Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2087228	09/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Pain Medicine Institute (Apmi)	7501 Greenway Center Drive, Suite 690, Greenbelt, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the testing person, the laboratory failed ensure that all the PT records were maintained for a minimum of two years. Findings: 1. The PT records from the 3rd event of 2017 and the 1st and 2nd events of 2018 (12 separate kits covering 5 different subspecialties) were reviewed. 2. The attestation worksheets were not available for 6 of the 12 kits. The instrument printouts with the PT results were not available for 3 of 12 kits. The PT worksheet with the results submitted to the PT agency were not available for 1 of 12 kits. 3. During the survey on 09/27/2018 at 2:30 PM the testing personnel confirmed that not all the PT records were available at the time of the survey.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a

	proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to investigate proficiency testing (PT) failures and successfully participate in the PT for routine chemistry and endocrinology. The laboratory failed to investigate when the PT reports indicated a score of 0% and 33% for multiple chemistry analytes (D2087); the laboratory did not investigate when the overall PT score for chemistry was less than 80% (D2088); the laboratory failed investigate the two of three failures in chemistry and implement a plan of correction to prevent additional failures (D2096); and the laboratory failed to investigate when the PT reports indicated a code "(20) No appropriate target/response cannot be evaluated" (D2098).
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: I. Based on review of proficiency testing (PT) documentation and interview with the testing personnel, the laboratory failed to investigate when the PT reports indicated a score of 0% for multiple chemistry analytes. Findings: 1. The PT reports that were reviewed at the laboratory showed that the laboratory received a score of 0% for the following analytes: alkaline phosphatase (AlkP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), albumin, total cholesterol, HDL cholesterol, creatinine, glucose and triglycerides for the 3rd event of 2107. 2. When interviewed the testing person stated that she did not realize that the code meant that the analyte had not been evaluated and had not investigated the lack of an acceptable score for AlkP, ALT and AST. 3. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that an investigation had not been conducted for the analytes that received a score of 0%. II. Based on review of proficiency testing (PT) documentation and interview with the testing personnel, the laboratory failed to investigate when the PT reports indicated a score of 33% (2 of 3 challenges failed to receive a correct result) for glycosylated hemoglobin (A1C) test results. Findings: 1. The PT reports that were reviewed at the laboratory showed that the laboratory received a score of 33% for glycosylated hemoglobin for the first event of 2018. 2. When interviewed the

	testing person stated that she did not realize that the A1C analyte had not been evaluated and had not investigated the lack of an acceptable score. 3. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that an investigation had not been conducted for the A1C score of 33%.
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2017 and 2018 and interview with the testing personnel, the laboratory did not investigate when the overall PT score for chemistry was less than 80%. Findings: 1. The PT reports that were reviewed at the laboratory showed that the laboratory received an overall score of 44% for routine chemistry for the 3rd event in 2017. 2. During the survey on 09/27 /18 at 2:30 PM the testing personnel confirmed that an investigation had not been conducted for the overall score of 44% for routine chemistry.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of CASPER Report 0155D Individual Laboratory Profile, review of proficiency testing (PT) documentation and interview with the testing personnel, the laboratory failed to investigate the two of three failures in chemistry and implement a plan of correction to prevent additional failures. Findings: 1. The CASPER Report 0155D showed that the laboratory received a score of 0% for creatinine during the 3rd event in 2017 and a score of 60% during the 2nd event of 2018. The CASPER Report 0155D showed that the laboratory received a score of 0% for HDL cholesterol during the 3rd event in 2017 and a score of 20% during the 2nd event of 2018. 2. The laboratory records reviewed during the survey showed that the 2nd event of 2018 for creatinine and HDL cholesterol had been investigated but not the failures for the 3rd event in 2017 where the laboratory received a score of 0%. 