Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2087228	12/02/2021
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
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: Based on review of the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the College of American Pathologists (CAP) PT program, the laboratory failed to successfully participate in the CAP PT program for chemistry testing (D2096).
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 the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the College of American Pathologists (CAP) PT program, the laboratory failed to achieve satisfactory performance for the same analyte in two or three consecutive chemistry testing events. The following analytes were noted as failed in the CAP 2020 2nd and 3rd events and the CAP 2021 1st event. Findings: 1. Chloride PT resulted in 40% for the CAP 2020 3rd event and 0% for the 2021 1st event. 2. Total protein PT resulted in 0% for both the CAP 2020 3rd and 2021 1st events. 3. Blood urea nitrogen (BUN) PT resulted in 20% for the CAP 2020 3rd event and 0% for the 2021 1st event. 4. Glucose PT resulted in 40% for the CAP 2020 2nd event, 20% for the 2020 3rd event and 0% for the 2021 1st event.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and the PT procedure and interview with the technical supervisor (TS), the laboratory failed to self-evaluate PT results that were not graded by the College of American Pathologists (CAP) PT program. Findings: 1. Proficiency testing records for 2020 and 2021 were requested via email on 01/07/2021 at 6:14 pm and received via email from the technical supervisor on 03/30/2021 at 10:10 pm. 2. The CAP PT program provided multiple codes when they did not grade a PT result including "[11] = Unable to analyze (documentation to be provided by laboratory)", "[20] = Response was not formally graded due to insufficient peer group data. Please see the participant summary for additional information", "[26] = Educational challenge", "[28] = Response qualified with a greater than or less than sign; unable to quantitate", and "[30] = Scientific committee decision." 3. The following PT samples were not graded by the CAP PT program and were given one of the codes listed above for the reason why. 4. In the chemistry 2019 2nd event (C-B 2019), three of five PT samples for high-density lipoprotein (HDL) and all five PT samples for alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), cortisol, ferritin, and free triiodothyronine (T3) were not graded by the CAP PT program (HDL code [30] and all others code [20]). 5. In the chemistry 2019 3rd event (C-C 2019), all five PT samples for alkaline phosphatase, AST, cortisol, and ferritin were not graded by the CAP PT program (all code [20]). 6. In the chemistry 2020 1st event (C-A 2020), all five PT samples for ALT, alkaline phosphatase, AST, cortisol, free T3, free thyroxine, thyroid stimulating hormone, and ferritin were not graded by the CAP PT program (all code [20]). 7. In the chemistry 2020 2nd event (C-B 2020), all five PT samples for ALT, alkaline phosphatase, AST, cortisol, free T3, free thyroxine, thyroid stimulating hormone, and ferritin were not graded by the CAP PT program (all code [20]). 8. In

	the chemistry 2020 3rd event (C-C 2020), all five PT samples for alkaline phosphatase, AST, thyroid stimulating hormone, ferritin, ALT, free T3, free thyroxine, cortisol, and low-density lipoprotein (LDL) were not graded by the CAP PT program (cortisol code [11] and all others code [20]). 9. In the ligand-general 2019 1st event (K-A 2019), all five PT samples for cortisol and all three PT samples for folate and free T3 were not graded by the CAP PT program (all code [20]). 10. In the ligand-general 2019 2nd event (K-B 2019), all five PT samples for cortisol and all three PT samples for folate and free T3 were not graded by the CAP PT program (all code [20]). 11. In the ligand-general 2019 3rd event (K-C 2019), all three PT samples for folate, free T3, and vitamin B-12 were not graded by the CAP PT program (all code [20]). 12. In the ligand-general 2020 1st event (K-A 2020), one of two PT samples for prostate specific antigen; one of five PT samples for cortisol; and all three PT samples for folate, free T3, and vitamin B-12 were not graded by the CAP PT program (prostate specific antigen code [22] and all others code [20]). 13. In the ligand-general 2020 2nd event (K-B 2020), one of five PT samples for cortisol; one of three PT samples for ferritin; and all three PT samples for folate, free T3, and vitamin B-12 were not graded by the CAP PT program (all code [20]). 14. In the ligand-special 2020 1st event (Y-A 2020), one of three PT samples for estradiol and progesterone; two of four PT samples for testosterone; and all three PT samples for dehydroepiandrosterone (DHEA) sulfate and growth hormone were not graded by the CAP PT program (estradiol code [11], testosterone codes [20] and [26], and all others code [20]). 15. In the drug monitoring for pain management 2019 1st event (DMPM-A 2019), oxymorphone in specimen DMPM-03 was not graded by the CAP PT program (code [20]). 16. In the drug monitoring for pain management 2019 2nd event (DMPM-B 2019), pregabalin in specimen DMPM-05 was not graded by the CAP PT program (code [30]). 17. In all DMPM PT events for 2019 and 2020, none of the educational challenges were graded by the CAP PT program (all code [26]). 18. The laboratory's procedure titled "Proficiency Testing" stated "All ungraded results must be reviewed, and the evaluation documented." 19. The laboratory had no documentation indicating that a self-evaluation was performed for the ungraded PT samples listed above to ensure that the laboratory's results were acceptable. 20. The laboratory was cited for not performing a self-evaluation when alkaline phosphatase, ALT, and AST were not graded by the PT program under tag D2096 on the statement of deficiencies issued for the survey completed on 09/28/2018. The laboratory's allegation of compliance stated a correction date of 11/07/2018. 21. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory did not perform a self-evaluation for PT specimens that were ungraded by the PT provider.
