Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2256625	09/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lakeside Orthopedic Inst Llc	1720 Mesquite Ave Ste 100, Lake Havasu City, AZ	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial survey was performed on September 26, 2024. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1240 - Toxicology 493.1403 - Moderate Complexity Laboratory Director 493.1409 - Technical Consultant - Moderate Complexity 493. 1421 - Laboratory Testing Personnel
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of manufacturer's package inserts for testing performed on the Indiko Plus analyzer and interview with the testing personnel (TP-1), the laboratory (A) failed to retain the manufacturer's package inserts for at least 2 years for each lot of Quality Control (QC) and test reagent material used on the analyzer; (B) failed to retain record of QC lot numbers and expiration dates used on the analyzer from 11/01 /2022 through 9/26/2024; and (C) failed to retain calibration records from 11/01/2022 through 1/04/2023. Findings include: 1. The laboratory began patient testing on 11/01 /2022 and reports 30,591 urine drug screen tests performed annually utilizing the Indiko Plus analyzer. A1. No evidence was presented for review to indicate the laboratory retained the manufacturer's assay information sheets for each lot of QC and test reagent material used on the Indiko Plus analyzer from 11/01/2022 through 9/26 /2024. B1. No evidence was presented for review to indicate the laboratory retained record of the lot numbers and expiration dates of QC material used on the Indiko Plus analyzer from 11/01/2022 through 9/26/2024. C1. No evidence was presented for review to indicate the laboratory retained record of calibration records for the Indiko Plus analyzer from 11/01/2022 through 1/04/2023. 2. TP-1 interviewed on 9/26/2024

	at 3:00 PM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the Indiko Plus analyzer, failed to retain record of the lot numbers and expiration dates of QC material used on the analyzer for at least two years, and failed to retain instrument calibration records from November 1, 2022 through January 4, 2023, as indicated 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 the number and severity of deficiencies cited herein for services provided in the subspecialty of Toxicology, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. See D5203, D5205, D5209, D5217, D5291, D5305, D5311, D5313, D5391, D5401, D5415, D5417, D5421, D5425, D5441, D5469, D5779, D5791, D5801, and D5891 for findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on lack of policies for review and interview with the facility personnel, the laboratory failed to establish written policies and procedures to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. Findings include: 1. The laboratory began patient testing on 11/01/2022 and reports 30,591 urine drug screen tests performed annually utilizing the Indiko Plus analyzer. 2. The laboratory failed to provide evidence of an established written policy and procedure to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. 3. The facility personnel interviewed on 9/26/2024 at 2:00 PM confirmed the laboratory failed to provide evidence of written policies and procedures to ensure positive identification and optimum integrity of a patient's specimen throughout the entire testing process, for testing performed on the Indiko Plus analyzer.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations

	of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on lack of established policies and procedures for review on 9/26/2024 and interview with the facility personnel, the laboratory failed to have a system in place to document all complaints and problems reported to the laboratory. Findings include: 1. No evidence was presented for review during the survey conducted on 9/26/2024 to indicate the laboratory has a system in place to investigate and document all complaints and problems reported to the laboratory. 2. The facility personnel interviewed on 9/26/2024 at 2:05 PM confirmed the laboratory failed to have a system in place to address complaints and problems reported to the laboratory. 3. The laboratory's annual test volume in the specialty of Chemistry is 30,591.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of employee competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess the competency of the Clinical Consultant (CC) and the Technical Consultant (TC). Findings include: 1. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on September 26, 2024 listed one Technical Consultant (TC-1) who provides technical oversight for testing performed in the specialty of chemistry, and one Clinical Consultant (CC-1) who provides consultation regarding the appropriateness of the testing ordered and interpretation of test results in the specialty of chemistry. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of the Technical Consultant and Clinical Consultant. 3. The facility interviewed on 9/26/2024 at 2:10 PM confirmed the laboratory failed to establish policies and procedures to assess the competency of the TC and CC indicated above. 4. The laboratory began testing patient specimens in November 2022 in the specialty of chemistry and reports 30,591 tests annually.
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 lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of urine drug screen testing performed under the subspecialty of Toxicology at least twice annually during 2023. Findings include: 1. The laboratory began patient testing on 11/01/2022 in the subspecialty of Toxicology, with an annual test volume of 30,591. 2. No documentation was presented for review to indicate the laboratory verified the

	accuracy of urine drug screen testing testing at least twice annually during 2023. 3. The facility personnel interviewed on 9/26/2024 at 2:20 PM confirmed the laboratory failed to verify the accuracy of urine drug screen testing testing at least twice annually during 2023.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 9/26 /2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236. 2. No documentation was presented for review to indicate the laboratory established policies and procedures related to the verification of accuracy process for testing performed in the specialty of Chemistry. 3. No documentation was presented for review to indicate the laboratory established policies and procedures related to training and evaluating the competency of Testing Personnel for testing performed in the specialty of Chemistry. 4. The facility personnel interviewed on 9/26/2024 at 3:40 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of 3 out of 3 test requisitions and interview with the facility