3. The PT reports that were reviewed at the laboratory showed that the laboratory did not receive a score for alkaline phosphatase (AlkP), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) during the 1st and 2nd events of 2018. The code that was listed next to the results was "(20) No appropriate target/response cannot be evaluated." 4. The laboratory records reviewed at the survey showed that the 1st and 2nd events of 2018 for AlkP, ALT and AST had not been evaluated due to no appropriate target/response by the PT agency and had not been investigated and evaluated by the laboratory. 5. When interviewed the testing person stated that she did not realize that the code meant that the analytes had not been evaluated and had not investigated the lack of an acceptable score for AlkP, ALT and AST. 6. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that an investigation had not been conducted for the analytes that had received a 0% (creatinine and HDL

	cholesterol) and the analytes that had not been evaluated (AlkP, ALT and AST) to prevent future failures and ensure the accuracy of patient testing during that time period.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the testing personnel, the laboratory did not investigate when the PT reports indicated a code "(20) No appropriate target/response cannot be evaluated." Findings: 1. The PT reports that were reviewed at the laboratory showed that the laboratory did not receive a score for insulin during the 1st event of 2018. The code that was listed next to the results was "(20) No appropriate target/response cannot be evaluated." 2. When interviewed the testing person stated that she did not realize that the code meant that the analyte had not been evaluated and had not investigated the lack of an acceptable score for Insulin. 3. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that an investigation had not been conducted for the analyte that had not been evaluated (insulin) to prevent future failures and ensure the accuracy of patient testing during that time period.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation in the laboratory and interview with the testing personnel, the laboratory failed to secure the hose from the Mindray BS-480 (chemistry analyzer) to the drain in the middle of the floor that was under the work table that the surveyors were seated at. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety in the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. The laboratory has 5 different analyzers spread throughout the laboratory. Each has its own hoses and tubes for drainage of waste into containers to be disposed of by the laboratory staff. 3. When interviewed the testing person stated that the hose from the Mindray BS-480 that empties into the drain in the middle of the floor contained distilled water. The building maintenance staff told them that it was fine to have the hose empty into the drain in the middle of the floor. 4. The hose is taped to the floor for approximately 18 inches right next to the analyzer. Approximately an additional 4 feet is not taped as it lies across the floor in the walkway/clearance around the worktable and down to the drain. While conducting the survey the surveyor tripped over the hose at least two times. 5. During the survey on 09/28/2018 at 12:00 PM the testing person confirmed that the hose was not secured to the floor from the analyzer to the drain under the worktable.

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 interview with the laboratory manager, the laboratory failed to establish written policies and procedures for assessing the testing personnel as defined in subpart M- CFR 493.1413(b)(8) through (9) for the specialty of hematology and the subspecialties of routine chemistry and endocrinology. Findings: 1. Since the last recertification survey on 10/06/2016, the laboratory has added the specialty of hematology and the subspecialties of routine chemistry and endocrinology. The laboratory now has 5 different analyzers on which to evaluate the testing personnel. The evaluation forms that were reviewed included six different categories of competency. The forms failed to capture the initial training and orientation; the six month competency review and the annual evaluation of the testing personnel on the new analyzers. 2. The laboratory's written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently for the specialty of hematology and the subspecialties of routine chemistry and endocrinology. 3. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable; specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 4. Evaluations must be performed at six months and annually thereafter unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. 5. During the survey on 09/27/18 at 2:30 PM the laboratory manager confirmed that the policies and procedure manual did not include a written training program along with worksheets for the documentation of the training of the testing personnel for the specialty of hematology and the subspecialties of routine chemistry and endocrinology.
