

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1102090	<b>(X3) Date Survey Completed</b>  10/14/2019
<b>Name of Provider or Supplier</b>  Southwest Anesthesia And Pain Management Pa	<b>Street Address, City, State</b>  5979 Vineland Rd Ste 207, Orlando, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial Certification survey for the reinstatement of the laboratory's CLIA certificate was conducted on October 14, 2019. Southwest Anesthesia and Pain Management PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain quality control records for the CLC 480 (Carolina Liquid Chemistries) chemistry analyzer for at least 2 years. Findings: 1. Review of the calibration documentation for the CLC 480 chemistry analyzer showed that there were no record of calibrations done from 1/13 /19 to 7/12/19, and the calibrations performed on 7/13/19 showed only 2 points of the 5 point calibration is required by the manufacturer. During an interview on 10/14/19 at 11:50 PM, the Testing Personnel stated that the calibration documentation are stored in the instrument, but she is unable to access the records. 2. Review of the quality control records showed that the laboratory did not have any package inserts for the reagents used on the CLC 480 chemistry analyzer. During an interview on 10/14 /19 at 12:06 PM, the Testing Personnel stated she did not have the package inserts for the reagents for the CLC 480 chemistry analyzer.</p>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general</p>

laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the general laboratory system and correct problems identified. Findings: 1. Cross Reference D5217. Based on record review and interview, the laboratory failed to provide documentation to verify the accuracy of the testing methods for 5 out of 5 analytes tested in urine toxicology from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19, at least twice annually. 2. Cross Reference D5291. Based on record review and interview, the laboratory failed to follow their written quality assessment policy.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform and provide documentation to verify the accuracy of the testing methods for 5 out of 5 analytes tested in urine toxicology from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19, at least twice annually. Findings: The laboratory performs urine toxicology testing on the following analytes: Benzodiazepine, Cocaine, Opiates, Oxycodone, and THC (Tetrahydrocannabinol). The laboratory was unable to provide documentation that showed the proficiency testing was performed at least twice annually for the above mentioned analytes. During an interview on 10/14/19 at 1:44 PM, the Testing Personnel stated that she was told they performed proficiency testing once in 2018 with API (American Proficiency Institute) but did not have the documentation, and that no proficiency testing has been done in 2019.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow their written quality assessment policy. Findings: The laboratory procedure titled "Quality Assessment Checklist" read, "The checklist will be generated and reviewed by the lab staff on a monthly basis followed by a report to the laboratory director." Review of the laboratory's logs showed that there were no forms titled "Monthly Quality Assessment Checklist" filled out from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19.

	<p>During an interview on 10/16/19 at 1:45 PM, the Testing Personnel stated that they were not doing a monthly checklist.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: 1. Cross Reference D5437. Based on record review and interview, the laboratory failed to follow manufacturer's instructions requiring the laboratory to run a 5 point calibration. This is a repeat deficiency from the survey conducted on 10/25/17. 2. Cross Reference D5469. Based on record review and interview, the laboratory failed to provide documentation of quality control lot to lot comparisons from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19 for urine toxicology.</p>
<p><b>D5437</b></p>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow manufacturer's instructions requiring the laboratory to run a 5 point calibration. This is a repeat deficiency from the survey conducted on 10/25/17. Findings: Review of the manufacturer's calibration product insert titled "Cannabinoids (cTHC) 50 Drug of Abuse Calibrators" read, "For semi-quantitative calibration, use all 5 calibrators." Review of calibrations record for the CLC 480 (Carolina Liquid Chemistries) chemistry analyzer revealed that only a 4 point calibration was performed on THC (Tetrahydrocannabinol) on 11/30/17, 2/12/18, 10/22/18, 11/26/18, 12/02/18, 12/17/18, 1/05/19, 1/12/19, 7/20/19, 8/07/19, 8/14/19, 8/24/19, 9/08/19, 9/22/19, and 10/06/19. During an interview on 10/14/19 at 11:35 AM, the Testing Person confirmed that the laboratory ran only a 4 point calibration for THC.</p>
<p><b>D5469</b></p>	<p><b>CONTROL PROCEDURES</b></p>

