Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2151125	06/15/2023
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 06/15/2023. The laboratory was found out of compliance with the following CLIA Conditions: 493.1213; D5022: Toxicology 493.1403; D6000: Laboratory Director, Moderate Complexity Testing 493.1409; D6033: Technical Consultant 493.1441; D6076: Laboratory Director, High Complexity Testing 493.1487; D6168: Testing Personnel, High Complexity Testing The findings were reviewed with the technical consultant during a conference call on 06/16/2023.
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 records, manufacturer's instructions, written policies and procedures, FDA database, email correspondence with an FDA representative, observation, and interview with the technical consultant and testing person, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology for 20 of 20 months of patient testing. Findings include: (1) The laboratory failed to verify the accuracy of Urine Drug Screen testing performed on the Medica Easy RA analyzer at least twice annually. Refer to D5217; (2) The laboratory failed to follow the manufacturer's instructions for storing patient urine specimens prior to urine drug screen testing on the Medica Easy RA analyzer. Refer to D5311; (3) The laboratory failed to provide written instructions to clients collecting and referring specimens for Urine Drug Screen testing on the Medica Easy RA analyzer. Refer to D5317; (4) The laboratory failed to follow their written policies and procedures for labeling urine specimens for urine drug screen testing on the Medica Easy RA analyzer. Refer to D5401; (5) The laboratory failed to follow the

	manufacturer's instructions for the storage and stability of the rapid urine drug screen test using the ECO II test cups for nine of nine test cups. Refer to D5411; (6) The laboratory failed to ensure the laboratory room and refrigerator temperatures were being maintained as required; and failed to ensure ten of ten boxes of ECO II urine drug screen test cups were being stored as required by the manufacturer. Refer to D5413; (7) The laboratory failed to perform calibration verification procedures at least once every 6 months for the Urine Drug Screen testing performed on the Medical Easy RA analyzer. Refer to D5439; (8) The laboratory failed to perform a negative and positive control material eight of ten days of patient Urine Drug Screen testing using the Medica Easy RA analyzer; and failed to perform a negative and positive control material each of rapid Urine Drug Screen testing using the ECO II cups. Refer to D5449.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to verify the accuracy of Urine Drug Screen testing performed on the Medica Easy RA analyzer at least twice annually during the review period of November 2021 through the current date. Findings include: (1) On 06/15/2023 at 09: 20 am, the technical consultant stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine using the Medica Easy RA analyzer; (2) A review of records from November 2021 through the current date identified the following: (a) No evidence the laboratory had enrolled and partipated in proficiency testing prior to the first 2023 event; (b) No evidence the laboratory verified the accuracy of Urine Drug Screen testing at least twice annually prior to 2023. (3) Interview with the technical consultant on 06/15/2023 at 11:40 am confirmed the laboratory had not verified the accuracy of Urine Drug Screen testing at least twice annually prior to performing proficiency testing for the first 2023 event; (4) Refer to D5311 and D5449 for examples of patient Urine Drug Screen testing performed.
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: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person, the laboratory failed to follow the manufacturer's instructions for storing patient urine specimens prior to Urine Drug