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: I. Based on review of the procedure manual and interview with the laboratory manager, the laboratory failed to establish written procedures for the transportation of the hematology, routine chemistry and endocrinology specimens from the satellite offices to the main laboratory. The laboratory did not have courier and transportation information for transportation of the urine toxicology specimens. Findings: 1. According to the testing person the whole blood samples are picked by the laboratory director or another person in the satellite office and transported to the main laboratory. 2. Review of the procedure manual showed that no instructions were provided to the satellite offices that included- patient preparation; specimen collection; specimen labeling, including patient name or unique patient identifier; specimen storage and preservation; and conditions for specimen transportation. 3. The "Urine Collection Procedure" did not have specific instructions defining the courier and how the urine toxicology specimens are transported to the main laboratory for testing. 4. During the survey on 09/27/2018 at 2:30 PM the laboratory manager confirmed that there were no defined policies and procedures for the satellite offices to follow when collecting and transporting hematology, routine chemistry, endocrinology and urine samples to the main laboratory. II. Based on review of the "Criteria for Rejection of Urine Specimens" procedure and interview with the testing personnel, the laboratory failed to ensure that the policy reflected the actual practice of the laboratory. Findings: 1. The "Criteria for Rejection of Urine Specimens" procedure states "Urine specimens should be sent to the Laboratory as soon as possible after collection; preferably daily unless refrigerated immediately." 2. According to the testing personnel the urine specimens from the satellite office may be delivered in the evening and be left in a locked box until the testing personnel arrive the next day. These specimens are not being refrigerated and therefore, should be rejected according to the procedure. 3. During the survey on 09/27/2018 at 2:30 PM the testing person confirmed that the rejection procedure did not reflect the practice of the laboratory.
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:
I. Based on review of the procedure manual and interview with the testing personnel, the laboratory failed to provide written instructions to follow when routine chemistry quality control (QC) materials are not within limits of acceptability. Findings: 1. According to the testing personnel when QC fails they follow the following protocol until the QC results are acceptable. They retest the QC, open fresh bottles of QC material and repeat the test and then calibrate and repeat the QC and repeat again and then calibrate until the QC is acceptable. 2. The procedure did not include written instructions to be followed when routine chemistry QC results are not acceptable. 3. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that the policy and procedure manual did not contain a written protocol to follow when QC results are not within acceptable limits. II. Based on review of the procedure manual and interview with the testing personnel, the laboratory failed to provide written instructions for calling and documenting panic or alert values and the course of action to be taken when the test system becomes inoperable for routine chemistry, endocrinology, and hematology. Findings: 1. Review of the procedure manual showed that there were no written instructions for calling and documenting panic or alert values for routine chemistry, endocrinology, and hematology. 2. Review of the procedure manual showed that there were no written instructions for the course of action to be taken when the test system becomes inoperable for routine chemistry, endocrinology, and hematology. 3. When interviewed the testing person stated that the laboratory information system (LIS) had been down 03/13/2018 through 09/25/2018. The testing person stated that the patient results had to be entered manually into the LIS and the quality control (QC) results did not transfer from each of the analyzers into the LIS. The laboratory staff had to manually enter all the patients and QC results during this time period. 4. During the survey on 09/28/18 at 12:00 PM the testing personnel confirmed that there were no written policies and procedures to follow when manually entering the patient results into the LIS and managing and reviewing the QC results. III. Based on review of the procedure manual and interview with the testing personnel, the laboratory failed to ensure that there were written instructions for how to document the appropriate information on the laboratory worksheets. Findings: 1. The "Sample Submission Log Form" requires the testing person to document the Date; Time; Sample dropped by; Sample received by; Number of samples; Sample received from Greenbelt; Sample received from Chevy Chase; Sample received from New Carrollton and Remark. 2. The "Sample Submission Log Form" from 09/13/18 through 09/27/18 was reviewed. The dates were recorded. No times were recorded. For 09/21, 24, 25, 26 and 27/18 the testing personnel split the column labeled "Number of samples" into 2 columns labeled "urine" and "blood." No samples were received from New Carrollton and there were no remarks. 3. The testing person confirmed that there were no written instructions for documenting the information on the "Sample Submission Log Form"; when to split the column into "urine" and "blood"; and why the time column was blank. 4. The form labeled "Sheet1" requires the testing person to document the "Patients Name"; "Orders"; Date of Birth "DOB"; Male or Female "M/F"; "Loaded by"; and "Date". 5. Review of "Sheet1" dated "8-30 ? 9- 5" had a new column to the far left prior to the "Patient Name" column labeled "Collection date." The column labeled "M/F" showed that 23 of 31 rows did not list M or F. 6. Review of "Sheet1" dated "09/05/17" had a new column to the far left prior to the "Patient Name" column labeled "Collection date." The column labeled "M/F" showed that 12 of 14 rows did not list M or F. 7. Review of "Sheet1" dated "2-26-18" listed the following information- next to #1 was written 2 /23; next to #13 was written 2/26; next to #21 was written 2/27; next to #22 was written 2/26; and next to #29 was written 2/27. The column labeled "M/F" showed that 27 of 31 rows did not list M or F. In addition to the far right of the worksheet

