Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2274386	05/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Pain Relief Institute	16922 Telge Rd Suite 2b, Cypress, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced revisit of the laboratory was conducted on 09/11/2023. The laboratory remains out of compliance with the CLIA regulations. The CONDITIONS NOT MET were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director Noted deficiencies and allegations of compliance/plans of correction were discussed with the laboratory re-presentative(s) at the exit conference. ---------- The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and allegations of compliance/plans of correction were discussed with the laboratory representative(s) at the exit conference. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by:

	Based on review of manufacturer instructions for use, laboratory's random patient test records from May 1 to May 8, 2023, and staff interview, the laboratory failed to follow manufacturer instructions for Rapid ETG (Ethylglucoronide) Alcohol Test Strip for 17 of 17 samples reviewed. Findings included: 1. Review of manufacturer instructions for use for the 12PANELNOW Rapid ETG Alcohol Test Strip (document P/N 230201 Rev. 02.2023) revealed: "For best results, test specimens immediately following collection. Urine specimens may be refrigerated (2-8C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20C or below). 2. Review of random patient test records from May 1 to May 8, 2023, revealed 17 of 17 reviewed samples did not have documentation of being stored at refrigerated or frozen temperatures and did not have testing performed immediately following collection as they were received in the laboratory beyond 48 hours from collection. The samples were: Patient: Time (collection to receipt): 4740 75 hours, 16 minutes 1775 57 hours, 25 minutes 3404 76 hours, 16 minutes 5048 55 hours, 44 minutes 3018 76 hours, 31 minutes 967 53 hours, 09 minutes 5046 52 hours, 34 minutes 4650 57 hours, 16 minutes 2680 99 hours, 39 minutes 4804 101 hours, 10 minutes 3683 147 hours, 39 minutes 2337 80 hours, 48 minutes 3258 127 hours, 26 minutes 3795 98 hours, 56 minutes 582 123 hours, 39 minutes 3642 127 hours, 16 minutes 3499 123 hours, 58 minutes Note: Refer to master list for details. 3. In an interview on 05/18/2023 at 1500 hours in the laboratory, the laboratory's Testing Person number 2 (as evident on submitted form CMS 209) stated that the laboratory received all samples for Rapid ETG Alcohol testing from a provider in Arizona, shipped overnight at ambient temperature. This confirmed the findings. Legend: C = degrees Celsius CMS = Centers for Medicare and Medicaid
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: An unannounced revisit of the facility was conducted on 09/11/2023. This condition remains uncorrected. Based on review of laboratory's plans of correction, specimen transport studies, transport eLab logs, quality assurance (QA) documents and staff interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems as evidenced by: 1. The laboratory failed to follow its own plan of correction for specimen transport temperature monitoring. Refer to D5311. 2. Laboratory's QA failed to evaluate the effectiveness of corrective actions in preanalytic systems. Refer to D5393. ---------- Based on review of the laboratory's test establishment studies, laboratory's policies/procedures, patient records, specimen transport logs and staff interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems. Findings included: 1. The laboratory failed to follow its own policies for specimen transport temperature requirements. Refer to D5311. 2. The laboratory's quality assessment failed to recognize, assess and correct problems identified in the preanalytic systems. Refer to D5391.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: An unannounced revisit of the facility was conducted on 09/11/2023. This standard remains uncorrected. Based on review of the laboratory's submitted plan of correction, transportation stability study, eLab logs and staff interview, the laboratory failed to ensure specimen stability during transport was monitored for 136 of 136 samples tested by the facility from 08/14/2023 to 09/11/2023. Findings included: 1. Review of the laboratory's submitted plan of correction (signed off on 06/16/2023) revealed: "Transportation Stability Study to be completed by Lab Staff. Review and QA to be completed by Lab Consultant and signed by Lab Director. " And, "Update Urine Collection, Storage and Transportation for Toxicology Testing SOP." And, "Create a section in eLab Logs to store a scanned copy of the Responsibility Waiver received with each shipment of samples." 2. Review of laboratory's 2023 transportation study revealed the study included specimen stability studies at room temperature (still undefined), to be tested day 1 and 3, refrigerated temperature (2-8C) tested on day 7 and 14, freezer temperatures (undefined) tested on day 30. The study did not include day 2, 4 and 5 at room temperature. The study did not include possible variations in temperature and other environmental parameters during transport for out of state samples. 3. Review of laboratory's eLab logs revealed there was no documentation of transport temperature to ensure specimen stability for the 136 of 136 samples tested by the facility from 08/14/2023 to 09/11/2023. 4. In an interview on 09/11/2023 at 1000 hours in the laboratory, the laboratory's Technical Supervisor (as indicated on submitted form 209) confirmed the findings. Key: C = Degrees Celsius ---------- Based on review of the laboratory's test establishment (validation) studies, laboratory's policies/procedures, specimen transport logs, patient test records and staff interview, the laboratory failed to follow its own policy and monitor specimen stability during transport for 414 of 414 specimens received in the laboratory between February 20, 2023, and May 12, 2023. Findings included: 1. Review of the laboratory's test establishment studies revealed the "Validation Study" (approved by laboratory director on 04/01/2023) did not address specimen stability during transport. 2. Review of laboratory's policies/procedures revealed: a. Policy "Storage of Laboratory Specimens: Toxicology" (approved by laboratory director on 04/01/2023) stated: "All urine samples for LC-MS/MS testing will be kept in original container, refrigerated at a temperature of 2-8 degrees and kept for a period of 7-14 days, depending on laboratory stability validation study." Note: Laboratory's sample stability study is ongoing and has not been completed. The above policy did not specify degree specification of Celsius or Fahrenheit. b. Policy "Urine Collection, Storage and Transportation for Toxicology Testing" (approved by laboratory director on 04/01/2023) stated: "Storage: ... For testing to occur the sample must be stored per the laboratory stability requirements Laboratory stability requirements: - 3 days at room temperature - Acceptable room temperature is between 64F to 80F (17.8C to 26.7C) - Sample is allowed to stay at room temp (temperature) for a max (maximum) of 3 days, which includes transportation - 7 days at refrigerator temperature -