	personnel, the laboratory's test requisition failed to include the test(s) to be performed and the date and time of specimen collection. Findings include: 1. The laboratory began patient testing on 11/01/2022 under the sub-specialty of Toxicology, with a reported annual test volume of 30,591. 2. The laboratory performs a urine drug screen test on the Indiko Plus Analyzer which includes the following analytes: Creatinine, pH, Specific Gravity, Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Hydrocodone, Methadone, Opiate, and Oxycodone. 3. Three out of three test requisitions presented for review (Accession #010001055, 010004676 and 010006814) failed to include the date and time of specimen collection. 4. Three out of three test requisitions presented for review (Accession #010001055, 010004676 and 010006814) failed to include the test(s) to be performed, specific to the analytes tested. The test requisitions reviewed listed the test to be performed as "UDS/11-panel drug screen", with no indication of the specific analytes included in a 11-panel drug screen, whether in laboratory policy or listed on the test requisition. 5. The facility personnel interviewed on 9/26/2024 at 2:40 PM confirmed that the test requisitions reviewed during the survey and all the test requisitions for testing performed from 11 /01/2022 through 9/26/2024 failed to include the information listed above.
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 lack of written policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, and specimen referral. Findings include: 1. The laboratory began urine drug screen testing on the Indiko Plus analyzer on November 1, 2022. The laboratory's reported annual test volume in the specialty of Chemistry is 30,591. 2. No documentation was presented for review during the survey conducted on September 26, 2024 to indicate the laboratory established policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, and specimen referral. 3. The facility personnel interviewed on 9/26/2024 at 2:05 PM confirmed the laboratory failed to provide evidence of the above referenced policies and procedures at the time of the survey.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of 3 out of 3 test requisitions and test reports reviewed during the

	survey and interview with the facility personnel, the laboratory failed to document the date and time it receives a specimen for all specimens tested by the laboratory from November 1, 2022 through September 26, 2024. Findings include: 1. The laboratory performs urine drug screen testing in the specialty of Chemistry with a reported annual test volume of 30,591. The laboratory began patient testing on November 1, 2022. 2. No evidence was presented for review to indicate the laboratory documented the date and time it receives a specimen for 3 out of 3 records reviewed during the survey (Accession# 010004676, 010001055 and 010006814). 3. The laboratory failed to document the date and time it receives a specimen for all specimens tested by the laboratory between November 1, 2022 through the date of the survey, September 26, 2024. 4. The facility personnel interviewed on 9/26/2024 at 2:40 PM confirmed the laboratory failed to document the date and time it receives a specimen.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. Findings include: 1. No QA documentation was provided for review during the survey conducted on 9/26/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. 2. The facility personnel interviewed on 9/26/2024 at 3:40 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the preanalytic systems.
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 lack of a written procedure manual for review and interview with the facility personnel, the laboratory failed to have a written procedure manual for urine drug screen testing performed under the sub-specialty of toxicology. Findings include: 1. The laboratory began patient testing on November 1, 2022 on the Indiko Plus analyzer, with a reported annual test volume of 30,591. 2. No evidence of an approved procedure manual for urine drug screen testing was presented for review during the survey conducted on 9/26/2024. 3. The facility personnel interviewed on 9/26/2024 at 1:57 PM confirmed that the laboratory failed to have an approved, written procedure manual for urine drug screen testing at the time of the survey.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of Quality Control (QC) and Calibration material located in the laboratory and interview with the testing personnel (TP-1), the laboratory failed to label two of two vials of QC and Calibration material used on the Indiko Plus analyzer with the preparation and expiration dates. Findings include: 1. Observation of QC vials located in the laboratory for the Indiko Plus analyzer showed one bottle of drug screen control, DOAT 5 control lot #DAT 26035A, opened and in use with no preparation (open date) and expiration date. 2. Observation of calibration materials located in the laboratory for the Indiko Plus analyzer showed one bottle of DRI Hydrocodone Calibrator lot #74969724, opened and in use with no preparation (open date) and expiration date 3. Interview with the TP-1 on 9/26/2024 at 3:25 PM confirmed the laboratory failed to label the DOAT 5 control and DRI Hydrocodone calibrator with a preparation and expiration date. 4. The laboratory reports 30,591 patient results annually under the specialty of Chemistry.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of quality control (QC) and calibration material and interview with the testing personnel (TP-1), the laboratory used QC and calibration materials past the expiration date. Findings include: 1. During the survey conducted on 9/26/2024, direct inspection of the control and calibration materials in use at the time of the survey for the Indiko Plus analyzer revealed the laboratory used the control and calibration materials past the expiration date as evidenced below: Manufacturer's open vial stability requirement of 30 days after opening: - DOAT 2 control, lot# DAT 24032A, mfg. exp. date listed on vial - 3/31/24, open date listed on vial was 6/18/24, control was in use for 179 days past the expiration date - DOAT 3 control, lot# DAT 24033A, mfg. exp. date listed on vial - 3/31/24, open date listed on vial was 6/18/24, control was in use for 179 days past the expiration date - DOAT 4 control, lot# DAT 26084B, mfg. exp. date listed on vial - 8/31/26, open date listed on vial was 5/08/24, control was in use for 112 days past the expiration date - DOAT 5 control, lot# DAT 26035A, mfg. exp. listed on vial - 3/31/26, no open date listed on vial Manufacturer's open vial stability requirement of 60 days after opening: - DRI Hydrocodone Low control, lot#74939683, mfg. exp. date listed on vial - 11/2024, open date listed on vial was 6/27/24, control was in use for 33 days past the expiration date - DRI Hydrocodone calibrator, lot# 74969724, mfg. exp. date listed on vial - 01 /2025, no open date listed on vial Manufacturer's expiration date printed on vial is the