	were listed numerous dates, initials, names of tests and other documentation that was not defined. 8. Two worksheets dated 07/31/18 and 09/13/18 for the urine toxicology liquid chromatography-mass spectrometry (LC-MS) analyzer were reviewed. The worksheet had no title. The first column was the number of the position on the LC-MS run. The second column was the name of the standard, control or patient. 9. When interviewed the testing person stated that the 5 digit numbers written to the left of the position column or after the second column were the accession numbers of the patients. 10. The LC-MS worksheet dated 07/31/18 had 5 digit numbers written on the left side of the first column and 6 digit numbers written on the right side of the second column with the name of the patient. There were 4 separate notations on the first page of the worksheet and 5 different name changes listed to the far right of the 6 digit number. The name changes were not addressed in any follow-up documentation. 11. The worksheets dated 07/31/18 and 09/13/18 consisted of two pages. There was no identifier on the second page to link it to the first page. 12. During the survey on 09/28 /18 at 12:00 PM the testing personnel confirmed that there were no written policies and procedures to follow when using the laboratory worksheets so that accurate and reliable information was documented. 38127 IV. Based on standard operating procedure manual (SOPM) review and interview with the laboratory manager, the laboratory did not ensure that there was a policy for testing with the Mindray BC-3600 hematology analyzer. Findings: 1. A review of the SOPM showed a procedure, "Standard Operating Procedure for the Mindray BC-3600." The procedure did not include step-by-step instructions for running the hematology analyzer, including test calculations and interpretation of results; preparation of solutions, calibrators, controls, reagents, and other materials used in testing; calibration and calibration verification procedures; the reportable range for test results for the test system as established or verified; corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; limitations in the test methodology, including interfering substances; reference intervals (normal values); imminently life-threatening test results, or panic or alert values; 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; or a description of the course of action to take if a test system becomes inoperable. 2. Document review showed that there was a "Basic Operational Quick Guide" but no instrument operator's manual available at the time of the survey. 4. During an interview on 9/27/18 at 3:00 PM, the laboratory manager confirmed that the SOPM did not contain written preanalytical, analytical, and post analytical policies and procedures for testing with the Mindray BC-3600 hematology analyzer.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the "Policy Manual" and interview with the laboratory manager, the laboratory failed to ensure that the procedures used by the laboratory staff were signed and dated by the current laboratory director. Findings: 1. The laboratory's procedure manuals were reviewed. The procedure manual labeled "Policy Manual" was not approved (signed and dated) by the current laboratory director. 2. The 3 page procedure labeled "Standard Operating Procedure for the Mindray BS-480" (chemistry analyzer) was not signed and dated by the current laboratory director. 3.

	The procedure labeled " Test Method Pain Panel P-43" (toxicology analyzer) was not signed and dated by the current laboratory director. 4. During the survey on 09/27 /2018 at 2:30 PM the laboratory manager confirmed that not all policies and procedures were signed and dated by the current laboratory director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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 determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of the maintenance records for the AIA 2000 ST (endocrinology analyzer) and interview with the testing person, the laboratory failed to follow the manufacturer's instructions when performing maintenance on the endocrinology analyzer. Findings: 1. The laboratory started using a new endocrinology analyzer in August 2017. 2. The manufacturer's instructions require the user to perform and document weekly cleaning on the BF Probe. The last documented cleaning listed in the analyzer was 06/21/2017. 3. The manufacturer's instructions require the user to perform and document maintenance on the Wash Solution Tank and Dilution Tank Cleaning every 3 months. The last documented maintenance listed in the analyzer was 06/21/2017. 4. During the survey on 09/28/18 at 12:00 PM the testing person confirmed that the maintenance was not being performed and documented as required by the manufacturer of the endocrinology analyzer. II. Based on review of the maintenance records for the liquid chromatography-mass spectrophotometer (LC-MS) (urine toxicology analyzer) and interview with the testing person, the laboratory failed to follow the manufacturer's instructions when performing maintenance on the urine toxicology analyzer. Findings: 1. The laboratory started using a urine toxicology analyzer prior to the previous survey on October 6, 2016. 2. The manufacturer's instructions require the user to perform and document weekly cleaning on the "Weekly Cleaning Maintenance Log For HPLC." The last documented cleaning listed on the worksheet was 10/27/2017. No records for 2018 could be found at the time of the survey. 3. During the survey on 09/28/18 at 12:00 PM the testing person confirmed that the maintenance was not being performed and documented as required by the manufacturer of the urine toxicology analyzer.
