

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2142238	(X3) Date Survey Completed 01/30/2026
Name of Provider or Supplier Advanced Orthopedics And Sports Medicine	Street Address, City, State 801 W Bayou Pines Dr, Lake Charles, LA	
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	A Recertification survey was performed at Advanced Orthopedics and Sports Medicine, CLIA #19D2142238 on January 30, 2026. Advanced Orthopedics and Sports Medicine was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1213 CONDITION: Toxicology 42 CFR 493.1403: CONDITION: Laboratories performing moderate complexity testing: Laboratory Director 42 CFR 493.1409: CONDITION: Laboratories performing moderate complexity: Technical Consultant
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: **Repeat deficiency from previous survey February 22, 2024** Based on review of the laboratory's proficiency testing (PT) records and interview with personnel, the laboratory failed to ensure proficiency samples were tested in the same manner as patients for three (3) of three (3) testing events reviewed. Findings: 1. Review of the laboratory's 2024 and 2025 American Proficiency Institute (API) proficiency testing records revealed the laboratory received the following two (2) testing kits per testing event shipment: a) Urine Drug Screen b) Urine Drug Screen (Verification) 2. Further review of the laboratory's PT records revealed the following testing instructions from API: "Verification Samples" * "CLIA regulations specify that laboratories are not to

test PT samples on more than one instrument/method unless that is how patient samples are routinely handled. Verification samples are intended to verify the performance of additional instruments/methods after the PT reporting deadline has passed." * "The designated testing period for Verification samples is after the testing period for proficiency samples. If you have ordered a Verification program, the dates of this testing period appear on the front cover of this packet, as well as online." * "Store the Verification samples in the refrigerator unless otherwise noted on the sample packaging. Do not test the Verification samples until the designated testing period." 3. Review of the following testing events revealed the laboratory tested the verification samples before the designated testing period: a) 2024 Chemistry - Miscellaneous 1st Event * "Proficiency Online & Postmark Due Date: Wednesday, 5/8/2024 11:59 ET" * "Verification Programs Start Date: Thursday, 5/9/2024" - All PT and verification samples tested on 05/03/2024 which was before the designated testing period for verification samples. b) 2024 Chemistry - Miscellaneous 2nd Event * "Proficiency Online & Postmark Due Date: Wednesday, 10/30/2024 11:59 ET" * "Verification Programs Start Date: Thursday, 10/31/2024" - All PT and verification samples tested on 10/16/2024 which was before the designated testing period for verification samples. c) 2025 Chemistry - Miscellaneous 1st Event * "Proficiency Online & Postmark Due Date: Wednesday, 5/7/2025 11:59 ET" * "Verification Programs Start Date: Thursday, 5/8/2025" - PT samples tested 05/01/2025 and verification samples tested on 05/07/2025 which was before the designated testing period for verification samples. 4. In interview on January 30, 2026 at 9:50 a.m., Testing Personnel 1 stated she did not know the laboratory was not supposed to test the verification samples during a different testing period on a different analyzer. She confirmed she tested both the verification samples and PT samples on the same analyzer on the dates identified above.

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 observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the subspecialty of Toxicology. Findings: 1. The laboratory failed to ensure specimen collection and preparation requirements were maintained as required by the manufacturer for urine drug screen (UDS) testing. Refer to D5311. 2. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing for urine drug screen (UDS) testing. Refer to D5317. 3. The laboratory failed to maintain complete policies for urine drug screen (UDS) testing. Refer to D5403. 4. The laboratory failed to verify complete performance specifications for the Beckman AU480 analyzer. Refer to D5421. 5. The laboratory failed to perform maintenance on the Siemens Viva-E analyzer as required by the manufacturer. Refer to D5429. 6. The laboratory failed to perform function checks as required by the laboratory for the centrifuge timer for one (1) of one (1) timer checks reviewed in 2025. Refer to D5435. 7. The laboratory failed to perform three (3) of three (3) instrument comparison studies reviewed in 2024 and 2025 for urine drug screen (UDS) testing. Refer to D5775. 8. The laboratory failed to perform corrective actions when the room temperature was not maintained between 15 to 25 degrees Celsius (C) as required by

the manufacturer for fifteen (15) of twenty-seven (27) days reviewed. Refer to D5781. 9. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