	Screen testing on the Medica Easy RA analyzer for 14 of 28 patient reports reviewed from June 2022 through June 2023. Findings include: (1) On 06/15/2023 at 09:20 am, the technical consultant stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine using the Medica Easy RA analyzer; (2) Interview with the testing person on 06/15/2023 at 11:45 am confirmed urine samples were stored in the refrigerator up to five days prior to testing; (3) A review of the manufacturer's package inserts for the above analytes identified the following storage requirements under "Specimen Collection and Handling" for each analyte: (a) "If a sample cannot be analyzed immediately, it may be refrigerated at 2-8 C for up to three days". (4) A review of patient reports for urine specimens collected from 06/21/2022 through 06/08/2023 identified urine specimens had been stored beyond three days before testing for 14 of 28 patient reports reviewed; (5) The findings were reviewed with the technical consultant and testing person. Both stated on 06/15/2023 at 01:15 pm, the urine samples had been stored beyond the manufacturer's refrigerated storage stability; (6) The following were the patient reports reviewed that confirmed urine specimens had been stored refrigerated longer than three days: (a) Patient #18 - Sample collected on 06/21/2022 and tested on 07/25/2022 (b) Patient #19 - Sample collected on 06/30/2022 and tested on 07/28/2022 (c) Patient #20 - Sample collected on -7/13/2022 and tested on 08/02/2022 (d) Patient #21 - Sample collected on 07/14 /2022 and tested on 08/04/2022 (e) Patient #22 - Sample collected on 07/20/2022 and tested on 07/26/2022 (f) Patient #23 - Sample collected on 07/28/2022 and tested on 09/07/2022 (g) Patient #24 - Sample collected on 08/01/2022 and tested on 09/07 /2022 (h) Patient #1 - Sample collected on 10/19/2022 and tested on 10/31/2022 (i) Patient #25 - Sample collected on 10/20/2022 and tested on 10/31/2022 (j) Patient #27 - Sample collected on 10/24/2022 and tested on 11/10/2022 (k) Patient #26 - Sample collected on 10/25/2022 and tested on 11/08/2022 (l) Patient #28 - Sample collected on 11/29/2022 and tested on 12/06/2022 (m) Patient #29 - Sample collected on 11/30 /2022 and tested on 12/08/2022 (n) Patient #30 - Sample collected on 12/01/2022 and tested on 12/09/2022
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on interview with the technical consultant, the laboratory failed to provide written instructions to clients collecting and referring specimens for Urine Drug Screen testing on the Medica Easy RA analyzer. Findings include: (1) On 06/15/2023 at 09:20 am, the technical consultant stated the following: (a) The laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine Medica Easy RA analyzer; (b) Urine specimens were transported to the laboratory from two sister clinics (2) Interview with the technical consultant on 06/15 /2023 at 09:45 am confirmed the laboratory did not provide written instructions (i.e., client service manual) to the clients to explain the laboratory's specimen handling policies.
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 records, written policies and procedures, and interview with the technical consultant and testing person, the laboratory failed to follow their written policy for labeling urine specimens for Urine Drug Screen testing for 51 of 51 patient specimens. Findings include: (1) On 06/15/2023 at 09:20 am, the technical consultant stated the following: (a) The laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine Medica Easy RA analyzer; (2) Observation of the laboratory refrigerator on 06/15/2023 at 10:00 am identified the following: (a) 29 urine specimens on the top shelf of the refrigerator labeled with the patient's last name or the first initial and last name; (b) 22 urine specimens on the bottom shelf of the refrigerator labeled with the patient's last name or the first initial and last name. (3) A review of the policy titled, "Patient and Sample Identification Policy" stated, "Laboratory staff will identify patients before obtaining a laboratory sample from them. All patient specimen containers will be labeled with at least two unique patient identifiers"; (4) Interview with the testing person on 06/15/2023 at 10:10 am confirmed the following: (a) The urine specimens on the top shelf had been collected on 06/14/2023 and the specimens on the bottom shelf had been collected on 06/15 /2023, but the dates had not been documented on the specimens; (b) The specimens had been labeled with the last name or first initial and last name and were in the refrigerator waiting to be sent to the reference laboratory for testing. (5) The findings were reviewed with the technical consultant who stated on 06/15/2023 at 11:30 am, the laboratory had not followed their policy for labeling the patient specimens.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant and testing person, the laboratory failed to follow the manufacturer's instructions for the storage and stability of the rapid Urine Drug Screen test using the ECO II test cups for nine of nine test cups. Findings include: (1) On 06/15/2023 at 10:45 am, the testing person stated rapid Urine Drug Screen testing was performed using the ECO II test cup (refer to D5449 for information about the test cup not being cleared or approved by the FDA); (2) Observation of the nurses station/front desk area identified nine test cups, that had been removed from the sealed pouch, stored in a bin on the counter; (3) Review of the manufacturer's instructions contained in the package insert under the heading "Storage and Stability" stated "Store as packaged in the sealed pouch at 39 F- 86 F (4 C-30 C). The test is stable through