	acceptable refrigerator temperature is between 35.6F to 46.4F (2C to 8C) - Sample is allowed to stay at room temp (temperature) for a max (maximum) of 3 days, which includes transportation - Correct storage temperature must be marked on a Sample Shipment Documentation Form to ensure a delay does not occur with the processing and testing of the samples." And, "Transportation Each package of shipment must include a Sample Shipment Documentation Form to ensure a delay does not occur with the processing and testing of the samples. ... - If samples are stored at room temperature at the office then they must be sent to lab no more than every 3 days to keep with the stability protocol of the lab. - If samples are stored at refrigerator temperature at the office then they must be sent to lab no more than every 5 days to keep with the stability protocol of the lab. - Samples must be transported with 2 frozen ice packs to keep temperature correct during transport. - Package must contain signed Responsibility Waver to document office stored the samples at correct temperature range." 3. Review of laboratory's specimen transport logs revealed no documentation for Sample Shipment Documentation Forms or Responsibility Wavers for received samples. There was no documentation of monitoring the temperature of the transported samples at receipt to verify samples' stability was not compromised during transport. 4. Review of patient test logs revealed the laboratory performed toxicology testing on 414 samples received from an outside facility between February 20, 2023, and May 12, 2023. 5. In an interview on 05/18/2023 at 1055 hours in the laboratory, the laboratory's Testing Person number 2 (as evident on submitted form CMS 209) stated that the laboratory did not record/verify temperature of samples at receipt, the samples did not come accompanied by Sample Shipment Documentation Forms or Responsibility Wavers, nor did they have frozen ice packs. This confirmed the findings. Legend: C = degrees Celsius F = degrees Fahrenheit CMS = Centers for Medicare and Medicaid LC-MS/MS = Liquid Chromatography Mass Spectrometry /Mass Spectrometry
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's test establishment (validation) studies, laboratory's policies/procedures, specimen transport logs, patient test records, quality assessment and staff interview, the laboratory's quality assessment failed to identify and correct issues with specimen transport stability. Refer to D5311.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by:

	An unannounced revisit of the laboratory was conducted on 09/11/2023. This is a new deficiency. Based on review of laboratory's quality assurance (QA) records and staff interview the laboratory's QA failed to ensure preanalytic systems assessment included an evaluation of the effectiveness of corrective actions implemented through the submitted plan of correction from 08/14/2023 through 09/11/2023. Findings included: 1. Review of the laboratory's QA records revealed QA assessments were performed on: 09/01/2023 09/10/2023 2. Further review of the QA records revealed there was no documentation of evaluation of plan of correction's effectiveness. 3. In an interview on 09/11/2023 at 1010 hours in the laboratory, the laboratory's Technical Supervisor (as indicated on submitted form 209) confirmed the findings.
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 laboratory's policies/procedures, patient test records and staff interview, the laboratory failed to ensure policies and procedures were approved, signed and dated prior to use for patient testing. Findings included: 1. Review of the laboratory's policies and procedures manual revealed all the documents were approved, signed and dated by laboratory director on April 1, 2023. 2. Review of patient test records revealed the laboratory started testing patient samples on February 28, 2023. 3. Further review of patient test records revealed the laboratory tested 155 samples from February 28, 2023, to April 1, 2023, the day policies/procedures were approved. Refer to patient master list for details. 4. In an interview on 05/18/2023 at 1030 hours in the laboratory, the facility's Technical Supervisor (as evident on submitted form CMS 209), after review of the data, confirmed the findings. Legend: CMS = Centers for Medicare and Medicaid
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: An unannounced revisit of the facility was conducted on 09/11/2023. This standard remains uncorrected. Based on review of the laboratory's submitted plan of correction, 2023 stability study records, transportation stability quality assurance follow-up and staff interview, the laboratory failed to address validation of sample stability claims, and variables that may affect the samples during transportation from outside of the