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: I. Based on review of proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory failed to document that the accuracy of the toxicology screening testing was verified at least twice annually. Findings: 1. Proficiency testing records for 2019 and 2020 were requested via email on 01/07/2021 at 6:14 pm and received via email from the TS on 03/30/2021 at 10:10 pm. 2. The laboratory performed toxicology screening testing using the Mindray BS-480 instrument. 3. The laboratory was enrolled in the College of American Pathologists (CAP) PT program

	for Drug Monitoring for Pain Management (DMPM). 4. The TS stated during a video conference call on 10/25/2021 that the toxicology screening should have been combined with the confirmation testing to perform the CAP DMPM PT. 5. There were no instrument printouts or documentation that toxicology screening was performed using the Mindray BS-480 instrument for the CAP DMPM PT. 6. No documentation was provided to show that the accuracy of the toxicology screening testing performed using the Mindray BS-480 was verified at least twice annually. II. Based on review of the laboratory testing menu and PT records, the laboratory failed to verify the accuracy of all analytes tested on the liquid chromatography tandem mass spectrometry (LC/MS/MS) analyzer for toxicology confirmation testing at least twice annually. Findings: 1. Proficiency testing records for 2019 and 2020 were requested via email on 01/07/2021 at 6:14 pm and received via email from the TS on 03/30/2021 at 10:10 pm. 2. The laboratory performed toxicology confirmation testing using a LC/MS/MS analyzer. 3. The TS provided the surveyors with a document titled "APMI LAB Test Menu" listing all drug analytes performed by the laboratory using the LC/MS/MS analyzer. 4. The laboratory was enrolled in the CAP DMPM PT which sent three PT samples two times a year. Each sample contained a mix of drug analytes that were selected from a master list of drug analytes located in the CAP survey catalog. 5. Not all drug analytes listed on the laboratory's test panel were included in the CAP PT master list of drug analytes. 6. Not all drug analytes listed on the laboratory's test panel that were included in the CAP PT master list of drug analytes were included in the PT samples twice a year. 7. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory was not performing any additional PT to ensure that the accuracy of all drug analytes evaluated by the laboratory was verified at least twice 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: I. Based on review of proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory failed to document the investigation into and corrective actions taken for analytes that failed College of American Pathologists (CAP) PT events. Findings: 1. Proficiency testing records for 2019 and 2020 were requested via email on 01/07/2021 at 6:14 pm and received via email from the TS on 03/30/2021 at 10:10 pm. 2. Of two PT samples for prostate specific antigen in the CAP ligand-general 2020 1st PT event (K-A 2020), the laboratory received an unacceptable score for one specimen and the other specimen was not graded. Cross refer to tag D5215 #12 for the ungraded result. 3. The laboratory received a 60% for carbon dioxide in the CAP chemistry 2020 1st PT event (C-A 2020). 4. The laboratory received a 40% for chloride, a 20% for glucose, a 20% for blood urea nitrogen (BUN), and a 0% for total protein in the CAP chemistry 2020 3rd PT event (C-C 2020). Cross refer to tag D2096 for details. 5. There was no documentation of an investigation into the root cause of the above analytes' PT failures, what corrective actions were taken to prevent future occurrences, or whether the failures affected patient results and if so, what corrective actions were taken to address the affected results. 6. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory did not perform investigations for all CAP PT failures. II. Based on review of PT records and the corrective action logbook form and interview with the technical supervisor (TS), the laboratory failed to document whether patient results were affected by CAP PT

	failures, and if so, what corrective actions were taken to address the affected specimens. Findings: 1. Proficiency testing records for 2019 and 2020 were requested via email on 01/07/2021 at 6:14 pm and received via email from the technical supervisor on 03/30/2021 at 10:10 pm. 2. The laboratory recorded any testing issues and corrective actions taken on a "Corrective Action Logbook Form." 3. The laboratory received a 33% for parathyroid hormone (PTH) in the CAP ligand-special 2019 1st PT event (Y-A 2019). The PT samples were originally tested on 05/01/2019. The PT investigation worksheet was dated 06/12/2019 and stated "We've called instrument manufacturer to check instrument and will not release PTH results." There was no documentation of the resolution of the issue or when or if the patient specimen results were released on either the PT investigation worksheet or the corrective action logbook form. There was no documentation of whether the laboratory looked back at the patient specimen results from 05/01/2019, when the PT samples were originally tested, to determine if patient results may have been affected by the same issues that affected the PT samples, and if so, what corrective actions were taken to address the affected patient results. 