****Repeat deficiency from previous survey February 22, 2024**** Based on observation, review of the manufacturers' package inserts and the laboratory's policy and procedures, and interview with personnel, the laboratory failed to ensure specimen collection and preparation requirements were maintained as required by the manufacturer for urine drug screen (UDS) testing. Findings: 1. Observation by surveyor during the laboratory tour on January 30, 2026 at 8:39 a.m. revealed the laboratory utilized the following analyzers for UDS testing: a) Siemens Viva-E - Utilized Siemens reagents for UDS testing of the following drugs: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Phencyclidine, and Opiates. b) Beckman AU480 - Utilized Immunalysis reagents for UDS testing of the following drugs: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Opiates, Phencyclidine, Methamphetamines, and Oxycodone. 2. Review of the manufacturer's package inserts for Siemens the reagents and kits revealed the following "Specimen Collection and Preparation" instructions: "Internal testing has shown that, if not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days. Specimens may be stored refrigerated for 30 days before analysis. After 7 days unrefrigerated or 30 days refrigerated, samples should be stored frozen." 3. Review of the manufacturer's package inserts for Immunalysis reagents and kits revealed the following "Specimen Collection - Storage and Handling" instructions: a) "Benzodiazepines Urine HEIA" - "Urine specimens may be stored at 22-30 degrees Celsius for up to 7 days prior to analysis." - "Specimen Shipping" - "Do not exceed the storage limitations listed above." b) "Barbiturates Urine HEIA" - "Urine specimens may be stored at 22-30 degrees Celsius for up to 14 days prior to analysis." - "Specimen Shipping" - "Do not exceed the storage limitations listed above." c) "Amphetamine Urine HEIA" - "Urine specimens may be stored at 22-30 degrees Celsius for up to 14 days prior to analysis." - "Specimen Shipping" - "Do not exceed the storage limitations listed above." d) "Benzoylcegonine" (Cocaine) - "Urine specimens may be stored at 22-30 degrees Celsius for up to 7 days prior to analysis." - "Specimen Shipping" - "Do not exceed the storage limitations listed above." e) "Methamphetamine Urine HEIA" - "Urine specimens may be stored at 22-30 degrees Celsius for up to 14 days prior to analysis." - "Specimen Shipping" - "Do not exceed the storage limitations listed above." f) "Opiates Urine Enzyme Immunoassay" - "Urine specimens stored at ambient temperature up to 30 degrees Celsius up to 14 days may be used." g) "Oxycodone Urine HEIA" - "Urine specimens may be stored at 22-30 degrees Celsius for up to 14 days prior to analysis." - "Specimen Shipping" - "Do not exceed the storage limitations listed above." h) "PCP Urine HEIA" - "Urine specimens may be stored at 22-30 degrees Celsius for up to 3 days prior to analysis." -

	"Specimen Shipping" - "Do not exceed the storage limitations listed above." 4. Review of the laboratory's policy "Urine Collection with Patient Instructions" section "Storage of Patient Specimens Prior to Testing" revealed the following storage instructions which did not meet the manufacturers' instructions: "Labeled patient specimens are stored at ambient (room) temperature for up to 24 hours or at 4 degrees Celsius for up to 4 days prior to testing. After proper collection, the concentration of the following drugs in urine will not change significantly for at least ten (10) days at room temperature, for several weeks at refrigerated temperature or indefinitely when frozen. Benzodiazepines Barbiturates Amphetamines or methamphetamines Cocaine Methadone Phencyclidine (PCP) Propoxyphene (PXP) 5. In interview on January 30, 2026 at 1:34 p.m., Testing Personnel 1 stated the laboratory stored urine specimens in the refrigerator before testing. She further stated specimens were stored in the freezer if testing was delayed for an extended period of time.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (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 review of the laboratory's policies and interview with personnel, the laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing for urine drug screen (UDS) testing. Findings: 1. In interview on January 30, 2026 at 1:30 p.m., Testing Personnel 1 stated the laboratory received samples from outside clinics. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have detailed instructions for providers that included the following: a) Conditions for specimen transportation. b) Specimen processing. c) Specimen acceptability and rejection. 3. In interview on January 30, 2026 at 2:30 p.m., Testing Personnel 1 confirmed the laboratory did not provide written instructions to outside providers who submit samples as identified above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting

	patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to maintain complete policies for urine drug screen (UDS) testing. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include the following: a) "Standard Operational Procedures for Beckman Coulter AU480" - Step by step performance of the procedure b) "Normal Lab Values" - Normal reference interval for oxycodone 2. In interview on January 30, 2026 at 1:34 p.m., the Technical Consultant confirmed the laboratory's policies did not include the information identified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: **Repeat deficiency from previous survey February 22, 2024** Based on observation, review of the laboratory's policies and performance specification studies, and interview with personnel, the laboratory failed to verify complete performance specifications for the Beckman AU480 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on January 30, 2026 at 8:39 a.m. revealed the laboratory utilized the Beckman AU480 analyzer for urine toxicology testing. 2. Review of the laboratory's policy "Method Validation Plan Qualitative Assays" revealed "Validation provides evidence that the precision, accuracy, reportable range, and reference ranges will be adequate to meet the physician's needs in managing their patient's health care... After completing all the validation experiments, raw data and results should be compiled and filed in an organized manner. All validation records should be retained indefinitely. A validation summary should be prepared that contains the signature of the Laboratory Director or designee, indicating the validation has been reviewed and approved." 3. Review of the laboratory's performance specification studies for the Beckman AU480 revealed the following information was not included: a) Raw data to support precision studies to include day-to-day, run-to-run, within run, and operator variance. b) Raw data to support accuracy studies. c) Reference range studies 4. Further review of the laboratory's performance specification studies revealed the laboratory did not include a validation summary and/or documentation of approval by the Laboratory Director. 5. In interview on January 30, 2026 at 10:59 a.m., Testing Personnel 1 confirmed the laboratory was unable to match the raw data to the studies performed and the laboratory could not provide evidence of the Laboratory Director's approval.
D5429	MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

****Repeat deficiency from previous survey February 22, 2024**** Based on observation, review of the manufacturer's operator's manual and the laboratory's maintenance records, and interview with personnel, the laboratory failed to perform maintenance on the Siemens Viva-E analyzer as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on January 30, 2026 at 8:39 a.m. revealed the laboratory utilized a Siemens Viva-E analyzer for urine drug screen (UDS) testing. 2. Review of the "Viva-E Operator's Manual" revealed the following required maintenance: a) "Daily" * "Fill container with system liquid and distilled water (25 ml system liquid on a full 10 liter container). * "Empty the waste container (follow the safety instructions for working with potentially infectious material!). * "Check cuvette rotor blank results. Replace cuvette rotor if necessary." * "Check printer paper." * "Fill HCl-bottle in the reagent rotor with 0.1 mol/l HCl." * "Fill tube in W-position of sample rotor with hypochlorite solution." * "Fill tube in B-position of sample rotor with distilled water." * "Remove cuvette cover and check wash arm, mixers and cuvette rotor visually." * "Make sure that the cooling unit is on and operating correctly." b)"Weekly" * "Perform needle rinse procedure: clean the sample and reagent needle with hypochlorite solution." * "Check syringes for large air gaps and leakage; clean or replace syringes if necessary." * "Press CTRL+F10 EXIT PROGRAM to exit the analyzer program and then restart the computer." c) "Monthly" * "Clean water and waste container(s) with 0.1 mol/l NaOH. Afterwards rinse several times with water." * "Press CTRL+F10 EXIT PROGRAM to exit the analyzer program. Shut down the computer and turn the instrument off. Switch the instrument and the computer on to restart the analyzer." d) "Quarterly" * "Replace mixer belts. If not done by the service technician during preventive maintenance:" * "Replace water filter." * "Replace drying block on wash arm." 3. Review of the laboratory's maintenance logs for the Viva-E analyzer revealed the laboratory did not perform the daily, weekly, monthly, and quarterly maintenance as follows: a) Daily maintenance - Not performed on January 8, 2025: One (1) of ten (10) days reviewed in January 2025. b) Weekly maintenance - Not performed from August 1, 2025 through January 30, 2026: Twenty-six (26) of fifty-six (56) weeks reviewed from January 2025 through January 2026. c) Monthly maintenance - Not performed from August 1, 2025 through December 31, 2025: Five (5) of twelve (12) months reviewed in 2025. d) Quarterly maintenance - Not performed for three (3) of four (4) quarters reviewed. - Not performed April 2025 (last performed January 2, 2025) - Not performed August 2025 (last performed June 30, 2025) - Not performed November 2025 (last performed June 30, 2025) 4. In interview on January 30, 2026 at 1 p.m., Testing Personnel 1 stated she was consolidating the documentation of maintenance of two (2) analyzers from two (2) forms to one form and in doing so forgot to include the second page of maintenance which included the weekly, monthly, and quarterly maintenance tasks. She confirmed the laboratory could not provide documentation maintenance was performed on the dates identified above. 5. Review of the laboratory's test menu revealed the laboratory performs 48,000 UDS testing annually.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

