Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2023410	04/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Connecticut Behavioral Health Associates	620 Gold Star Hwy, Groton, CT	

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
D5022	TOXICOLOGY CFR(s): 493.1213 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. This CONDITION is not met as evidenced by: Based on surveyor observation, record review and staff interview, the toxicology laboratory failed to meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure that accuracy and reliability of patient test results. refer to D5209, D5217, D5221, D5291, D5403, D5429, D5441, D5469, D5783, and D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel and they were not assessed. Findings include: 1. Record review of the laboratory's competency records on 4/8/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the clinical consultant (CC), technical supervisor (TS), and general supervisor (GS). b. Competency documentation for the TS and CC was not available.

	2. Staff interview with the laboratory director on 4/8/19 at 11:10 AM confirmed the above findings.
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 staff interview, the laboratory failed to evaluate all non-regulated analytes at least twice annually for confirmatory drug testing on the Sciex Multiquad 5500 instrument in the subspecialty of toxicology. Findings include: 1. Record review of the "College of American Pathologists" (CAP) proficiency testing (PT) summary reports on 4/8/19 revealed the laboratory failed to test all 23 analytes analyzed on the liquid chromatography tandem mass spectrometry (LC/MS/MS) Sciex Multiquad 5500 instrument twice annually in 2017 and 2018. 2. Record review of the laboratory's PT CAP enrollment "Drug Monitoring For Pain" (DMPM) survey program list on 4/8/19 revealed the DMPM PT program list contained all 23 analytes, but not all are sent to the laboratory twice a year. Instead only a mix of the drugs from the list are sent for each survey. 3. Staff interview with the laboratory director on 4/8 /19 at 2:15 PM confirmed the above findings. 4. The laboratory performs 276,000 LC /MS/MS toxicology confirmation tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to properly investigate unacceptable proficiency test (PT) results and take remedial action to prevent recurrence in the subspecialty of toxicology. Findings include: 1. Record review on 4/8/19 of the laboratory's 2017 and 2018 PT records revealed: a. 2018 Survey Medical Laboratory Evaluations (MLE) 2, AUR-3 Urine Ph, the required response was abnormal. The laboratory submitted a response of normal. 2. Record review on 4/8/19 of the laboratory's investigation for the unacceptable result referenced in 1 above revealed: a. The test was repeated using a new lot of reagent and the results were acceptable. b. The above investigation was incomplete and lacked procedural changes/corrective action to prevent recurrence. 3. Staff interview with the laboratory director on 4/8/19 at 11:10 AM confirmed the above findings. 4. Record review of the College of American Pathologists (CAP) Drug Monitoring Pain Management Proficiency Testing (PT) summary report on 4/8/19 revealed unacceptable results for methadone for Event 1 in 2018 for confirmatory testing on the Sciex Multiquad 5500 instrument. 5. Record review of the laboratory's plan of correction for the above PT event on 4/8/19 revealed the laboratory failed to provide remedial action to prevent recurrence. 6. Staff interview with the laboratory director (LD) on 4/8/19 at 2:30 PM confirmed the findings in 4 and 5 above. 7. The laboratory performs 12,000 methadone confirmation tests annually.
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 staff interview, the laboratory failed to 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. Refer to D5217 and D5221.
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: Based on record review and staff interview, the laboratory failed to meet the high complexity analytical system requirements in the subspecialty of toxicology. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the subspecialty of toxicology. Refer to D5403, D5429, D5441, D5469, D5783 and D5791.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a procedure for verification of new quality control (QC) material prior to patient testing in the subspecialty of toxicology. Findings include: 1. Record review of the laboratory's toxicology procedure manual on 4/8/19 for confirmatory toxicology tests by liquid chromatography tandem mass spectrometry (LC/MS/MS) revealed the lack of the following procedures: a. Lot to lot quality control (QC) policy for verifying new lots/shipments or acceptable criteria. b. Validation policy for newly prepared QC to establish ranges prior to patient testing. c. Acceptable criteria for coefficient of variation when monitoring monthly QC for shifts and trends. d. Lot to lot verification policy for the hydrolysis QC. 2. Staff interview with the laboratory director on 4/8/19 at 3:00 PM confirmed the procedure manual in the subspecialty of toxicology is incomplete and needs to be updated. 3. The laboratory performs 276,000 toxicology confirmation tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document routine maintenance and function checks for laboratory equipment in the subspecialty of toxicology. Findings include: 1. Record review on 4/8/19 of the maintenance logs for the Biolis 24i revealed: a. The maintenance logs were incomplete and lacked documentation for either daily, weekly, and/or monthly maintenance for 24 of 24 months from May 2017 through April 2019. b. The logs were signed as reviewed. 