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to provide documentation of quality control lot to lot comparisons from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19 for urine toxicology. Findings: The procedure titled "Control Validation" read, "Whenever a new lot of controls are received they should be validated side to side with the old controls for 5 days." Review of the quality control logs showed that there were no lot to lot comparisons of the toxicology controls from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19 for the CLC 480 (Carolina Liquid Chemistries) chemistry analyzer. During an interview on 10/14/19 at 12:38 PM, the Testing Personnel stated that she was told they didn't have to do a lot to lot comparisons of the controls.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to provide overall management and direction. Findings: 1. Cross Reference D6082. Based on record review and interview, and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19. 2. Cross Reference D6089. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory perform and provide documentation to verify the accuracy of the testing methods for 5 out of 5 analytes tested in urine toxicology from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19, at least twice annually. 3. Cross Reference D6094. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory follow their written quality assessment policy.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each

of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on record review and interview, and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19. Findings: 1. Cross Reference D5437. The laboratory director failed to ensure the laboratory followed manufacturer's instructions requiring the laboratory to run a 5 point calibration. This is a repeat deficiency from the survey conducted on 10/25/17. Calibrations record for the CLC 480 (Carolina Liquid Chemistries) chemistry analyzer revealed that only a 4 point calibration was performed on THC (Tetrahydrocannabinol) on 11/30/17, 2/12/18, 10/22/18, 11/26/18, 12/02/18, 12/17/18, 1/05/19, 1/12/19, 7/20/19, 8/07/19, 8/14/19, 8/24/19, 9/08/19, 9/22/19, and 10/06/19. During an interview on 10/14/19 at 11:35 AM, the Testing Person confirmed that the laboratory ran only a 4 point calibration for THC. 2. Cross Reference D5469. The laboratory director failed to ensure that the laboratory had documentation of quality control lot to lot comparisons from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19 for toxicology. The quality control logs did not show lot to lot comparisons of the toxicology controls from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19 for the CLC 480 (Carolina Liquid Chemistries) chemistry analyzer. During an interview on 10/14/19 at 12:38 PM, the Testing Personnel stated that she was told they didn't have to do a lot to lot comparisons of the controls. Therefore, the laboratory director did not ensure provision of quality laboratory services for test performance.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to ensure the performance and provision of documentation to verify the accuracy of the testing methods for 5 out of 5 analytes tested in urine toxicology from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19, at least twice annually. Findings: Cross Reference D5217. Although the laboratory performs urine toxicology testing on the following analytes: Benzodiazepine, Cocaine, Opiates, Oxycodone, and THC (Tetrahydrocannabinol), they were unable to provide documentation that showed the proficiency testing was performed at least twice annually for the above mentioned analytes. On 10/14/19 at 1:44 PM, the Testing Personnel stated that she was told they performed proficiency testing once in 2018 with API (American Proficiency Institute) but did not have the documentation, and that no proficiency testing has been done in 2019. Therefore, the laboratory director did not ensure that proficiency samples were tested as required.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 record review and interview, the Laboratory Director failed to ensure that the laboratory follow their written quality assessment (QA) policy. Findings: Cross Reference D5291. The "Quality Assessment Checklist" procedure read, "The checklist will be generated and reviewed by the lab staff on a monthly basis followed by a report to the laboratory director." However, the laboratory's logs did not contain any "Monthly Quality Assessment Checklist" forms from 10/14/17 to 6/01/18 and 10/02/18 to 10/14/19. During an interview on 10/16/19 at 1:45 PM, the Testing Personnel stated that they were not doing a monthly checklist. Therefore, the medical director did not ensure that the laboratory followed their QA policy.