	the expiration date printed on the sealed pouch. The test cup must remain in the sealed pouch until use"; (4) The findings were reviewed with the testing person who stated on 06/15/2023 at 11:15 am the laboratory had not followed the manufacturer's instructions for storing the test cup in the sealed pouch until ready to use for testing; (5) Refer to D5449 for examples of patient testing performed using the test cup.
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 a review of records, observation, and interview with the technical consultant, the laboratory failed to ensure the laboratory room and refrigerator temperatures were being maintained as required for 14 of 17 months reviewed in 2022 and 2023; and failed to ensure ten of ten boxes of ECO II urine drug screen test cups were being stored as required by the manufacturer. Findings include: REFRIGERATOR TEMPERATURES (1) On 06/15/2023 at 09:20 am, the technical consultant stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine using the Medica Easy RA analyzer; (2) Observation of the contents of the laboratory refrigerator on 06/15/2023 at 10:55 am identified the following materials: (a) Three containers of Medica Cocaine 2-part reagent, ref #14241, the storage requirement as stated on the container was 2-8 degrees C (Centigrade); (b) Two containers of Medica Amphetamine 2-part reagent, ref #14240, the storage requirement as stated on the container was 2-8 degrees C (Centigrade); (c) Two containers of Opiate 2-part reagent, ref #14243, the storage requirement as stated on the container was 2-8 degrees C (Centigrade). (3) A review of temperature records for 17 months (January 2022 through May 2023) identified no documentation the refrigerator temperature had been monitored for 14 of 17 months (January through December 2022; January and February 2023); (4) The records were reviewed with the technical consultant who stated on 06/15/2023 at 12:55 pm, the refrigerator temperatures had not been documented until January 2023. ROOM TEMPERATURE (1) The operator's manual for the analyzer was requested. Interview with the testing person on 06/15/2023 at 12:30 pm confirmed the operator's manual was not available; (2) Review of the Medica Easy RA brochure online, under the section titled, "Easy RA Specifications" identified the manufacturer required an operating temperature of 15-30 degrees C; (3) A review of temperature records for 17 months (January 2022 through May 2023) identified no documentation the laboratory room temperature had been monitored for 14 of 17 months (January through December 2022; January and February 2023); (4) The records were reviewed with the technical consultant who stated on 06/15/2023 at 12:55 pm, the laboratory room temperature had not been documented until January 2023. ECO II CUP URINE DRUG SCREEN TEST CUPS (1) On 06/15/2023 at 10:45 am, ;the testing person stated rapid urine drug screen testing was performed using the ECO II test cup (refer to D5449 for information about the test cup not being classified or approved by the FDA); (2) Observation of the