2. Record review on 4/8/19 of the laboratory's Biolis 24i Technical SOP, signed by the laboratory director on 6/29/17, revealed: a. Maintenance protocols need to be performed and documented on a daily, weekly, and monthly schedule in order to ensure accurate and reliable test results. b. It is the responsibility of testing personnel to provide the completed monthly maintenance logs to the technical supervisor for review. 3. Staff interview with the laboratory director on 4/8/19 at 2:30 PM confirmed the above 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 surveyor observation, record review and staff interview, the laboratory failed to establish a morphine 3-beta-glucoronide (M3G) hydrolysis (HQC) control procedure to monitor the accuracy and precision of the complete analytic process for confirmatory testing in the subspecialty of toxicology. Findings include: 1. Surveyor observation of the HQC bottle lot# 20190109 currently in use on 4/8/19 at 2:30 PM revealed, the concentration listed on the bottle was 2000 ng/ml for M3G HQC. 2. Record review on 4/8/19 of the instrument QC acquisition data printout, dated 11/29 /18 revealed the HQC concentration was listed as 3000 ng/ml. 3. Record review on 4/8 /19 of the laboratory's 'Making HC Control Stock for LCMS' policy revealed: a. The M3G HQC stock concentration was 20,000 ng/ml. b. Calculation, final concentration, and acceptable criteria was not listed. 4. Record review on 4/8/19 of the HQC linearity, dated 2/2/19 revealed the morphine upper limit of linearity was 3,500 ng/ml. 5. Record review of 2 of 2 patient final reports on 4/8/19 revealed the reportable range for morphine is 100 to 2000 ng/ml. 6. During staff interview with the laboratory director (LD) on 4/8/19 at 3:00 PM, the LD stated the HCG concentration was 4,000 ng/ml. The LD also stated he/she was not aware the concentration had to be within the laboratory's linear range. Refer to D5403
D5469	CONTROL PROCEDURES 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 staff interview, the laboratory failed to establish acceptable quality control (QC) ranges for their prepared in-house unassayed QC analyzed on the Sciex Multiquad 5500 instrument in the subspecialty of toxicology. Findings include: 1. Record review of the laboratory's QC currently in use on 4/8/19 revealed the laboratory did not verify or establish ranges for the following QC placed into service on 11/29/18: a. Negative QC - CO lot# 110218 b. 15ng/ml QC - C1 lot# 110118 c. 150ng/ml QC - C2 lot# 110118 d. 500ng/ml QC - C3 lot#110118 2. Record review of the laboratory's policy/procedure manual on 4/8/19 revealed the laboratory failed to have a policy in place to verify newly prepared in-house unassayed QC lots and establish ranges prior to patient testing for 23 analytes performed on the Sciex Multiquad 5500 instrument used for confirmation. 3. Record review of the sequence tables for the Sciex Multiquad 5500 instrument on 4/8/19 revealed on 11/29/18, sixty patient samples were analyzed and reported using the unverified QC listed in #1 above for batch number 204181129-17482-60. Further review of the sequence tables revealed all batches of patient samples analyzed and reported from 11/29/18 to 4/8/19

	used the unverified QC listed in #1 above. 4. Staff interview with laboratory director on 4/8/19 at at 12:15 PM confirmed the laboratory failed to established ranges for the newly prepared QC listed above and do not have a policy established. Refer to D 5403.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to take corrective action when the quality controls (QC) were outside the acceptable limits for confirmatory testing. Findings include: 1. Record review of the negative QC results for the Sciex Multiquad 5500 on 4/8/19 revealed the negative QC failed and was positive for all 23 analytes for the following batches with no corrective action: a. Batch 11032018 run on 11/3/18-60 patients were reported. b. Batch 11072018 run on 11/7/18- 60 patients were reported. c. Batch 11092018 run on 11/9/18-60 patients were reported. 2. Record review of the laboratory's corrective action log on 4/8/19 revealed the laboratory discovered the negative QC was contaminated on 11/5/18. No documentation of remedial action was available to prevent recurrence. 3. Record review of the negative QC chromatography for the above batches on 4/8/19 revealed the chromatography was gaussian shape, with Q1/Q3 masses and retention times indicating a positive result. 4. Record review on 4/8/19 of the QC instrument acquisition data revealed: a. The laboratory director (LD) reviewed the above batches. b. All 23 analytes were above the limit of quantitation. c. Patient results were reported. 5. Interview with the LD on 4/8/19 at 2:30 PM confirmed the above findings. The LD stated upon review of the QC instrument acquisition data above he /she thought the concentrations were erroneous and the chromatography was unacceptable.
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. This STANDARD is not met as evidenced by: A. Based on record review and staff interview, the laboratory failed to establish a quality assessment (QA) plan to ensure new lots of quality control (QC) are acceptable. Findings include: 1. Record review of the laboratory's QC monthly review logs on 4/8/19 revealed the following: a. Quality control records are monitored on a monthly basis using the EP Evaluator program by the laboratory director (LD). b.