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 validation records and interview with laboratory staff and the

	laboratory manager, the laboratory failed to complete verification procedures for the laboratory's new hematology analyzer. Findings: 1. The laboratory installed a new Mindray BC-3600 hematology analyzer in March, 2017. During an interview at 2:00 PM, laboratory staff stated that the validation procedures were performed by a representative from the company. 2. A review of validation records showed that the validation samples were run and the raw data was recorded on "Linearity Worksheets." Instructions on the "Linearity Worksheets" instruct the user to "send the worksheets" back to the company "to obtain a computerized data analysis." 3. During an interview on 9/27/18 at 3:00 PM, the laboratory manager stated that the validation data was not sent to the company for analysis and confirmed that the validation of the new hematology analyzer was not completed before running patient samples.
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 hematology instrument maintenance record review and interview with laboratory staff and the laboratory manager, the laboratory did not ensure that weekly maintenance was performed on the hematology analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses a Mindray BC-3600 hematology analyzer to perform CBC analysis. The instrument's "Basic Operational Quick Guide" recommends that the "Probe cleanser Soak" be performed "weekly to maintain the analyzer." 2. A review of monthly hematology analyzer maintenance records from May, 2017 to July, 2018 showed that the weekly "probe cleanser soak was not performed or documented for 51 out of 70 weeks. 3. During an interview on 9/27/18 at 3:00 PM, the laboratory manager confirmed that weekly hematology analyzer maintenance was not performed and documented as recommended by the manufacturer.
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 calibration record review and interview with laboratory manager and laboratory staff, the laboratory failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months. Findings: 1. A review of hematology analyzer records from March, 2017 to September, 2018 for the Mindray BC-3600 hematology analyzer showed that there were no calibration verifications performed. 2. During an interview at 1:30 PM, the laboratory staff stated that "MedTest" is the company that services the instrument and does the calibrations, that "If there's no calibrations in the binder, then they haven't been here," and that "We don't even keep materials in the fridge to calibrate." 3. During an interview on 9/28/18 at 3:00 PM, the laboratory manager confirmed that the hematology analyzer had not been calibrated.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the laboratory manager, the laboratory failed to document corrective action when freezer temperatures were out of range. Findings: 1. The temperature range for the laboratory's "Freezer #001" is "-30 to -15" degrees Celsius. 2. From June, 2018 to August, 2018 the freezer temperatures were out of range 40 out of 66 times recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 9/27/18 at 3:00 PM, the laboratory manager confirmed that there were no corrective actions documented for the days that the freezer temperatures were out of range.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

	This STANDARD is not met as evidenced by: Based on review of the calibration records for the toxicology analyzer and interview with the testing personnel, the laboratory's record system failed to include the identity of the personnel who performed the calibration on the liquid chromatography-mass spectrophotometer (LC-MS) urine toxicology analyzer. Findings: 1. Review of the current calibration records for the LC-MS showed that there was no documentation of the person who performed the test. 2. During the survey on 09/28/2018 at 12:00 PM the testing personnel confirmed that the calibration records for the LC-MS did not include the identity of the person who performed the daily calibration.
