The laboratory was asked to provide a specimen stability study to ensure performance characteristics of saliva specimens during transport and storage, and none was provided. 3. Review of LC/MS laboratory establishment studies for Saliva toxicology testing, revealed the laboratory failed to document performance of saliva specimen stability studies for 29 of 29 analytes performed on the LC/MS analyzer (Serial Number: 21086587). 4. Review of patient final reports revealed the laboratory performed testing on 21 saliva patient specimens in 2025 (October-December) and 8 in 2026 (January). a. See Patient Alias List 1 5. In an interview on 02/10/2026 at 10: 21 AM, GS-1 confirmed the laboratory failed to perform all performance characteristics of an FDA modified test, to include stability studies, on saliva specimen types for 29 of 29 analytes performed in 2025 (October-December) and 2026 (January). Word Key LC/MS- Liquid Chromatography/Mass Spectrometry FDA- Food and Drug Administration

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor observation, a review of the laboratory's policies, personnel records, and staff interview, the laboratory failed to have documentation of the technical supervisor performing a separate and distinct competency assessment on four of five testing personnel performing toxicology testing in 2025 and 2026. Findings include: 1. Surveyor observation of the laboratory on 2/11/26 at 9:35 a.m. revealed multiple laboratories operating in suite 2C. 2. A review of the laboratory's policy titled 'Separation of Lab for MultiLab Sites' revealed the following: "Multiple laboratories may operate at the same physical location (e.g. same building or suite, as applicable) with separate CLIA numbers, as long as each laboratory can demonstrate that is operating as a separate and distinct entity. The following separation must be made in the laboratory in order to comply with this requirement. Personnel Competencies: Competencies for lab staff are to be documented per each lab start date of receiving samples." 3. A review of the laboratory's personnel records revealed the technical supervisor performed competency assessments for the following 4 testing personnel, but there was no documentation of which laboratory they were for: a) Testing person #1 - Competency Assessment: LC-MS/MS Quanting and Resulting Performed: 12/29/25 - Competency Assessment: Specimen Processing and Storage Performed: 1/28/26 - Competency Assessment: LC-MS/MS Sample Prep Performed: 1/28/26 b) Testing person #3 - Competency Assessment: Specimen Processing and Storage Performed: 1/28/26 - Competency Assessment: LC-MS/MS Sample Prep Performed: 1/28/26 c) Testing person #4 - Competency Assessment: Specimen Processing and Storage Performed: 1/10/26 d) Testing person #5 - Competency Assessment: LC-MS/MS Quanting and Resulting Performed: 12/22/25 4. In an

interview on 2/11/26 at 11:00 a.m. in the office, after review of the records, the technical supervisor confirmed that the competency assessments performed were intended to be used for all laboratories operating in suite 2C.