	(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: **Repeat deficiency from previous survey February 22, 2024** Based on review of the laboratory's policies, observation, and interview with laboratory personnel, the laboratory failed to perform function checks as required by the laboratory for the centrifuge timer for one (1) of one (1) timer checks reviewed in 2025. Findings: 1. Review of the laboratory's "Centrifuge Operation" policy revealed "The timer will be checked once per year...The findings will be documented, and the timer findings tagged on the centrifuge." 2. Observation by surveyor during the laboratory tour on January 30, 2026 at 8:39 a.m. revealed the laboratory utilized a centrifuge, but the laboratory could not provide documentation of the timer check performance. 3. In interview on January 30, 2026 at 1:52 p.m., Testing Personnel 1 confirmed a timer check was not performed in 2025.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies and instrument comparison studies, and interview with personnel, the laboratory failed to perform three (3) of three (3) instrument comparison studies reviewed in 2024 and 2025 for urine drug screen (UDS) testing. Findings: 1. Observation by surveyor during the laboratory tour on January 30, 2026 at 8:39 a.m. revealed the laboratory utilized the following analyzers for UDS testing: a) Siemens Viva-E - Utilized for UDS testing of the following drugs: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Phencyclidine, and Opiates. b) Beckman AU480 - Utilized for UDS testing of the following drugs: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Opiates, Phencyclidine, Methamphetamines, and Oxycodone. 2. In interview on January 30, 2026 at 9 a.m., Testing Personnel 1 stated the laboratory utilized both a Sysmex Viva-E Pro analyzer and the Viva-E analyzer in 2024 and retired the Viva-E Pro analyzer in October 2025. She further stated the Beckman AU480 analyzer was put into use in October 2025. 3. Review of the laboratory's comparison studies for 2024 and 2025 revealed the laboratory did not have a system in place to perform comparison studies between analyzers that perform the same testing and did not perform comparison studies in 2024 and 2025 between the Viva-E and Viva-E Pro analyzers. 4. In interview on January 30, 2026 at 1:54 p.m., Testing Personnel 1 confirmed the laboratory did not perform comparison studies in 2024 or 2025 as identified above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation, review of the laboratory's temperature logs, and interview with personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained between 15 to 25 degrees Celsius (C) as required by the manufacturer for fifteen (15) of twenty-seven (27) days reviewed. Findings: 1. Observation by the surveyor during the laboratory tour on January 30, 2026 at 9:50 a. m. revealed the laboratory stored the following reagent in the laboratory: Vital Scientific, System Solution, For Viva Drug Testing Systems: Manufacturer's storage requirements 15 to 25 degrees C. 2. Review of the laboratory's room temperature logs revealed the laboratory defined the acceptable room temperature limits as 15 to 30 degrees Celsius which exceeded the manufacturer's upper storage limit. 3. Review of the laboratory's room temperature logs from January 2025 through March 2025 revealed the room temperature was documented as outside of the manufacturer's requirements without corrective actions and on the following dates: January 24, 2025: Room temperature documented as 28 degrees C January 27, 2025: Room temperature documented as 28 degrees C January 30, 2025: Room temperature documented as 28 degrees C January 31, 2025: Room temperature documented as 28 degrees C February 3, 2025: Room temperature documented as 27 degrees C February 6, 2025: Room temperature documented as 27 degrees C February 12, 2025: Room temperature documented as 28 degrees C February 13, 2025: Room temperature documented as 28 degrees C February 18, 2025: Room temperature documented as 28 degrees C February 24, 2025: Room temperature documented as 28 degrees C February 28, 2025: Room temperature documented as 28 degrees C March 10, 2025: Room temperature documented as 28 degrees C March 11, 2025: Room temperature documented as 28 degrees C March 12, 2025: Room temperature documented as 28 degrees C March 24, 2025: Room temperature documented as 28 degrees C 4. In interview on January 30, 2026 at 11:08 a.m., Testing Personnel 1 confirmed the temperatures identified above were outside of the manufacturer's requirements and the laboratory did not perform corrective actions.

