

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2023803	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Advance Pain Management, Llc	Street Address, City, State 2950 Stone Hogan Connector, Bldg A, Ste B, Atlanta, 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) in survey was completed on August 27, 2019. The laboratory was found not compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. An Immediate Jeopardy was identified due to the laboratory's failure to monitor and evaluate the overall quality of the analytic systems in regard to the establishment and verification of test performance for all tests performed for a moderate complexity laboratory. The following deficiencies were cited:
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and an interview with the testing personnel, the laboratory failed to have an eyewash station for immediate emergency use within the laboratory area. The findings include: 1. The laboratory failed to have an eyewash station in the laboratory to for immediate emergency use. A tour of the laboratory confirmed an eyewash station was absent from the laboratory area. 2. Testing Personnel #1, confirmed on 8/27/19, at 10:30 AM, in the laboratory, that an eyewash station was not present in the laboratory.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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</p>

through 493.1236.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's policies and procedures, review of Quality Assessment (QA) records, and staff interview, the laboratory failed to follow its written policies and procedures for monitoring, assessing, and, when indicated, correcting problems identified in the QA process. The findings include: 1. The laboratory's quality assessment plan stated, "The laboratory director will review the QA checklist monthly." 2. A review of QA records revealed that the laboratory director did not review the QA checklist from May 2019 through July 2019. 3. The laboratory supervisor confirmed on August 27, 2019, at 11:45 AM, in the conference room, that the laboratory director did not review QA checklists as stated in the laboratory's quality assessment plan.

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

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.

This CONDITION is not met as evidenced by:

The laboratory failed to monitor and evaluate the overall quality of the analytic systems in regard to the establishment and verification of test performance for all test performed in the laboratory. This condition level deficiency contributed to the Immediate Jeopardy determination. (Refer to D5421)

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and staff interview, it was determined that the laboratory failed to meet analytic system requirements for their Toxicology drug test panel. 1. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for the Toxicology drug test panel. The laboratory did not have validation records for the Thermo Fisher Indiko Plus Clinical Chemistry Analyzer. The facility began using the instrument in May of 2019. 2. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for their urine drug

	<p>screen assay for the specialty of toxicology. 3. An interview with the Laboratory Supervisor, on 8/27/19, at 1:00PM, in the laboratory, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, and reportable range for their Toxicology drug test panel.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory supervisor, the laboratory failed to monitor and document all analyte activities for the urine drug screen assay for the specialty of Toxicology. The findings include: 1. A review of laboratory records indicated that the laboratory did not have documentation verifying that all QC analyte failures were monitored and documented. 2. On 5/9/19, 5 out of 10 Toxicology analytes failed their reportable ranges. The laboratory's corrective action records did not contain sufficient information on the resolution of the problem. 3. The laboratory supervisor confirmed on August 27, 2019, at 1:45 PM, in the conference room, that the laboratory did not monitor or document failures of the Toxicology QC analytes. A corrective action was not performed for the failures for May 2019.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory personnel, the laboratory director did not provide overall management and direction in accordance with 493.1407 resulting in Immediate Jeopardy. The Laboratory Director (LD) failed to monitor and evaluate the overall quality of the analytic laboratory system and failed to ensure and quality assessment (QA) program was maintained appropriately. (Refer to D6013 and D6021)</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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 laboratory records and initial method validation records, the Laboratory Director (LD) failed to ensure testing systems provided quality laboratory results for all tests performed in the laboratory. The findings include: 1. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for the Toxicology drug test panel. The laboratory did not have validation records for the Thermo Fisher Indiko Plus Clinical Chemistry Analyzer. The facility began using the instrument in May of 2019. 2. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for their urine drug screen assay for the specialty of Toxicology. 3. An interview with the Laboratory Supervisor, on 8/27/19, at 1:00PM, in the laboratory, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, and reportable range for their Toxicology drug test panel.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's policies and procedures, review of Quality Assessment (QA) records, and staff interview, the laboratory director failed to follow the laboratory's written policy and procedure for monitoring, assessing, and, when indicated, correcting problems identified in the QA process. The findings include: 1. The laboratory's quality assessment plan stated, "The laboratory director will review the QA checklist monthly." 2. A review of QA records revealed that the laboratory director did not review the QA checklist from May 2019 through July 2019. 3. The laboratory supervisor confirmed on August 27, 2019, at 11:45 AM, in the conference room, that the laboratory director did not review QA checklists as stated in the laboratory's quality assessment plan.