	Acceptable QC criteria was not available. c. QC means are not adjusted for shifts and trends. 2. Record review of the laboratory's QA plan on 4/8/19 revealed the plan does not include corrective action/investigation when shifts and trends are noted. a. Negative QC - CO lot# 110218 b. 15ng/ml QC - C1 lot# 110118 c. 150ng/ml QC - C2 lot# 110118 d. 500ng/ml QC - C3 lot#110118 3. Staff interview with the laboratory director (LD) on 4/8/19 at 12:45 PM confirmed the above findings. The LD stated he /she utilizes a plus or minus 20% of target value to determine QC acceptability. The TS stated he/she does not update the instrumentation to adjust the QC mean for shifts and trends because it is a lot of work. B. Based on record review and staff interview, the laboratory failed to follow their established QA plan when QC results are repeatedly unacceptable. Findings include: 1. Record review of the QC results for the Sciex Multiquad 5500 from 2017 and 2018 on 4/8/19 revealed the low QC for all 23 analytes tends to fail for most of the runs with no investigation available. 2. Record review of the laboratory's "Quality Management" procedure section 5B quality assessment flowchart on 4/8/19 revealed repetitive problems require the laboratory to perform a quality assesment, identify problem or weakness, investigate problem, determine the root cause and design a solution. 3. Interview with the laboratory director on 4/8/19 at 12:45 PM confirmed the findings in B1 and B2 above. The LD also stated for batches to be accepted, any 2 of 4 QC need to be in range in order for the run to be accepted for the Sciex Multiqaud 5500 instrument. 4. The laboratory performs 276,000 confirmatory toxicology tests annually. Refer to D5783.
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 surveyor observation, record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure accuracy and reliability of patient test results in the subspecialty of toxicology. 1. The LD failed to ensure training and/or competency of all laboratory testing personnel. Refer to D6079, D6086, D6102 and D6125. 2. The LD failed to ensure proficiency testing (PT) samples are tested as required. Refer to D6089. 3. The LD failed to ensure all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6092. 4. The LD failed to ensure an approved corrective action plan is followed when any PT results are found to be unacceptable or unsatisfactory. Refer to D6092. 5. The LD failed to ensure quality assessment programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6094. 6. The LD failed to ensure quality control (QC) values were in range before reporting out patient test results. Refer to D6093. 7. The LD failed to ensure the laboratory maintained a qualified technical supervisor. Refer to D6108 and D6109.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to have a policy in place to assess the competency of all laboratory personnel and they were not assessed. Refer to D5209.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 record review and staff interview, the laboratory director failed to establish policies/procedures to ensure accurate reporting of test results. Refer to D5403, D5441, D5469 and D5791
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 staff interview the labortory failed to evaluate all non-regulated analytes a least twice annually. Refer to D5217
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure a corrective action plan is followed when any proficiency testing result is found to be unacceptable. Refer to D5221.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to establish and ensure quality control policy/procedures were in place to identify failures in quality as they occur. Refer to D5291, D5403, D5441 and D5469.
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 staff interview the laboratory failed to establish a quality assessment plan to monitor and ensure verification of new lots of quality control in the subspecialty of toxicology. Refer to D5791 and D5291.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure new testing personnel (TP) received appropriate training to perform high complexity testing prior to reporting patient test results. Findings include: 1. Record review on 4/8 /19 of 1 of 1 new TP files revealed the training documentation for the sample preparation for LC/MS/MS was not available. 2. Staff interview with the laboratory director on 4/8/19 at 10:00 AM confirmed the above findings. B. Based on record review and staff interview, the laboratory director failed to ensure all TP tested previously analyzed specimens, blind samples or external proficiency testing (PT) samples in the subspecialty of toxicology prior to patient testing. Refer to D6125.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a technical supervisor (TS) in the subspecialty of toxicology. Refer to D6109.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a technical supervisor (TS) in the subspecialty of toxicology from July 2017 until January 2019. Findings include: 1. Record review on 4/8/19 of the laboratory's 'State of Connecticut Laboratory Personnel Report', signed by the current laboratory director (CLD) on 4/9 /19 revealed testing personnel #1 (TP1) was also listed as the TS. 2. Record review on 4/8/19 of the laboratory's 'State of Connecticut Laboratory Personnel Report', signed by the former laboratory director (FLD) on 4/21/17 revealed, the former laboratory director was listed as the TS. 3. Record review on 4/8/19 of the Automated Survey Processing Environment (ASPEN) 116 inquiry for Connecticut Behavioral Health, revealed the LD was changed from the FLD to the CLD on 7/19/17. 4. Record review on 4/8/19 of the laboratory's 'Technical Supervisor Delegation' form signed by the CLD on 1/7/19 revealed, TP1 was authorized to perform TS duties. 5. Record review of the laboratory's competency records on 4/8/19 revealed, the laboratory did not have TS competency records for the new TS. 6. Staff interview with the CLD on 4/8/19 at 11:00 AM confirmed the above findings. The CLD stated he/she was told that the company that sold the laboratory the instrumentation was the TS.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure competency assessment for all testing personnel (TP) includes testing previously analyzed specimens, blind samples or external proficiency testing (PT) samples in the subspecialty of toxicology. Findings include: 1. Record review on 4/8/19 of the laboratory's 2017 and 2018 competency files revealed the laboratory failed to document the examination of previously analyzed specimens, blind samples or external PT material for 1 of 2 toxicology screening TP to accurately assess their skills in 2017 and 2018. 2. Staff interview with the laboratory director on 4/8/19 at 10: 00 AM confirmed the above findings.