	storage closet, located outside of the laboratory, on 06/15/2023 at 10:50 am identifed ten boxes with 25 cups each of ECO II Urine Drug Screen test cups, lot# B3170214; (3) A review of the package insert for the test cup identified the test cups were to be stored at 4-30 degrees Centigrade; (3) Interview with the testing person on 06/15/2023 at 10:55 am confirmed the urine drug screen test cups were being stored in the closet and the temperature was not being monitored.
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 technical consultant, the laboratory failed to perform calibration verification procedures at least once every 6 months for the Urine Drug Screen testing performed on the Medical Easy RA analyzer for 20 of 20 months reviewed. Findings include: (1) On 06/15/2023 at 09:20 am, the technical consultant stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine using the Medica Easy RA analyzer; (2) A review of 2023 calibration records identified calibration procedures had been performed using one or two data points; (3) A review of records from November 2021 through the current time identified no evidence calibration verification procedures had been performed at least once every six months; (4) Interview with the technical consultant on 06/15/2023 at 11:40 am confirmed the laboratory had not performed calibration verification at least once every six months during the review period. (5) Refer to D5311 and D5449 for examples of patient urine drug screen testing performed.
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, FDA database, email correspondence with an FDA representative, and interview with the technical consultant and testing person, the laboratory failed to perform a negative and positive control material eight of ten days of patient Urine Drug Screen testing using the Medica Easy RA analyzer during the review period of October 2022 through June 2023; and failed to perform a negative and positive control material 17 of 17 days of rapid Urine Drug Screen testing using the ECO II cups during the review period of November 2021 through June 2023. Findings include: CONTROL TESTING ON MEDICA EASY RA ANALYZER (1) On 06/15/2023 at 09:20 am, the technical consultant stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine using the Medica Easy RA analyzer; (2) A review of QC (Quality Control) and patient testing records for testing performed from October 2022 through June 2023 identified negative and positive QC materials had not been performed each day of patient testing for eight of ten days; (3) The records were reviewed with the technical consultant who stated on 06/15/2023 at 01:05 pm, QC materials had not been performed each day of patient testing; (4) The following were the days of patient testing reviewed when negative and positive QC materials had not been documented as performed: (a) Patient #1 - Testing performed on 10/31/2022 (b) Patient #2 - Testing performed on 01 /05/2023 (c) Patient #3 - Testing performed on 03/01/2023 (d) Patient #4 - Testing performed on 03/06/2023 (e) Patient #5 - Testing performed on 03/09/2023 (f) Patient #6 - Testing performed on 06/05/2023 (g) Patient #7 - Testing performed on 06/06 /2023 (h) Patient #8 - Testing performed on 06/08/2023 CONTROL TESTING USING THE ECO II CUP (1) On 06/15/2023 at 10:45 am, the testing person stated rapid Urine Drug Screen testing was performed using the ECO II test cup; (2) A review of the urine drug screen package insert for the test showed the name of the test as "One-Step Drug of Abuse Cup Test" which did not match the name on the test cup; (3) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity; this was also definitively confirmed during email correspondence with an FDA representative on 06/20/2023); (4) A review of patient urine drug screen testing using the test cup from November 2021 through June 2023 identified no evidence negative and positive QC materials had been performed each day of patient testing; (5) The records were reviewed with the testing person who stated on 06/15/2023 at 12:10 pm, QC testing had not been performed because the laboratory believed the test cups were waived; (6) The following were the days of patient testing when negative and positive QC materials had not been performed: (a) Patient #9 - Testing performed on 11/04/2021, 01/27/2022, and 06/15/2023 (b) Patient #10 - Testing performed on 11/08/2021, 01/31/2022, and 10/10/2022 (c) Patient #11 - Testing performed on 06/01/2022, 06/30/2022, and 10/31/2022 (d) Patient #12 - Testing performed on 06/16/2022, 10/06/2022, and 01/25/2023 (e) Patient #13 - Testing performed on 01/17/2023 (f) Patient #14 - Testing performed on 01/23/2023 (g) Patient #15 - Testing performed on 03/08/2023 (h) Patient #16 - Testing performed on 03/16/2023 (i) Patient #17 - Testing performed on 03/21/2023
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 records, written policy, manufacturer's instructions, observation, and interview with the technical consultant and testing person, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment for 20 of 20 months reviewed. Findings include: (1) The laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issues identified during the survey: (a) The laboratory failed to follow their written policy for labeling urine specimens for Urine Drug Screen testing for 51 of 51 patient specimens. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for the storage and stability of the rapid Urine Drug Screen test using the ECO II test cups. Refer to D5411; (c) The laboratory failed to ensure the laboratory room and refrigerator temperatures were being maintained as required; and failed to ensure ten of ten boxes of ECO II urine drug screen test cups were being stored as required by the manufacturer. Refer to D5413; (d) The laboratory failed to perform calibration verification procedures at least once every 6 months for the Urine Drug Screen testing performed on the Medical Easy RA analyzer. Refer to D5439; (e) The laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screen testing using the Medica Easy RA analyzer; and failed to perform a negative and positive control material each day of rapid Urine Drug Screen testing using the ECO II cups. Refer to D5449.
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 records, written policies and procedures, manufacturer's instructions, observation, and interview with the technical consultant and testing person, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure quality laboratory services were provided for all aspects of test performance, which included the preanalytic phase of testing. Refer to D6007; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Refer to D6014; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (5) The laboratory director failed to ensure that personnel performing moderate complexity testing had the appropriate training for one of one person. Refer to D6029; (6) The laboratory director failed to ensure that an approved procedure manual was available and followed by all personnel responsible for the testing process. Refer to D6031.

D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) 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 a review of records, manufacturer's instructions, and interview with the technical consultant and testing person, the laboratory director failed to ensure quality laboratory services were provided for all aspects of test performance, which included the preanalytic phase of testing. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for storing patient urine specimens prior to urine drug screen testing on the Medica Easy RA analyzer. Refer to D5311.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the technical consultant and testing person, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Findings include: (1) The laboratory failed to ensure the laboratory room and refrigerator temperatures were being maintained as required. Refer to D5413.
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 technical consultant and testing

	person, 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 the accuracy of Urine Drug Screen testing performed on the Medica Easy RA analyzer had been verified at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months on the Medica Easy RA analyzer. Refer to D5439; (3) The laboratory director failed to ensure negative and positive control materials had been performed each day of Urine Drug Screen testing using the Medica Easy RA analyzer. Refer to D5449.
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, manufacturer's instructions, obseration, and interview with the technical consultant and testing person, 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.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure that personnel performing moderate complexity testing had the appropriate training for one of one person. Findings include: (1) On 06 /15/2023 at 09:20 am, the technical consultant stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Barbiturates, Cocaine, Methadone, Opiate, Oxycodone, and Phencyclidine using the Medica Easy RA analyzer; (2) A review of personnel records identified the following: (a) The current testing person had been hired to perform patient testing on 07/09/2022; (b) There was no documentation this person had been initially trained; (c) A competency evaluation had not been documented as performed until 01/04/2023. (3) The records were reviewed with the technical consultant who stated on 06/15/2023 at 11:58 am,

