Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2151125	02/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ada Pain Management	1601 N Broadway Ave, Ada, OK	

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	The initial survey was performed on 02/20/2020. The laboratory was found out of compliance with the following CLIA regulations: 493.1213; D5022: Toxicology 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director, Moderate Complexity Testing The findings were reviewed with the laboratory director in an exit conference at the conclusion of the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to retain laboratory room temperature records, humidity records, and refrigerator records for at least 2 years for 4 of 12 months. Findings include: ROOM TEMPERATURE RECORDS (1) At the beginning of the survey, the laboratory director stated to the surveyor urine drug screen testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Ecstasy, Opiates, and Oxycodone) was performed using the Medica EasyRA analyzer; (2) Later during the survey, the surveyor reviewed the laboratory room temperature records between January 2019 through December 2019 with the following identified: (a) September 2019 records were not available (b) October 2019 records were not available (c) November 2019 records were not available (d) December 2019 records were not available (3) The surveyor ask the laboratory director if the laboratory room temperature records for September 2019, October 2019, November 2019, and December 2019 could be located. The laboratory director stated the room temperature records for the four months could not be located. Therefore, the surveyor could not determine if the room temperature, for the above months, had been monitored and evaluated. HUMIDITY

	RECORDS (1) At the beginning of the survey, the laboratory director stated to the surveyor urine drug screen testing was performed using the Medica EasyRA analyzer; (2) Later during the survey, the surveyor reviewed the laboratory humidity records between January 2019 through December 2019 with the following identified: (a) September 2019 records were not available (b) October 2019 records were not available (c) November 2019 records were not available (d) December 2019 records were not available (3) The surveyor ask the laboratory director if the laboratory humidity records for September 2019, October 2019, November 2019, and December 2019 could be located. The laboratory director stated the humidity records for the four months could not be located. Therefore, the surveyor could not determine if the laboratory humidity, for the above months, had been monitored and evaluated. REFRIGERATOR RECORDS (1) At the beginning of the survey, the laboratory director stated to the surveyor urine drug screen testing was performed using the Medica EasyRA analyzer; (2) The surveyor observed the quality control and calibrator materials in the laboratory refrigerator; (3) Later during the survey, the surveyor reviewed the laboratory refrigerator temperature records between January 2019 through December 2019 with the following identified: (a) September 2019 records were not available (b) October 2019 records were not available (c) November 2019 records were not available (d) December 2019 records were not available (3) The surveyor ask the laboratory director if the laboratory refrigerator temperature records for September 2019, October 2019, November 2019, and December 2019 could be located. The laboratory director stated the refrigerator temperature records for the four months could not be located. Therefore, the surveyor could not determine if the laboratory refrigerator temperature, for the above months, had been monitored and evaluated.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of the policy and procedure manual, records, and interview with the laboratory director, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology. Findings include: (1) The laboratory failed to have a written competency policy for the clinical consultant based on the job responsibilities as listed in Subpart M. Refer to D5209; (2) The laboratory failed to follow written procedures for urine drug screen testing. Refer to D5401; (3) The laboratory failed to perform calibration verification procedures at least once every 6 months for the analytes performed on the Medica EasyRA analyzer for 1 of 12 months. Refer to D5439; (4) The laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screening testing for 26 of 94 days of patient testing. Refer to D5449; (5) The laboratory failed to ensure corrective actions were taken when quality control was not acceptable; and failed to evaluate patient test results obtained when quality control was not acceptable to determine if the results had been adversely affected for for 5 of 5 patients tested. Refer to D5783; (6) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to have a written competency policy for the clinical consultant based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2019 through the day of the survey (02/20/2020). There was no evidence competencies had been performed for the clinical consultant based on their job responsibilities; (2) The surveyor asked the laboratory director if a written policy to evaluate the positions based on job responsibilities was available and if competencies had been performed during the review period. The laboratory director stated a policy to evaluate the clinical consultant based on job responsibilities had not been written; and competencies had not been performed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the written policy and procedure manual and interview with the laboratory director, the laboratory failed to follow written procedures for urine drug screen testing. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor: (a) Urine Drug Screen testing was performed on the Medica EasyRA analyzer; (b) The laboratory tested 2 levels (positive and negative) of LinZhi Quality Control (QC) materials each day of patient testing. (2) Later during the survey, the surveyor reviewed the written procedure for verifying new lots of QC which stated, (a) "Quality control material should also be tested when comparing old and new lots. For qualitative tests, parallel testing must include re-testing at least one known positive (or abnormal) and one known negative (or normal) sample." (3) The surveyor reviewed records for 14 control lot numbers. There was no evidence the laboratory performed parallel testing, as required by policy, before the lot numbers were put into use for 2 of 14 lot numbers as follows: (a) Cocaine negative control (lot #1905128) and Cocaine positive control (lot #1905130) put into use on 01/20/20. (4) The findings were reviewed with the laboratory director, who stated parallel testing had not been performed before the above lot numbers had been put into use as indicated above.
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 a review of records and interview with the laboratory director, the laboratory failed to perform calibration verification procedures at least once every 6 months for the analytes performed on the Medica EasyRA analyzer for 2 of 12 months. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor an 8-panel urine drug screen (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Ecstasy, Opiates, and Oxycodone) testing was performed using Medica EasyRA analyzer; (2) The surveyor reviewed 2019 calibration records with the laboratory director, and identified calibration procedures had been performed with one level of calibrator. Since the calibration procedures included only one level, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) The surveyor reviewed calibration verification records for 2019 for the analyzer and identified calibration verification had not been performed since 09/25/18 (due 03/2019 and 09/2019); (4) The surveyor then reviewed the records with the laboratory director, who stated calibration verification procedures had not been performed in 2019 as indicated above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screening testing for 9 of 94 days of patient testing. Findings include: (1) On the first day of the survey, the laboratory director stated to the surveyor the laboratory performed Urine Drug Screen testing using the Medica EasyRA analyzer; (2) The