4. The laboratory received a 40% for glucose and a 60% for low-density lipoprotein (LDL) in the CAP chemistry 2020 2nd PT event (C-B 2020). The PT samples were originally tested on 06/16/2020. The PT investigation worksheet was dated 07/13/2020 and stated that "Reagent was onboard analyzer since April 23,2020. There were multiple QC and Cal failures prior to analyzing CAP samples for Glucose. Calibration and QC did pass however reagent seemed unstable and onboard stability expired." There was no documentation on either the PT investigation worksheet or the corrective action logbook form of whether patient results were released when the reagent onboard stability expired, and if so, what corrective actions were taken to address the affected patient results. 5. The laboratory was cited for not ensuring that chemistry PT failure investigations included a review of patient results under tag D6018 on the statement of deficiencies issued for the survey completed on 09/28/2018. The laboratory's allegation of compliance stated a correction date of 11/07 /2018. 6. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory did not address whether patient specimen results were affected in the investigations into the CAP PT failures mentioned above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS), the laboratory failed to record the relative humidity in the laboratory where chemistry, hematology, endocrinology and toxicology testing was performed. Findings: 1. The laboratory performed routine chemistry and toxicology screening testing using a Mindray BS-480 instrument. The manufacturer's technical specifications stated an operating relative humidity (RH) of 30-85%. 2. The laboratory performed hematology testing using a Mindray BS-3600 instrument. The manufacturer's technical specifications stated an operating RH of 30-85%. 3. The laboratory performed

	endocrinology testing using a TOSOH AIA-2000 instrument. The manufacturer's technical specifications stated an operating RH of 40-80% non-condensing. 4. The laboratory performed toxicology confirmation testing using an API 3000 LC/MS/MS instrument. The manufacturer's technical specifications stated an operating relative humidity of 20-80% non-condensing. 5. The laboratory had no records of relative humidity for the testing area. 6. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory was not recording humidity in the areas where testing was performed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the standards and quality control (QC) preparation log and interview with the technical supervisor (TS), the laboratory failed to confirm whether the standards and QC were used beyond their expiration date for toxicology confirmation testing performed on the liquid chromatography tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The laboratory recorded the preparation of the LC/MS/MS internal standard, standard and QC solutions on a worksheet titled "Internal Standard, Standard, and QC Stock Solution Log Form." 2. The TS confirmed during a video conference call on 10/25/2021 that the LC/MS/MS analyzer was in operation from 06/20/2019-08/2021. 3. The first set of solutions recorded on the log was prepared on 02/17/2020 with an expiration date of 02/17 /2021. 4. The second set of solutions recorded on the log was prepared on 03/31/2021 with an expiration date of 03/31/2022. 5. During the video conference call on 10/25 /2021 at 1:45 pm, the TS could not confirm what lot numbers were used between 06 /20/2019-02/16/2020 or if patient specimens were tested in the timeframe between 02 /18/2021-03/30/2021, when the first lot of solutions was expired and the second lot of solutions was prepared to ensure that patient results reported during those timeframes were accurate and reliable.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, observation of the laboratory, and interview

	with the technical supervisor (TS), the laboratory failed to provide documentation for the establishment of the performance specifications for the laboratory developed toxicology confirmation testing performed on the liquid chromatography tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The laboratory's "Corrective Action Logbook Form" had an entry dated 07/31/2019 indicating that a new toxicology analyzer was purchased. 2. There was no LC/MS/MS analyzer in the laboratory during the on-site survey on 08/17/2021. The TS stated that the laboratory was in the process of obtaining a new LC/MS/MS analyzer. 3. The TS confirmed during a video conference call on 10/25/2021 that the old LC/MS/MS analyzer was in operation from 06/20/2019-08/2021 and the new LC/MS/MS analyzer was validated on 09/13/2021. 4. The validation documentation for both analyzers was requested via email on 10/01 /2021 and 10/27/2021 and via video conference call on 10/25/2021. 5. As of 12/02 /2021 the validation documentation for both LC/MS/MS analyzers was not received.