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 patients' final reports and interview with the testing personnel, the laboratory failed to ensure that the final test report listed the address of the laboratory performing the tests. Findings: 1. During the survey two patient charts were pulled to review the final report with the patients' test results. The two charts were from the satellite offices. Two of the two that were reviewed did not include the address of the laboratory performing the tests. 2. During the survey on 09/28/2018 at 12:00 PM the testing personnel confirmed that the final reports from the satellite offices did not include the address of the laboratory performing the tests.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to provide a safe environment in which employees are protected from physical hazards (D6011); failed to ensure that the verification records included accurate information prior to signing and dating the documentation and ensuring that the information was accurate and reliable prior to testing patient samples (D6013); failed to be enrolled in an approved proficiency testing (PT) program for all the subspecialties for which its seeks certification (D6015); failed to identify problems with the PT results and ensure corrective actions were taken and documented (D6018); failed to ensure that the monthly quality control (QC) forms were signed and dated indicating that the laboratory director had reviewed the QC for all the instruments, and failed to establish and follow written quality assurance policies and procedures for an ongoing

	mechanism to monitor the laboratory (D6022); and failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the laboratory testing (D6032).
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation and interview with the testing personnel, the laboratory director failed to provide a safe environment in which employees are protected from physical hazards. Cross refer to Tag D3011 for details.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(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 the validation records for the Mindray BS-480 (chemistry analyzer) and interview with the testing person and laboratory director, the laboratory director failed to ensure that the verification records that were signed on 04/03/2017 included accurate information prior to signing and dating the documentation and ensuring that the information was accurate and reliable prior to testing patient samples. Findings: 1. Review of the verification records showed that the routine chemistry analyzer was labeled as "Instrument BS-200 Chem" and not the "BS-480". The "Sample Type" was listed as urine for the two levels of quality control materials used for the verification. 2. When interviewed the testing person stated that the laboratory tested serum samples on the Mindray BS-480 analyzer and did not test urine samples. 3. During the survey on 09/27/18 at 2:30 PM the laboratory director confirmed that the verification printouts did not include the correct name of the analyzer and the correct "Sample Type" to ensure the accuracy and reliability of the analyzer prior to testing and reporting patient test results.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the testing personnel, the laboratory director failed to be enrolled in an approved PT program for all the subspecialties for which it seeks certification. Findings: 1. Since the last recertification survey on 10/06/2016, the laboratory has added the discipline of hematology and the subspecialties of routine chemistry and endocrinology. 2. The PT records show that the laboratory was not enrolled in PT for the following analytes: cortisol, dehydroepiandrosterone (DHEA), estradiol, ferritin, follicle-stimulating hormone (FSH), thyroid stimulating hormone (TSH), free triiodothyronine (FT3), free thyroxine (FT4), human growth hormone (HGH), luteinizing hormone (LH), prostate specific antigen (PA), progesterone, testosterone, vitamin B12, folate, Vitamin D, and sex hormone binding globulin (SHBG). 3. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that the laboratory was not enrolled in an approved PT program for all laboratory tests performed. See the analytes listed in #2.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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; This STANDARD is not met as evidenced by: I. Based on review of the proficiency testing (PT) reports and interview with the testing personnel, the laboratory director failed to identify problems with the PT results and ensure corrective actions were taken and documented. Cross refer to Tags D2015, D2016, D2087, D2088, D2096, and D2098 for details. II. Based on review of the PT reports and interview with the testing personnel, the laboratory director failed to identify problems with the PT results and ensure corrective actions were taken and documented. Findings: 1. The laboratory records show that investigations had been performed for PT failures for the 2nd event of 2018. HDL cholesterol 60%; creatinine 20%; magnesium 0%; and sodium 60%. The investigation documentation did not include a review of the potential effects on patient outcome. 2. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that the laboratory's investigation did not review patients tested around the time of the PT failure to ensure the accuracy of patient test results.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