	facility, before reporting results for 136 of 136 patient samples tested between 08/14 /2023 and 09/11/2023. Findings included: 1. Review of the laboratory's submitted plan of correction (signed of on 06/16/2023) revealed: "Transportation Stability Study to be completed by Lab Staff." Note: There was no document titled "Transportation Stability Study" addressing specimen stability during transport available for review. 2. Review of laboratory's "Quality Assurance - 2023 Stability Study" (signed off on 08 /10/2023) revealed: "Objective: To assess the stability of all drugs tested in the laboratory utilizing: Three room temperature samples tested on Day1 and Day 3 Three refrigeration temperature samples tested on Day 7 and Day 14 Three freezer samples tested on Day 1 and Day 3" Stability Study plan did not define what samples would be used (patient samples of known concentration, negative patient samples spiked with known concentrations, etc.) nor the room, refrigeration and freezer temperatures. Study plan did not address elevated temperatures that may be encountered during transport of samples. Study plan did not address room temperature stability at day 5 (same week delivery). 3. Review of laboratory's "Quality Assurance - Transportation Stability Follow-up" (signed of on 09/10/2023) revealed: "Basis of Topic Selection: To review if clients (are) following urine collection, storage and transportation SOP (standard operating procedure)." The review did not address samples' conditions during transportation. 4. In an interview on 09/11/2023 at 1030 hours in the laboratory, the laboratory's Technical Supervisor (as indicated on submitted form 209) confirmed the findings. ---------- Based on review of laboratory's Validation (establishment) Study for its laboratory developed urine toxicology test, patient test records and staff interview, the laboratory failed to address validation of sample stability claims, and variables that may affect the samples during transportation from outside of the facility, before reporting results for 414 of 414 patient samples tested between February 28, 2023, and May 15, 2023. Findings included: 1. Review of laboratory's urine toxicology test Validation Study (approved by laboratory director on 04/01/2023) revealed the study did not address validation of sample transport stability claims, or variables that may affect the samples during transportation from outside of the facility. 2. Review of patient test records revealed the laboratory performed testing only on samples received from an outside facility located in Arizona. The laboratory received, performed testing and released results for 414 patient samples between February 28, 2023, and May 15, 2023. 3. In an interview on 05/18/2023 at 1515 hours in the laboratory, the facility's Technical Supervisor (as evident on submitted form CMS 209), after review of the data, confirmed the findings. Legend: CMS = Centers for Medicare and Medicaid
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 laboratory's policies/procedures, urine toxicology test validation (establishment) studies, manufacturer instructions for use, patient test records, quality assessment records and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory, as evident by: 1. Laboratory Director failed to ensure the laboratory provided quality laboratory services. Refer to D6082. 2. Laboratory Director failed to ensure test verification/validation studies were adequate. Refer to D6086. 3. Laboratory Director failed to ensure laboratory's quality

	assurance identified and corrected issues as they occurred. Refer to D6094. 4. Laboratory Director failed to ensure a policy/procedure manual was approved and signed prior to testing patient samples. Refer to D6106.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, urine toxicology test validation (establishment) studies, patient test records, quality assessment records and staff interview, the Laboratory Director failed to ensure the laboratory provided quality laboratory services. Refer to D1001, D5311.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: An unannounced revisit of the facility was conducted on 09/11/2023. This standard remains uncorrected. Based on review of laboratory's submitted plan of correction, transportation and stability studies, transport eLab logs and staff interview, the Laboratory Director failed to ensure verification/validation studies were adequate prior to patient testing. Refer to D5423. ---------- Based on review of laboratory's policies/procedures, urine toxicology test validation (establishment) studies, patient test records and staff interview, the Laboratory Director failed to ensure verification/validation studies were adequate prior to patient testing. Refer to D5423.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, quality assessment records patient test records and staff interview, the Laboratory Director failed to ensure laboratory's quality assurance identified and corrected issues as they occurred. Refer to D5391.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, patient test records and staff interview, the Laboratory Director failed to ensure approved manual of policies /procedures was available to personnel prior to testing patient samples. Refer to D5407.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: An unannounced revisit of the facility was conducted on 09/11/2023. This standard remains uncorrected. Based on review of laboratory's submitted plan of correction, transportation and stability studies, transport eLab logs and staff interview, the Technical Supervisor failed to ensure test verification/validation/establishment studies were adequate prior to patient testing. Refer to D5423. ---------- Based on review of laboratory's policies/procedures, urine toxicology test validation (establishment) studies, patient test records and staff interview, the Technical Supervisor failed to ensure test verification/validation/establishment studies were adequate prior to patient testing. Refer to D5423.