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: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 09/28/2018 for not performing calibration verification on the Mindray BC-3600 analyzer at least once every six months. The laboratory's allegation of compliance stated a correction date of 11/07/2018. Based on review of instrument logs and interview with the technical supervisor (TS), the laboratory failed to document that calibration verification was performed at least once every six months for the Mindray BC-3600 hematology analyzer. Findings: 1. Records for the calibration verification of the Mindray BC-3600 hematology analyzer for 2019 and 2020 were requested via email on 01/07/2021 at 6:15 pm and received by the TS on 04 /26/2021 at 9:10 am. 2. The documentation showed that a calibration verification was performed on 01/02/2019, 06/20/2019 and 07/01/2020. The TS stated in an email received on 09/01/2021 at 1:39 pm that the laboratory ceased patient testing on the

	BC-3600 in 07/2020. 3. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory had no records of a calibration verification performed for the BC-3600 hematology analyzer around 12/2019.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure (SOP), review of instrument printouts, and interview with the technical supervisor (TS), the laboratory failed to ensure that quality control (QC) results met the laboratory's acceptability criteria prior to reporting patient results for toxicology confirmation testing performed on the liquid chromatography tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The SOP and instrument printouts were not available during the on-site visit on 08/17 /2021. They were requested via email on 08/18/2021 at 2:11 pm and received via email on 09/01/2021 at 1:39 pm. After review of the submitted instrument printouts, additional questions were sent via email to the TS on 10/01/2021 at 9:44 am in preparation for a video conference call on 10/25/2021 at 1:00 pm. 2. The surveyors requested the instrument printouts for a random batch of toxicology confirmation testing performed in 05/2021 using the LC/MS/MS analyzer. The laboratory provided the handwritten worksheets titled "LCMS BATCH SHEET" and the instrument printouts showing results for the QC, calibrators and patient specimens for batch 2021-05/05282021 #1. 3. Based on the handwritten worksheet and instrument printouts, 74 patient specimens were tested in batch 2021-05/05282021 #1. 4. Section "Sample Batch Acceptance Criteria" of the SOP titled "APMI Panel 40 THC /6 MAM Opiates MDEA LCMSMS" stated that the r value of the calibration curve regression must be greater than or equal to 0.9900. The instrument printouts for the batch calibration results showed that the r value for drug analyte Normeperidine was 0.9885. 5. The laboratory tested 4 levels of QC for each batch of patent specimens: QC neg, QC low, QC mid, and QC high. Though the plate map on the bottom of page 33 of the SOP showed that each level of QC was run 2x, the instrument printouts showed that each level of QC was run 3x. 6. Section "Sample Batch Acceptance Criteria" of the SOP stated that QC accuracy must be plus or minus 20% of the nominal concentration at each level, except for the QC neg which must be plus or minus 25%; QC precision must be less than or equal to 20% CV (coefficient of variation), except for the QC neg which must be less than or equal to 25% CV; 62% of overall QC results must meet the acceptance criteria; and 50% of QC at each level must meet the acceptance criteria. 7. The instrument printouts for the batch QC results showed that precision at QC concentration 75 ng/mL (QC low) had a CV of 21.62% for Amphetamine. The precision at QC concentration 400 ng/mL (QC mid) was "N/A" for Amphetamine, Gabapentin, Norbuprenorphine, Norfentanyl, Normeperedine, O-DSMT, Pregabalin, and THC-COOH. During a video conference call on 10/25/2021 at 2:00 pm, the TS confirmed that samples should be rerun if a drug analyte has a CV >20% and wasn't sure what corrective actions to take when the CV results were "N/A". 8. The instrument printouts for the batch QC results showed that 62% of overall QC accuracy results failed to meet the acceptability criteria for Buprenorphine, Norfentanyl, Normeperidine, Oxymorphone, and Tramadol. 9. The instrument printouts for batch QC results showed that 50% of QC neg accuracy results failed to meet the