I. Based on review of the quality control (QC) records and interview with the testing personnel, the laboratory director failed to ensure that the monthly QC form was signed and dated indicating that the laboratory director had reviewed the QC for all the instruments. Findings: 1. The "Monthly QC For APMI" (Advanced Pain Management Institute) worksheet showed that the last time the laboratory director had documented review of the QC results was 03/26/2018. 2. During the survey on 09/28 /18 at 12:00 PM the testing personnel confirmed that the "Monthly QC For APMI" had not been reviewed since 03/26/2018. II. Based on review of the policies and procedures and interview with the testing personnel, the laboratory director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified to prevent recurrence of problems and discuss the assessments with the appropriate staff in the pre-analytic, and post analytical systems. Findings: 1. Review of the policies and procedures at the laboratory showed that there was no consolidated written quality assurance (QA) plan. There was a worksheet labeled "Laboratory Director Review." This worksheet included documentation of Facility or Equipment changes; Personnel changes; Procedural changes; Reference Lab Problems; Temperature, Maintenance, and Lot numbers reviews; Equipment problems; PT problems; QC review performed daily; QA problems; Continuing education planned and Follow-up with the laboratory director/technical consultant. These topics only address the analytical portion of the testing. 2. The written QA worksheet did not include pre-analytical review of test requisitions, specimen submission, handling and referral. The written QA worksheet did not include post analytical review of test reports and errors in patient names. See Tag D5403 III. #10. 3. There were no consolidated written policies and procedures that addressed specific QA reviews and follow-up of problems identified in the laboratory. Problems are randomly documented on analyzer worksheets (See Tag D5403 III) with no resolution or implementation of a corrective action to prevent the problem from occurring again. 4. During the survey on 09/27/18 at 2:30 PM the laboratory director confirmed that there were no written policies and procedures defining the pre-analytic, and post analytical QA systems. III. Based on review of the QA records and interview with the laboratory manager, the laboratory director failed to ensure that the proficiency testing failures were investigated and resolved (Tags D2015, D2016, D2087, D2088, D2096 and D2098); and that testing personnel were evaluated on the new analyzers (Tag D5209). IV. Based on review of the Levy-Jennings (L-J) graphs and interview with the testing personnel and laboratory manager, the laboratory director failed to ensure that the technical consultant implemented remedial actions whenever the test system deviated from the laboratory's established performance specifications. Findings: 1. Review of the L-J graphs for HDL cholesterol for Level 1 and 2 from December 2017 through July 2018 showed that the mean had shifted. The reference range listed on the L-J graphs for Level 1 was 8-40 with a mean of 24 and the reference range for Level 2 was 28-88 with a mean of 58. 2. In December 2017 the mean for HDL cholesterol Level 1 was 32.33 and Level 2 was 95.23. For the month of December 2017 Level 1 was >1 SD from the mean and Level 2 was >3 SD. 3. In May 2018 the mean for HDL cholesterol Level 1 was 33.72 and Level 2 was 100.41. For the month of May 2018 Level 1 was >2 SD from the mean and Level 2 was >4 SD. 4. In July 2018 the mean for HDL cholesterol

	Level 1 was 35.50 and Level 2 was 100.12. For the month of July 2018 Level 1 was >2 SD from the mean and Level 2 was >4 SD. 5. The L-J charts from January 2018 through August 2018 showed the same shifts of >2SD for Level 1 and >4 SD for Level 2 for the HDL cholesterol QC. 6. Review of the procedure manual showed that the laboratory did not have written policies and procedures for documenting remedial actions when QC results fail to meet the laboratory's criteria for acceptability. Cross refer to Tag D5403 II. 7. The testing personnel stated that the HDL cholesterol QC results showed a relatively straight line so they were not concerned about the results. 8. The technical consultant failed to ensure that the testing personnel had policies and procedures to review the QC results for acceptability and take remedial actions when the QC results were unacceptable. See Tag D5403 I and II. 9. During the survey on 09 /27/18 at 2:30 PM the testing personnel confirmed that the laboratory's policy and procedures did not include procedures to review the QC results for acceptability and take remedial actions when the QC results were unacceptable. V. Based on review of the L-J graphs and interview with the testing personnel and laboratory manager, the laboratory director failed to ensure that the technical consultant implemented remedial actions whenever the test system deviated from the laboratory's established performance specifications. Findings: 1. Review of the L-J graphs for creatinine Level 1 and 2 from June 2018 showed that both levels of QC materials had been tested 8 times before the results were within acceptable limits. When interviewed the testing personnel explained what they had done to get the correct answers for the QC materials prior to testing and releasing patient test results but did not document the remedial actions taken. 