

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2091367	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Select Interventional Pain, Pc	Street Address, City, State 794 McDonough Road, Suite 108, Jackson, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) initial certification survey was completed on August 21, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer assay procedure reviews and staff interviews, the laboratory failed to follow the manufacturer's instructions for processing samples for confirmation testing. Findings include: 1. Review of the Thermo Scientific Assay sheets revealed the assays provide a preliminary test result and a more specific alternative method must be used to obtain a confirmed result. 2. Interviews with the lab director and staff #3 (CMS 209 form) on 8/21/18 in the lab at approximately 11:30 AM, confirmed the samples were not referred for confirmation testing.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as</p>

determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on manufacturer and specimen testing procedure review and staff interview, the laboratory failed to follow the manufacturer's instructions for processing samples. Findings include: 1. Review of the Thermo Scientific Fentanyl, Cannabinoid, and Methadone Assay Sheets and the specimen testing procedure revealed turbid specimens be centrifuged before analysis. The lab did not contain a centrifuge. 2. Review of the Thermo Scientific Cannabinoid, and Methadone Assay Sheets and the specimen testing procedure revealed samples are to be tested for pH before testing. 3. Interview with the lab director and staff #3 (CMS 209 form) on 8/21/18 in the lab at approximately 11:00 Am, confirmed the lab did not have a centrifuge to spin turbid specimens or tested samples for pH before testing.

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 report documents and staff interviews, the lab failed to include the units of measurement and interpretation guidance for results. One reported assay is labeled as use for Criminal Justice and Forensic use only and reports did not include the required disclaimer. Findings include: 1. Review of in-house laboratory patient reports #2145 and #1501 revealed the lab did not include the unit of measurement or interpretation values used to determine the positive or negative result. 2. Review of in-house laboratory patient reports #2145 and #1501 revealed the lab did not include the disclaimer: "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration". 3. Interviews with the lab director and staff #3 (CMS 209 form) on 8/21/18 in the lab at approximately 11:15 Am, confirmed the lab's reports did not include the aforementioned information.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) competency record review and staff interviews, the technical supervisor (TS) (lab director) failed to perform the required 6 month

competency evaluation. Findings include: 1. Review of the personnel competency records revealed the TS failed to perform the 6 month competency due on TP in February 2018. 2. Interview with TS (CMS 209 form) on 8/21/18 in the lab at approximately 11:15 AM, confirmed the 6 month competency was not performed.