	acceptability criteria for Amphetamine, Buprenorphine, Gabapentin, Hydromorphone, Ketamine, Norbuprenorphine, Normeperidine, O-DSMT, Oxazepam, and Pregabalin. 10. The instrument printouts for batch QC results showed that 50% of QC low accuracy results failed to meet the acceptability criteria for Norfentanyl, Oxymorphone, and Tramadol. 11. The instrument printouts for batch QC results showed that 50% of QC mid accuracy results failed to meet the acceptability criteria for Benzoylecgonine, Lorazepam, Norfentanyl, Normeperidine, Oxymorphone, and Tramadol. 12. The instrument printouts for batch QC results showed that 50% of QC high accuracy results failed to meet the acceptability criteria for MDMA. 13. The TS confirmed during the video conference call on 10/25/2021 that the instrument printout for the patient results is the final report. 14. For the drug analytes that failed to meet calibration and QC acceptability criteria, of 74 patients tested in the batch, values were detected and reported for Amphetamine in 34 patients, Benzoylecgonine in 11 patients, Buprenorphine in 6 patients, Gabapentin in 35 patients, Hydromorphone in 26 patients, Ketamine in 5 patients, Lorazepam in 3 patients, MDMA in 13 patients, Norbuprenorphine in 8 patients, Norfentanyl in 8 patients, Normeperidine in 3 patients, O-DSMT in 12 patients, Oxazepam in 5 patients, Oxymorphone in 44 patients, Pregabalin in 19 patients, THC-COOH in 3 patients, and Tramadol in 12 patients. 15. The SOP contained no instructions for what corrective actions should be taken when the calibration and QC results fail to meet acceptability criteria, no instructions for what corrective actions should be taken when the QC precision results are "N/A", and no instructions for if and when results can be reported when specific QC levels fail. 16. There was no documentation that the testing personnel or TS were reviewing the calibration and QC results to ensure they met acceptability criteria to ensure that patient results were accurate and reliable. 17. During the video conference call on 10/25/2021 at 2:00 pm, the TS stated that a 3rd party software application analyzed the batch calibration and QC, the testing personnel released the results and the instrument printout for the patient results was the final report.
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 review of Levey-Jennings (L-J) charts, corrective action logs and monthly quality assurance (QA) audits and interview with the technical supervisor (TS), the laboratory failed to document corrective actions taken when quality control (QC) results fell outside the acceptable range and failed to evaluate patient test results to determine if the results may have been adversely affected for routine chemistry testing. Findings: 1. Monthly QA and QC records, including L-J charts and corrective action logs, were requested via email on 01/07/2021 at 6:15 pm and again on 04/08 /2021 at 12:27 pm. The corrective action logs were received via email on 04/26/2021 at 9:10 am, the L-J charts were received via email on 05/03/2021 at 10:15 am and the QA records were received via email on 06/17/2021 at 11:55 am. 2. According to the "Laboratory Corrective Action Log Policy", the laboratory was to document all pre-

	analytical, analytical, and post-analytical issues on the "Corrective Action Logbook Form" which captured what the issue was, what corrective actions were taken, and if the corrective actions worked. 3. The L-J charts from 09/2019-12/2019 and 06/2020-09/2020 were reviewed. The L-J charts included the QC lot number and acceptable results range, dates QC was run and the results, and a graph plotting results against the standard deviation (SD). 4. The laboratory performed a monthly QA audit that included reviewing the QC log and printouts and reviewing 5 random test reports for each analyzer. 