2. Review of the L-J graphs from December 2017 showed that the glucose QC materials were repeated without documentation of the remedial actions taken. Level 1 was repeated 6 times on 12/07/2017 and Level 2 was repeated 5 times on 12/07/2017 and 6 times on 12/15/2017. 3. Review of the L-J graphs from June 2018 showed that the glucose QC materials were repeated without documentation of the remedial actions taken. Level 1 was repeated 4 times on 06/05 /2018; 5 times on 06/06/2018; 4 times on 06/18/2018; 5 times on 06/25/2018; and Level 2 was repeated 4 times on 06/14/2018. 4. The technical consultant failed to ensure that the testing personnel had policies and procedures to review the QC results for acceptability and take remedial actions when the QC results were unacceptable. Cross refer to Tag D5403 II. 5. During the survey on 09/27/18 at 2:30 PM the testing personnel confirmed that the laboratory's policy and procedures did not include procedures for documenting remedial actions when the QC results were unacceptable.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person, the

	laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the survey on 09/27/18 at 2:30 PM the testing person confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the laboratory director, clinical consultant, technical supervisor, technical consultant, general supervisor, and testing personnel.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the testing personnel, the technical consultant failed to ensure that the verification records included accurate information prior to testing patient samples (D6040); failed to enrolled in proficiency testing for all tests performed in the laboratory (D6041); failed to ensure that remedial actions were taken whenever the test system deviated from the laboratory's established performance specifications (D6043); failed to ensure that the testing personnel completed the appropriate information on the laboratory worksheets (D6049); and failed to ensure that all testing personnel received an evaluation on the new instruments installed in the laboratory in August 2017 prior to testing and releasing patient test results (D6055).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the verification records included accurate information prior to testing patient samples. Cross refer to Tag D6013.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the laboratory was enrolled in proficiency testing for all tests performed in the laboratory. Cross refer to Tag D6015.

D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: I. Based on review of the Levy-Jennings (L-J) graphs and interview with the testing personnel and laboratory manager, the technical consultant failed to ensure that remedial actions were taken whenever the test system deviated form the laboratory's established performance specifications. Cross refer to D6022 IV. II. Based on review of the L-J graphs and interview with the testing personnel and laboratory manager, the technical consultant failed to ensure that remedial actions were taken whenever the test system deviated form the laboratory's established performance specifications. Cross refer to D6022 V.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing personnel, the technical supervisor failed to ensure that the testing personnel completed the "Sample Submission Log Form" with the appropriate information on the laboratory worksheets. Cross refer to Tag D5403 III.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the evaluations and interview with the laboratory manager, the technical consultant (TC) failed to ensure that all testing personnel received an evaluation on the new instruments installed in the laboratory in August 2017 prior to testing and releasing patient test results. Findings: 1. Since the last recertification survey on 10/06/2016, the laboratory has added the specialty of hematology and the subspecialties of routine chemistry and endocrinology. The laboratory now has 5 different analyzers on which to evaluate the testing personnel. The evaluation forms that were reviewed included six different categories of competency. The forms failed to capture the initial training and orientation; the six month competency review and the annual evaluation of the testing personnel on the new analyzers. 2. During the

	survey on 09/27/18 at 2:30 PM the laboratory manager confirmed that the evaluations did not include initial orientation and six month competency and annual evaluation of the testing personnel on the new analyzers being used in the laboratory.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing personnel, the testing personnel failed to use the "Correction Action Logbook Form" to document corrective actions taken when QC results fail to meet the laboratory's criteria for acceptability for routine chemistry, endocrinology, and hematology. Findings: 1. Review of the procedure manual showed that the laboratory had a "Correction Action Logbook Form" to record corrective actions when QC results fail to meet the laboratory's criteria for acceptability for routine chemistry, endocrinology, and hematology. Cross refer to Tag D6043 for details. 2. During the survey on 09/28/18 at 12:00 PM the testing personnel confirmed that the "Correction Action Logbook Form" was not being used to document corrective actions when QC results fail to meet the laboratory's criteria for acceptability.