

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D211113	(X3) Date Survey Completed 02/01/2018
Name of Provider or Supplier Advanced Toxicology	Street Address, City, State 4939 De Zavala, San Antonio, 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	<p>The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5022 - 42 C.F.R. 493.1213 Condition: Toxicology D5300 - 42 C.F.R. 493.1240 Condition: Pre-analytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director; high complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately. NOTE: THE LABORATORY HAD NOT PERFORMED TESTING SINCE JULY 2017.</p>
D5022	<p>TOXICOLOGY CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirements for the subspecialty of Toxicology. The findings were: 1. The laboratory failed to ensure establishment studies were complete (refer to D5423). 2. The laboratory failed to perform calibration verifications as</p>

required (refer to D5439). 3. The laboratory failed to follow its quality control policy (refer to D5441). 4. The laboratory failed to have a quality assessment plan which could identify and correct issues in analytic systems (refer to D5791).

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's College of American Pathologists' proficiency testing records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results which were not scored by the proficiency testing agency. The findings were: 1. A review of the laboratory's College of American Pathologists' proficiency testing records from 2017 (DAI - A and B, DMPM - A and B, ET - B, and UDS - A, B and C) revealed the laboratory failed to have documentation of evaluating the following results which were not scored by the proficiency agency: 2017 DMPM A Test- Clinical Study Specimen - DMPM-04 2017 UDS A Test - Ethanol Specimens - UDS - 01 UDS - 02 UDS - 03 UDS - 04 UDS - 05 2. The laboratory was asked to provide documentation of evaluating the identified results. No documentation was provided. 3. An interview with the general supervisor on 01/29/2018 at 1400 hours in the laboratory - after her review of the records- confirmed the findings.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirements for pre-analytic testing. The findings were: 1. The laboratory failed to have documentation of performing transportation studies and successful stability studies as part of its establishment studies for its modified FDA-approved assays (refer to D5311). 2. The laboratory failed to provide clients with instructions for proper sample shipping requirements (refer to D5317). 3. The laboratory's quality assessment plan failed to identify and correct issues in pre-analytic testing (refer to D5391).

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, surveyor observation of samples received by the laboratory, review of the laboratory's policies, review of the laboratory's stability studies, and staff interview, it was revealed the laboratory failed to have documentation of: A) transportation studies to support how it received patient samples, and B) performing an acceptable stability study. The findings were: A) Specimen Transport 1. A review of the laboratory's test menu revealed the laboratory performed testing utilizing the following modified FDA-approved assays on the Mindray BS-480 chemistry analyzer: ThermoScientific DRI Amphetamines Assay ThermoScientific DRI Ethyl Alcohol Assay ThermoScientific DRI Cannabinoid Assay ThermoScientific CEDIA Phencyclidine Assay ThermoScientific CEDIA Buprenorphine Assay ThermoScientific DRI Ecstasy Assay ThermoScientific DRI Cocaine Metabolite Assay ThermoScientific DRI Oxycodone Assay ThermoScientific DRI Opiate Assay ThermoScientific DRI Methadone Assay ThermoScientific DRI Gravity-Detect test ThermoScientific DRI General Oxidant-Detect test ThermoScientific DRI pH-Detect test ThermoScientific DRI Creatinine-Detect test Thus, the laboratory was required to establish specimen stability/preservation, transportation, and storage requirements. 2. Surveyor observation of patient samples received by the laboratory on 01/30/2018 at 1030 hours revealed the laboratory received samples which were sent to the facility at ambient temperatures (see patient alias list number 1). The laboratory did not utilize a method to monitor the temperature of the samples during shipment. 3. An interview with the general supervisor on 01/30/2018 at 1035 hours in the accessioning area revealed the laboratory had received samples at only ambient temperature since it started testing in February 2017. 4. A review of the laboratory's policy titled "Specimen Collection" (approved by the laboratory director on 03/01/2017) under the section titled "Specimen Handling" revealed: "Specimen will be transported at room temperature via overnight FedEx delivery service." 5. A review of the laboratory's policy titled "Specimen Rejection Policy" (approved by the laboratory director on 03/01/2017) revealed the laboratory's policy was to reject any specimen which was unrefrigerated and was received more than 2 weeks (14 days) after collection. 6. The laboratory was asked to provide documentation of performing a specimen transportation study to ensure specimens received at ambient temperature were acceptable for testing. No documentation was provided. 7. An interview with the general supervisor on 01/30/2018 at 1050 hours in the accessioning area revealed the laboratory did not perform studies to establish the required conditions for sample transport. This confirmed the findings. B) Specimen Stability 1. A review of the laboratory's "Sample Stability" study (approved by the laboratory director on 07/07/2017) revealed the laboratory tested 45 samples for each of the assays performed over a period of 12 days (day 1, 3, 5, 10 and 12) when stored at the following conditions: a) 15 stored at 'room temperature' - room temperature not defined b) 15 store at 2 -8C c) 15 stored in a freezer - freezer temperature was not defined 2. Further review of the 'Sample Stability' study revealed the laboratory's acceptability criteria was defined as results for each days were to be within +/- 20% of the 'day 1' results. The result of the study stated that all analytes met acceptance criteria. However, the following results failed to meet the laboratory's acceptable criteria: a) Ecstasy Freezer: Day 3 -31% Day 5 -36% Day 10 -32% Day 12 -32% b) Cocaine Room Temp: Day 3 +330% Day 5