5. The acceptable range for the low QC for blood urea nitrogen (BUN) was listed as 11-19. Results on 12/11/2019 were 22 with no repeats. The next testing date was 12/26/2019 and results were 38 and 13. The acceptable range for the high QC for BUN was listed as 40-56. Results on 12/11/2019 were 31 with no repeats. The next testing date was 12/26/2019 and results were 31 and 46. 6. The acceptable range for the low QC for creatinine was listed as 0.41-1.61. Results on 12/03/2019 were -9.73, -265.31, and 0.94. Results on 06/25/2020 were 3.20, 8.03, and 4.19 with no further repeats 7. The acceptable range for the high QC for creatinine was listed as 3.86-7.18. Results on 10/30/2019 were -4.56, -4.72, and 5.36. Results on 12/03/2019 were -3.54, -1339.50, and 5.83. Results on 06/25/2020 were 9.50, 33.98, and 34.41 with no further repeats. 8. The acceptable range for the low QC for glucose was listed as 70-106. Results on 10/17/2019 were -1735, -4999, and 81. Results on 10/30/2019 were -3813, -3723, and 84. Results on 11/26/2019 were 65, 63, 61, 54 and were not brought into range until 11/27/2019 on the 1st repeat. Results on 12/05/2019 were 59 with no repeats. The next testing date was 12/11/2019 and results were 810 with no repeats. The next testing date was 12/26/2019 and results were 539 and 78. Results on 06/25/2020 were 63, 58, and 54 with no further repeats. 9. The acceptable range for the high QC for glucose was listed as 223-335. Results on 10/17/2019 were -758, -17430, and 283. Results on 10/30/2019 were -181, -150, and 290. Results on 12/05 /2019 were 377 with no repeats. The next testing date was 12/11/2019 and results were 8903 with no repeats. The next testing date was 12/26/2019 and results were 183 and 263. Results on 12/30/2019 were 172 with no repeats. 10. The acceptable range for low QC for magnesium was listed as 0.7-2.3. Results on 12/11/2019 were 10.1 and 10.0 with no further repeats. 11. The low QC results for chloride were >2 SD for 16 of 20 testing days from 09/2019-11/2019. On the days when QC was >2 SD, no repeat testing was performed to bring the QC back in range. The monthly QA audits stated that 5 random test reports were reviewed on 09/16/2019, 10/17/2019, and 11/08/2019 (all days when QC was >2 SD) indicating that patient samples were tested and reported when QC was not within acceptable limits. 12. The low QC results for high-density lipoprotein (HDL) were >4 SD for 18 of 18 testing days from 09/2019-11 /2019. On the days QC was >4 SD, no repeat testing was performed to bring the QC back in range. The monthly QA audits stated that 5 random test reports were reviewed on 09/16/2019, 10/17/2019, and 11/08/2019 indicating that patient samples were tested and reported when QC was not within acceptable limits. 13. The above QC failures were not documented on the corrective action log or the monthly QA audit and there was no documentation of whether patient results were released, and if so, what corrective actions were taken for those that were adversely affected. 14. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that corrective actions and evaluation of patient results for failed QC were not documented.
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 the test report, the laboratory failed to identify the specimen source on the final test report for toxicology confirmation testing performed on the liquid chromatography tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The sample test report for toxicology confirmation testing performed on the LC/MS /MS analyzer provided to the surveyors during the on-site survey on 08/17/2021 consisted of the instrument printout printed on paper containing the laboratory address, director name, and license numbers. 2. Next to "Sample Type", the instrument printout/test report stated "Unknown." The specimen source was not indicated on the final report. 3. The instrument printouts from 74 patient specimens tested in batch 2021-05/05282021 #1 were reviewed. All 74 of 74 instrument printouts stated "Unknown" for "Sample Type." 4. During the video conference call on 10/25/2021 at 2:00 pm, the TS confirmed that the instrument printouts were what was printed for the final patient reports.