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.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems,

identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment Review" policy revealed "The purpose of the Quality Assessment Review Policy is to assure that all pertinent aspects of the laboratory department or monitored and reviewed to assure that patient testing is completed in a safe and compliant manner to meet regulatory requirements. The review process must be comprehensive enough to identify physical items and laboratory processes that are deficient/non-compliant or require improvement." 2. Observation by surveyor, review of records, and interview with personnel revealed the following issues identified within the analytic system: a) The laboratory failed to maintain complete policies for urine drug screen (UDS) testing. Refer to D5403. b) The laboratory failed to verify complete performance specifications for the Beckman AU480 analyzer. Refer to D5421. c) The laboratory failed to perform maintenance on the Siemens Viva-E analyzer as required by the manufacturer. Refer to D5429. d) The laboratory failed to perform function checks as required by the laboratory for the centrifuge timer for one (1) of one (1) timer checks reviewed in 2025. Refer to D5435. e) The laboratory failed to perform three (3) of three (3) instrument comparison studies reviewed in 2024 and 2025 for urine drug screen (UDS) testing. Refer to D5775 f) The laboratory failed to perform corrective actions when the room temperature was not maintained between 15 to 25 degrees Celsius (C) as required by the manufacturer for fifteen (15) of twenty-seven (27) days reviewed. Refer to D5781.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on observation; review of the manufacturer's instructions, the laboratory's patient test records, and the laboratory's test menu; as well as interview with personnel, the laboratory failed to report urine drug screen (UDS) results as required by the manufacturer for one (1) of one (1) final patient test report reviewed. Findings: 1. Observation by surveyor during the laboratory tour on January 30, 2026 at 8:39 a. m. revealed the laboratory utilized the Siemens Viva E and the Beckman AU480 analyzer for UDS testing. 2. Further observation by the surveyor revealed the laboratory utilized Immunalysis reagents on the Beckman AU480 analyzer for UDS testing of the following drugs: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Opiates, Phencyclidine, Methamphetamines, and Oxycodone. 3. Review of the Immunalysis package inserts for the above tests revealed the test "provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC-MS or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 4. Review of a random patient test report from January 30, 2026 (Sample number U0114) revealed the laboratory did not identify results as preliminary as defined by the

	manufacturer. 5. In interview on January 30, 2026 at 10:59 a.m., Testing Personnel 1 stated the Beckman AU480 was put into use in October 2025. She confirmed the laboratory did not report UDS results as preliminary on patient final reports from the Beckman AU480. 6. Review of the laboratory's test records revealed the laboratory performed 1,899 UDS tests from November 2025 through January 2026.
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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance specification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure proficiency testing samples are tested as required. Refer to D6016. 4. The Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Refer to D6020. 5. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 6. The Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D6024. 7. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure specimen collection and preparation

	requirements were maintained as required by the manufacturer for urine drug screen (UDS) testing. Refer to D5311. 2. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing for urine drug screen (UDS) testing. Refer to D5317. 3. The laboratory failed to perform three (3) of three (3) instrument comparison studies reviewed in 2024 and 2025 for urine drug screen (UDS) testing. Refer to D5775.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing samples are tested as required. Refer to D2006.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 record review and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Refer to D5791.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to perform maintenance on the Siemens Viva-E analyzer as required by the manufacturer. Refer to D5429. 2. The laboratory failed to perform function checks as required by the laboratory for the centrifuge timer for one (1) of one (1) timer checks reviewed in 2025. Refer to D5435.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is

	functioning properly; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5781.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 observation, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is

performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory.

Findings: 1. The laboratory failed to ensure proficiency samples were tested in the same manner as patients for three (3) of three (3) testing events reviewed. Refer to D2006. 2. The laboratory failed to ensure specimen collection and preparation requirements were maintained as required by the manufacturer for urine drug screen (UDS) testing. Refer to D5311. 3. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing for urine drug screen (UDS) testing. Refer to D5317. 4. The laboratory failed to maintain complete policies for urine drug screen (UDS) testing. Refer to D5403. 5. The laboratory failed to perform function checks as required by the laboratory for the centrifuge timer for one (1) of one (1) timer checks reviewed in 2025. Refer to 5429. 6. The laboratory failed to perform function checks as required by the laboratory for the centrifuge timer for one (1) of one (1) timer checks reviewed in 2025. Refer to D5435. 7. The laboratory failed to perform three (3) of three (3) instrument comparison studies reviewed in 2024 and 2025 for urine drug screen (UDS) testing. Refer to D5775. 8. The laboratory failed to perform corrective actions when the room temperature was not maintained between 15 to 25 degrees Celsius (C) as required by the manufacturer for fifteen (15) of twenty-seven (27) days reviewed. Refer to D5781. 9. The laboratory failed to report urine drug screen (UDS) results as required by the manufacturer for one (1) of one (1) final patient test report reviewed. Refer to D5805.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.