+263% Day 10 +122% Day 12 +202% Refrigerator Day 3 +444% Day 5 +370% Day 10 +205% Day 12 +185% Freezer Day 3 +139% Day 5 +80% Day 10 -25% c) Methadone Room Temp Day 3 +55% Day 5 +50% Day 10 +28% Day 12 +26% Refrigerator Day 3 +52% Day 5 +53% Day 10 +32% Day 12 +31% Freezer Day 10 -26% d) Opiate Freezer Day 3 -45% Day 5 -53% Day 10 -52% Day 12 -45% e) Amphetamine Room Temp Day 10 +32% Day 12 +38% Refrigerator Day 10 +26% Day 12 +30% Freezer Day 3 -69% Day 5 -74% Day 10 -52% Day 12 -48% f) Barbiturates Freezer Day 3 -42% Day 5 -51% Day 10 -46% Day 12 -41% g) Benzodiazepines Freezer Day 3 -35% Day 5 -67% Day 10 -58% Day 12 -52% h) Ethyl Alcohol Room Temp Day 3 -1121% Day 5 -999% Day 10 +99% Day 12 +97% Refrigerator Day 3 +860% Day 5 +790% Freezer Day 3 -1210% Day 5 -754% Day 10 -52% Day 12 -52% i) Oxycodone Freezer Day 3 -39% Day 5 -46% Day 10 -55% Day 12 -49% j) Phencyclidine Freezer Day 3 -31% Day 5 -34% Day 10 -37% Day 12 -30% k) Cannabinoids Room Temp Day 3 -79% Day 5 -98% Day 10 -97% Day 12 -97% Refrigerator Day 3 -404% Day 5 -404% Day 10 -82% Day 12 -82% Freezer Day 3 -95% Day 5 -94% Day 10 -83% Day 12 -84% k) Buprenorphine Freezer Day 3 -50% Day 5 -61% Day 10 -46% Day 12 -49% 3. The laboratory was asked to provide documentation of performing a stability study which met the laboratory's acceptability criteria. No documentation was provided. 4. An interview with the general supervisor on 01/30/2018 at 1030 hours in the laboratory - after her review of the records- confirmed the findings.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Based on surveyor observation of specimen received by the laboratory, review of the shipping instructions provided by the reference laboratory, and staff interview, it was revealed the laboratory failed to provide its clients with the proper instructions for sample transport. The findings were: 1. A review of patient specimens received on 01/30/2018 at 1030 hours revealed the laboratory received samples which were sent at ambient temperatures. 2. Because the laboratory had stopped testing in July 2017, the laboratory referred these specimens to another facility. 3. A review of the specimen requirements for the reference laboratory revealed it required samples to be shipped refrigerated to maintain a temperature of 2 - 8C. 4. An interview with the general supervisor on 01/30/2018 at 1035 hours in the accessioning area revealed the laboratory would repackage the specimens it received at ambient temperature and ship them to the reference facility with ice packs to maintain the required 2 - 8C. She stated that the reference laboratory did not know that specimens were shipped at a temperature range which would have caused the samples to be rejected for testing by the reference lab. 5. A review of patient test records from January 2018 revealed the laboratory sent 318 samples to the reference laboratory (see patient alias list #2) 6. An additional interview with the general supervisor on 01/30/2018 at 1100 hours in the laboratory revealed the laboratory did repackage samples to be shipped to the reference lab in a manner that would appear the samples had been shipped as required from collection site. This confirmed the findings.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in pre-analytic systems. The findings were: 1. The laboratory's quality assessment plan failed to have identify and correct that the laboratory did not have documentation of performing transportation studies and successful stability studies as part of its establishment studies for its modified FDA-approved assays (refer to D5311). 2. The laboratory's quality assessment plan failed to identify and correct that the laboratory failed to provide clients with instructions for proper sample shipping requirements (refer to D5317).