	surveyor reviewed QC (quality control) and patient testing records from 01/01/19 through 12/31/2019. The review indicated negative and positive QC materials had not been performed 9 of 94 days of patient testing reviewed; (4) The surveyor reviewed the records with the laboratory director who stated negative and positive QC materials had not been performed each day of patient testing; (5) The following patient Urine Drug Screen testing had been performed when negative and positive QC materials had not been tested: (a) Patient #1 - testing performed on 03/12/19 at 01:49 pm (b) Patient #2 - testing performed on 03/12/19 at 02:32 pm (c) Patient #3 - testing performed on 03/12/19 at 02:41 pm (d) Patient #4 - testing performed on 03/12/19 at 02:53 pm (e) Patient #5 - testing performed on 03/12/19 at 03:08 pm (f) Patient #6 - testing performed on 03/12/19 at 03:16 pm (g) Patient #7 - testing performed on 03/12/19 at 03:45 pm (h) Patient #8 - testing performed on 03/12/19 at 04:05 pm (i) Patient #9 - testing performed on 05/01/19 at 12:30 pm (j) Patient #10 - testing performed on 05/01 /19 at 12:34 pm (k) Patient #11 - testing performed on 05/01/19 at 12:38 pm (l) Patient #12 - testing performed on 05/01/19 at 12:52 pm (m) Patient #13 - testing performed on 05/02/19 at 03:46 pm (n) Patient #14 - testing performed on 05/02/19 at 03:53 pm (o) Patient #15 - testing performed on 05/06/19 at 02:15 pm (p) Patient #16 - testing performed on 05/06/19 at 02/18 pm (q) Patient #17 - testing performed on 05 /07/19 at 03:59 pm (r) Patient #18 - testing performed on 05/08/19 at 11:20 am (s) Patient #19 - testing performed on 05/08/19 at 01:25 pm (t) Patient #20 - testing performed on 05/13/19 at 12:45 pm (u) Patient #21 - testing performed on 05/13/19 at 01:44 pm (v) Patient #22 - testing performed on 05/13/19 at 01:49 pm (w) Patient #23 - testing performed on 05/14/19 at 09:22 am (x) Patient #24 - testing performed on 05 /14/19 at 09:25 am (y) Patient #25 - testing performed on 05/14/19 at 10:12 am (z) Patient #26 - testing performed on 05/16/19 at 02:26 pm
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 a review of records and interview with the laboratory director, the laboratory failed to ensure corrective actions were taken when quality control was not acceptable; and failed to evaluate patient test results obtained when quality control was not acceptable to determine if the results had been adversely affected for for 5 of 5 patients tested. Findings include: (1) On the first day of the survey, the laboratory director stated the following to the surveyor: (a) The laboratory performed Urine Drug Screen (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Ecstasy, Opiates, and Oxycodone) testing using the Medica EasyRA analyzer; (b) The laboratory tested 2 levels (positive and negative) of LinZhi Quality Control (QC) materials each day of patient testing; (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) Later during the survey, the surveyor then reviewed control records for testing performed from January 2019 through December 2019. For the review period, the following was identified for 1 of 12 months: (a) Acceptable quality control results could not located for one level

	(negative) of Oxycodone quality control material for 04/04/19. (3) The surveyor asked the laboratory director if two levels of acceptable quality control for the Oxycodone testing had been performed. The laboratory director stated one level of the Oxycodone quality control was not acceptable on 04/04/19; (4) The surveyor obtained examples of patient Oxycodone testing performed from January 2019 through December 2019, with Oxycodone results reported when there was no evidence that two levels of acceptable quality control. They were: (a) Patient #27 testing performed on 04/04/19 (b) Patient #28 testing performed on 04/04/19 (c) Patient #29 testing performed on 04 /04/19 (d) Patient #30 testing performed on 04/04/19 (e) Patient #31 testing performed on 04/04/19 (5) The surveyor asked the laboratory director if results had been evaluated to determine if they had been adversely affected. The laboratory director stated there was no evidence which would support that the results had been evaluated.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, records, and interview with the laboratory director, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow written procedures for urine drug screen testing. Refer to D5401; (b) The laboratory failed to perform calibration verification procedures at least once every 6 months for the analytes performed on the Medica EasyRA analyzer for 1 of 12 months. Refer to D5439; (c) The laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screening testing for 9 of 94 days of patient testing. Refer to D5449; (d) The laboratory failed to ensure corrective actions were taken when quality control was not acceptable; and failed to evaluate patient test results obtained when quality control was not acceptable to determine if the results had been adversely affected for for 5 of 5 patients tested. Refer to D5783.
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 a review of the policy and procedure manual, records, and interview with the laboratory director, the laboratory failed to provide overall management an direction. Findings include: (1) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (2) The laboratory director failed to ensure a quality assessment program had

	been established and maintained. Refer to D6021; (3) The laboratory director failed to ensure written policies and procedures were followed. Refer to D6031.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months. Refer to D5439; (2) The laboratory director failed to ensure a negative and positive control each day of patient testing. Refer to D5449; (3) The laboratory failed to ensure corrective actions were taken when quality control wa not acceptable; and failed to to evaluate a patient test result obtained when quality control was not acceptable to determine if the results had been adversely affected for 5 of 5 patients. Refer to D5783.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory director, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) 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 a review of written policies and procedures and interview with the laboratory director, the laboratory director failed to ensure policies and procedures were followed. Findings include: (1) Based on a review of the policy and procedure manual and interview with the laboratory director, the laboratory failed to follow written procedures for urine drug screen testing. Refer to D5401.