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 review of the laboratory's test menu, proficiency testing (PT) records, procedure manual, quality control (QC) records, corrective action logs, quality assurance (QA) records, and instrument printouts, the laboratory director failed to ensure that the laboratory was enrolled in an approved PT program for all testing performed (D6088), failed to ensure that ungraded PT results were reviewed and self-evaluated by the appropriate laboratory staff (D6091 I.), failed to ensure that all PT failures were investigated and the investigations included an evaluation of patient results around the time of the PT failures (D6091 II.), failed to ensure that an approved corrective action plan was followed when the laboratory failed to achieve satisfactory performance for the same analyte in consecutive PT events (D6092 I. and II.), failed to ensure that corrective actions were documented when chemistry QC results were out of range and failed to ensure that there were instructions for what corrective actions to take when calibration and QC results for toxicology confirmation testing failed to meet acceptability criteria (D6093), failed to ensure that the QA review was performed and documented on a monthly basis (D6094 I.), failed to ensure that the laboratory's allegation of compliance for the survey completed on 09/28 /2018 was implemented and maintained (D6094 II.), and failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, 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 (D6107).

D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must 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 laboratory's test menu and proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure that the laboratory was enrolled in an approved PT program for all routine chemistry testing performed. Findings: 1. The TS provided the surveyors with a documented titled "APMI LAB Test Menu" listing all routine chemistry tests performed by the laboratory. 2. Records of the PT program evaluations listing all chemistry analytes challenged in each PT event were reviewed for 2019 and 2020. 3. The laboratory's test menu listed vitamin D and sex hormone binding globulin (SHBG). None of the PT evaluations showed results for vitamin D and SHBG PT. 4. The laboratory was cited for not being enrolled in PT for vitamin D and SHBG under tag D6015 on the statement of deficiencies issued for the survey completed on 09/28 /2018. The laboratory's allegation of compliance stated a correction date of 11/07 /2018. 5. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory was not performing PT for vitamin D and SHBG.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: I. The laboratory director (LD) failed to ensure that ungraded PT results were reviewed and self-evaluated by the appropriate laboratory staff. Cross refer to tag D5215 for details. II. The LD failed to ensure that all PT failures were investigated and the investigations included an evaluation of patient results around the time of the PT failures. Cross refer to tags D5221 I. and II. for details.
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: I. The laboratory director (LD) failed to ensure that an approved corrective action plan was followed when the laboratory failed to achieve satisfactory performance for the same analyte in consecutive chemistry PT events. Cross refer to tag D2096 for details. II. Based on review of proficiency testing (PT) records and interview with the technical supervisor (TS), the LD failed to ensure that an approved corrective action plan was followed when PT results for Delta-9-THC-COOH were unacceptable in three consecutive PT events. Findings: 1. Proficiency testing records for 2019 and

	2020 were requested via email on 01/07/2021 at 6:14 pm and received via email from the TS on 03/30/2021 at 10:10 pm. 8. The laboratory was enrolled in the College of American Pathologists (CAP) PT program for Drug Monitoring for Pain Management (DMPM) which consisted of three PT samples sent two times a year (event A and B). Each sample contained a mix of drug analytes that were selected from a master list of drug analytes located in the CAP survey catalog. 2. Results for the drug analyte Delta-9-THC-COOH received a score of "Unacceptable" for 1 of 1 specimen in the DMPM-A 2019 event, 1 of 2 specimens in the DMPM-B 2019 event, and 1 of 1 specimen in the DMPM-A 2020 event. The analyte was not present in any of the DMPM-B 2020 PT samples. 3. The investigation for DMPM A-2019 stated that samples weren't tested according to the CAP procedure. The corrective actions documented for DMPM-B 2019 stated to better handle the specimens and follow CAP guidelines. The corrective actions documented for DMPM-A 2020 stated to handle specimens carefully. 4. The investigation forms included the question "Were patient results affected?". The investigations for DMPM-A and DMPM-B 2019 did not address whether patient results were affected. The investigation for DMPM A-2020 stated "No." 5. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the laboratory had three consecutive "Unacceptable" results for Delta-9-THC-COOH.
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: The laboratory director failed to ensure that corrective actions were documented when chemistry quality control (QC) results were out of range and failed to ensure that there were instructions for what corrective actions to take when calibration and QC results for toxicology confirmation testing failed to meet acceptability criteria. Cross refer to tags D5783 and D5481 for details.