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, review of the laboratory's establishment studies performed in December 2016, and staff interview, it was revealed the laboratory failed to have documentation of performing complete establishment studies. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed testing utilizing the following modified FDA-approved assays on the Mindray BS-480 chemistry analyzer: ThermoScientific DRI Amphetamines Assay ThermoScientific DRI Ethyl Alcohol Assay ThermoScientific DRI Cannabinoid Assay ThermoScientific CEDIA Phencyclidine Assay ThermoScientific CEDIA Buprenorphine Assay ThermoScientific DRI Ecstasy Assay ThermoScientific DRI Cocaine Metabolite Assay ThermoScientific DRI Oxycodone Assay ThermoScientific DRI Opiate Assay ThermoScientific DRI Methadone Assay ThermoScientific DRI Gravity-Detect test ThermoScientific DRI General Oxidant-Detect test ThermoScientific DRI pH-Detect test ThermoScientific DRI Creatinine-Detect test 2. A review of the laboratory's establishment studies performed in December 2016 and approved by the laboratory director on 01/27/2017 revealed the laboratory failed to have documentation of the following: a) pre-analytic studies (refer to D5311) - specimen stability/preservation - specimen transport - specimen storage b) evaluation of accuracy c) specificity d) defined quantities of interfering substances studied e) verification of patient normal ranges for: - specific gravity - pH - creatinine

3. The laboratory was asked to provide documentation of complete studies for its modified FDA-approved assays. No documentation was provided. 4. An interview with the general supervisor on 01/31/2018 at 1100 hours in the laboratory - after her review of the records - 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 records, and staff interview it was revealed the laboratory failed to have documentation of performing calibration verification for assays performed on the Mindray BS-480 analyzer. The findings were: 1. A review of the laboratory's establishment studies for assays performed on the Mindray BS-480 analyzer revealed the studies were performed in December 2016. Thus, calibration verification was required by June 2017. 2. A review of the laboratory's test menu revealed the following assays were performed on the Mindray BS-480 analyzer: ThermoScientific DRI Amphetamines Assay ThermoScientific DRI Ethyl Alcohol Assay ThermoScientific DRI Cannabinoid Assay ThermoScientific CEDIA Phencyclidine Assay ThermoScientific CEDIA Buprenorphine Assay ThermoScientific DRI Ecstasy Assay ThermoScientific DRI Cocaine Metabolite Assay ThermoScientific DRI Oxycodone Assay ThermoScientific DRI Opiate Assay ThermoScientific DRI Methadone Assay ThermoScientific DRI Gravity-Detect test ThermoScientific DRI General Oxidant-Detect test ThermoScientific DRI pH-Detect test ThermoScientific DRI Creatinine-Detect test 3. Further review of the laboratory's records revealed the following assays utilized two or few calibrators and less than three controls: ThermoScientific DRI Amphetamines Assay ThermoScientific DRI Ethyl Alcohol Assay ThermoScientific DRI Cannabinoid Assay ThermoScientific CEDIA Phencyclidine Assay ThermoScientific CEDIA Buprenorphine Assay ThermoScientific DRI Ecstasy Assay ThermoScientific DRI Cocaine Metabolite Assay ThermoScientific DRI Oxycodone Assay ThermoScientific DRI Opiate Assay ThermoScientific DRI Methadone Assay These assays required calibration verification. 4. The laboratory was asked to provide documentation of performing the