	there was no documentation to prove the testing person had been initially trained to perform moderate complexity testing.
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 records, written policies and procedures, and interview with the technical consultant and testing person, the laboratory director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process. Findings include: (1) The laboratory director failed to ensure the laboratory failed to follow written policies and procedures for Urine Drug Screen testing. Refer to D5401.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) 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: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person, the technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory verified the accuracy of Urine Drug Screen

	testing performed on the Medica Easy RA analyzer at least twice annually. Refer to D5217; (2) The technical consultant failed to ensure the manufacturer's instructions were followed for storing patient urine specimens prior to Urine Drug Screen testing on the Medica Easy RA analyzer. Refer to D5311; (3) The technical consultant failed to ensure the laboratory room and refrigerator temperatures were being maintained as required. Refer to D5413; (4) The technical consultant failed to ensure the laboratory performed calibration verification procedures at least once every 6 months for Urine Drug Screen testing performed on the Medical Easy RA analyzer. Refer to D5439; (5) The technical consultant failed to ensure the laboratory performed negative and positive control materials each day of patient Urine Drug Screen testing using the Medica Easy RA analyzer. Refer to D5449.
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 a review of records, manufacturer's instructins, FDA database, email correspondence with an FDA representative, observation, and interview with the technical consultant and testing person, the laboratory director failed to meet the qualification requirements for high complexity testing and failed to provide overall management and direction. Findings include: (1) The laboratory performed high complexity rapid Urine Drug Screen testing using the ECO II test cup and the laboratory director did not meet the requlatory qualifications for high complexity testing. Refer to D6078; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6087; (3) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093; (4) The laboratory director failed to ensure that a quality assessment program had been established and maintained. Refer to D6094.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at

	least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, email correspondence with an FDA representative, and interview with the technincal consultant and testing person, the laboratory director failed to ensure the laboratory director met the regulatory qualifications for rapid Urine Drug Screen testing using the ECO II test cup which was not cleared or approved by the FDA. Findings include: (1) On 06/15/2023 at 10: 45 am, the testing person stated rapid Urine Drug Screen testing was performed using the ECO II test cup; (2) A review of the package insert for the test showed the name of the test as "One-Step Drug of Abuse Cup Test" which did not match the name on the test cup; (3) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (4) A review of the laboratory director credentials identified the laboratory director did not meet the regulatory qualifications for a high complexity laboratory director; (5) Email correspondence with an FDA representative on 06/20/2023 at 08:57 am definitively confirmed the test had not been cleared or approved by the FDA.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant and testing person, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for the storage and stability of the rapid Urine Drug Screen test using the ECO II test cups for nine of nine test cups. Refer to D5411; (2) The laboratory director failed to ensure ECO II Urine Drug Screen test cups were being stored as required by the manufacturer. Refer to D5413.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the technical consultant and testing person, the laboratory director failed to ensure quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure negative and positive control materials had been performed each day of Urine Drug Screen testing using the ECO II cups. Refer to D5449.
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 a review of records, manufacturer's instructins, FDA database, observation, and interview with the technical consultant and testing person, the laboratory director failed to ensure that 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 D5421.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure one of one testing person met the qualification requirements to perform high complexity testing. Findings include: (1) The laboratory failed to ensure that each person performing high complexity Urine Drug Screen testing met the qualification requirements. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory

science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of records, FDA database, and interview with the technical consultant and testing person, the laboratory failed to ensure that each person performing high complexity testing met the qualification requirements for one of one

	person listed on the CMS-209. Findings include: (1) On 06/15/2023 at 11:58 am, the testing person stated rapid Urine Drug Screen testing was performed using the ECO II test cup (as stated on the test cup); (2) A review of the package insert showed the name of the test as "One-Step Drug of Abuse Cup Test" which did not match the name on the test cup; (3) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (4) A review of the Laboratory Personnel Report (Form CMS-209) and education records for one testing person identified the testing person did not meet the qualification requirements to perform high complexity testing; (5) Email correspondence with an FDA representative on 06/20/2023 at 08:57 am definitively confirmed the test had not been cleared or approved by the FDA; (6) The findings were communicated to the technical consultant during email correspondence on 06/20/2023 at 07:41 pm.