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: I. Based on review of the monthly and weekly quality assessment (QA) documentation and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure that the QA review was performed and documented on a monthly basis. Findings: 1. The monthly QA records from January 2020 through July 2021 were reviewed. 2. There were no monthly QA reviews documented from July 2020 through July 2021. 3. The weekly QA was performed and documented by the testing personnel in 2020. 4. The monthly chart audits were performed each month from July 2020 through December 2020 but the records failed to include a documented review by the LD or TS. The QA monthly chart audits were performed each month from January 2021 through July 2021 but the records failed to include the

	identity of the reviewer, and a documented review by the LD or TS. 5. During the on-site survey on 08/17/2021 at 2:30 pm, the TS confirmed that the QA policies and procedures failed to be implemented as required by the approved QA program. 43123 II. The LD failed to ensure that the laboratory's allegation of compliance for the survey completed on 09/28/2018 was implemented and maintained. Cross refer to tags D5215, D5221, D5439, and D6088 for details.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS), the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, 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 on-site exit interview on 08/17 /2021 at 2:30 pm, the TS 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, general supervisor, and testing personnel.
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 review of the laboratory's test menu, proficiency testing (PT) records, procedure manual, quality control (QC) records, corrective action logs, quality assurance records, and instrument printouts, the technical supervisor failed to ensure that the laboratory was enrolled in a PT program for vitamin D and sex hormone binding globulin (D6116), failed to ensure the procedure included instructions for what corrective actions to take when calibration and QC results for toxicology confirmation testing did not meet the laboratory's acceptability criteria (D6117), failed to ensure the testing personnel documented corrective actions when chemistry QC results were out of range (D6118), failed to ensure that patient test results were not reported when the quality control and calibration results did not meet the acceptability criteria for toxicology confirmation testing (D6119), and failed to have records of competency assessment performance for testing personnel 1 for 2019 and 2020 (D6128).

D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for 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 supervisor failed to ensure that the laboratory was enrolled in a proficiency testing program for vitamin D and sex hormone binding globulin. Cross refer to tag D6088 for details.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: The technical supervisor failed to ensure the procedure included instructions for what corrective actions to take when calibration and quality control results for toxicology confirmation testing did not meet the laboratory's acceptability criteria. Cross refer to tag D5481 for details.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for 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: The technical supervisor failed to ensure the testing personnel documented corrective actions when chemistry quality control results were out of range. Cross refer to tag D5783 for details.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: The technical supervisor failed to ensure that patient test results were not reported when the quality control and calibration results did not meet the acceptability criteria for toxicology confirmation testing. Cross refer to tag D5481 for details.

D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, 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. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records and interview with the technical supervisor (TS), the laboratory failed to have records of competency assessment performance for TP 1 for 2019 and 2020. Findings: 1. The recertification survey began as a remote survey. An email was sent to the laboratory on 01/07/2021 requesting the CLIA laboratory personnel report (CMS-209) and competency assessment documentation for all TP for 2019 and 2020. 2. The CMS-209 was received on 03/30/2021 listing two TP. No competency assessments were received via email. 3. During the on-site survey conducted on 08/17/2021, competency assessments for TP #1 were missing for 2019 and 2020. 4. The TS confirmed via an email received on 09/01/2021 at 1:39 pm that the competency assessments for TP #1 could not be located for 2019 and 2020.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure (SOP), sample test report, and instrument printouts and interview with the technical supervisor (TS), the testing personnel failed to ensure that test results were reported within the validated upper limit of quantification (ULOQ) for toxicology confirmation testing performed on the LC/MS/MS analyzer. Findings: 1. The section titled "Unknown Samples" in the SOP titled "APMI Panel-40-THC/6-MAM-Opiates MDEA LCMSMS" stated "Samples with concentrations above the uloq will be reported as '> 400' or '> 2000' or '> 4,000' or '> 8000' ng/mL." 2. The sample test report provided to the surveyors during the on-site survey on 08/17/2021 consisted of the instrument printout printed on paper containing the laboratory address, director name, and license numbers. 3. The instrument printouts from 74 patient specimens tested in batch 2021-05/05282021 #1 were reviewed. Of the 74 patient results, 45 patient results reported the numerical values instead of "> 8000" ng/mL. For example, results for injection vial 19 reported the result for Pregabalin 1 as 86100 ng/mL and results for injection vial 30 reported the result for Morphine 1 as 11300 ng/mL. 4. During the video conference call on 10 /25/2021 at 2:00 pm, the TS confirmed that the instrument printouts were what was printed for the final patient reports.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)

	Each individual performing high 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: The testing personnel failed to record corrective actions taken when chemistry quality control results were out of range. Cross refer to D5783 for details.