required calibration verification by June 2017. No documentation was provided. 5. An interview with the general supervisor on 01/31/2018 1000 hours in the laboratory revealed the laboratory was unaware calibration verification was required. This confirmed the findings.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality control policy, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have follow it policy for determining quality control acceptability. The findings were:
1. A review of the laboratory's policy titled "Quality Control" (approved by the laboratory director on 04/17/2017) revealed the laboratory was to utilize a mean +/- 2 standard deviations to access control acceptability. 2. A review of the laboratory control values programmed into the Mindray BS-480 analyzer revealed the evaluated quality control values by comparing the results to the mean +/- 10% of the mean. This resulted in the laboratory using ranges which were greater than 2 standard deviations. Some examples were: a) Cocaine Control: DOAT 3 Programmed SD: 36.271 actual SD: 6.4 Thus the laboratory was using the mean +/- 10 SD b) Opiates Control: DOAT 3 Programmed SD: 38.13 actual SD: 7.59 Thus the laboratory was using the mean +/- 10 SD c) Methadone Control: DOAT 3 Programmed SD: 43.201 actual SD: 10.9 Thus the laboratory was using the mean +/- 8 SD d) Amphetamine Control: DOAT 4 Programmed SD: 38.8 actual SD: 22.5 Thus the laboratory was using the mean +/- 3.5 SD e) THC Control: DOAT 4 Programmed SD: 4.352 actual SD: 1.29 Thus the laboratory was using the mean +/- 6.7 SD 3. The laboratory was asked to provide documentation of evaluating its quality control values utilizing the mean +/- 2SD as required by its policy. No documentation was provided. 4. An interview with the general supervisor on 02/01/2018 at 1045 hours in the laboratory revealed she was unaware the ranges programmed into the Mindray BS-460 analyzer were not representative of a 2 SD range. This confirmed the findings. Key: SD: standard deviation

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory's quality assessment policy failed to identify and correct issues in analytic systems. The findings were: 1. The laboratory's quality assessment plan failed to identify and correct that the laboratory's establishment studies were incomplete (refer to D5423). 2. The laboratory's quality assessment plan failed to identify and correct that calibration verification was not performed on the Mindray BS-460 analyzer (refer to D5439). 3. The laboratory's quality assessment plan failed to identify and correct that the laboratory failed to follow its quality control policy (refer to D5441).</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>
<p>D6082</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies, and staff interview, it was revealed the laboratory director failed to ensure test systems provided quality laboratory services. The findings were: 1. The laboratory director failed to ensure the laboratory's establishment studies were complete (refer to D5423).</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists' proficiency testing records from 2017, and staff interview, it was revealed the laboratory director failed to ensure reports were received and reviewed. The findings were: 1. A review of the laboratory's College of American Pathologists' proficiency testing records from 2017 ((DAI - A and B, DMPM - A and B, ET - B, and UDS - A, B and C) revealed the laboratory director failed to ensure reports were received and reviewed for 1 of 8 events. The laboratory failed to have documentation of the results for 2017 UDS - B. 2. The laboratory was asked to provide documentation of the receipt and review of the</p>

	<p>identified results. No documentation was provided. 3. An interview with the general supervisor on 01/29/2018 at 1400 hours in the laboratory - after her review of the records- confirmed the findings.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality control plan was followed (refer to D5441).</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure and quality assessment plan was developed and followed. The findings were: 1. The laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected issues in pre-analytic systems (refer to D5391). 2. The laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected issues in analytic systems (refer to D5791).</p>
D6115	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies, and staff interview, it was revealed the technical supervisor failed to ensure the laboratory's establishment studies were complete (refer to D5423).</p>
D6117	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)</p> <p>The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained</p>

throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of the laboratory's records, and staff interview, it was revealed the technical supervisor failed to ensure the laboratory's quality control plan was followed (refer to D5441).