	expiration date: - DRI pH Detect 3.6 control, lot# 74801007, mfg. exp. date listed on vial - 3/31/24, open date listed on vial was 5/06/24, control was in use for 179 days past the expiration date - DRI pH Detect 7.8 control, lot# 74860437, mfg. exp. date listed on vial - 5/31/24, open date listed on vial was 4/11/24, control was in use for 118 days past the expiration date - DRI pH Detect 10.0 control, lot# 74801008, mfg. exp. date listed on vial - 3/31/24, open date listed on vial was 4/04/24, control was in use for 179 days past the expiration date - DRI pH Detect 11.5 control, lot# 74801006, mfg. exp. date listed on vial - 4/30/24, open date listed on vial was 3/25/24, control was in use for 149 days past the expiration date 2. The total number of patients tested from 3/31/24 through 9/26/24 using the expired control or calibration materials could not be determined at the time of the survey. 3. Interview with the TP-1 on 9/26/2024 at 3:30 PM confirmed that the expired control and calibration materials indicated above were expired and in use at the time of the survey. 4. The laboratory performs urine drug screen testing on the Indiko Plus analyzer with a reported annual test volume of 30,591.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: Based on lack of performance specification documentation for the Indiko Plus analyzer and interview with facility personnel, the laboratory failed to verify the accuracy and precision prior to reporting patient test results, failed to verify the reportable range and failed to verify the manufacturer's reference intervals for the Indiko Plus analyzer prior to reporting patient test results. Findings include: 1. The laboratory began using the Indiko Plus analyzer (serial# 864000092297) to perform urine drug screen testing on patient specimens on November 1, 2022. 2. The performance characteristic documentation reveiwed for accuracy and precision studies for the analyzer referenced above indicated the studies were performed on 11/29/2022 though 11/30/2022. Patient test results were performed and reported by the laboratory on 11/01/2022 (accession# 010001005). 3. The laboratory failed to demonstrate that it can obtain the reportable range comparable to that established by the manufacturer for the Indiko Plus analyzer prior to reporting patient test results. 4. The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the Indiko Plus analyzer prior to reporting patient test results. 5. The facility personnel interviewed on 9/26/24 at 1:15 PM confirmed the laboratory failed to perform the accuracy and precision studies prior to reporting patient test results, and failed to verify the reportable range and reference intervals for the Indiko Plus analyzer prior to reporting patient test results. 6. The laboratory's reported annual test volume under the specialty of Chemistry is 30,591.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)

	The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on lack of written documentation for Quality Control (QC) and calibration procedures for review during the survey performed on 9/26/2024 and interview with the testing personnel (TP-1), the laboratory failed to determine control and calibration procedures for the Indiko Plus analyzer. Findings include: 1. The laboratory began urine drug screen testing on the Indiko Plus analyzer on 11/01/2022 in the subspecialty of Toxicology with a reported annual test volume of 30,591. 2. No evidence was presented for review to indicate the laboratory determined QC and calibration procedures for testing performed on the Indiko Plus analyzer from 11/01/2022 through 9/26/2024. 3. The TP-1 interviewed on 9/26/2024 at 2:45 PM confirmed the laboratory failed to provide evidence of written QC and calibration procedures for urine drug screen testing performed on the Indiko Plus analyzer.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of control procedure documentation, review of Quality Control (QC) records and interview with the testing personnel (TP-1), the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for the Indiko Plus analyzer, and the laboratory failed to establish control procedures that monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions. Findings include: 1. The laboratory began patient testing on 11/01/2022 in the subspecialty of Toxicology, with an approximate annual test volume of 30,591. 2. No evidence was presented for review during the survey conducted on 9/26/2024 to indicate the laboratory established control procedures for the Indiko Plus analyzer, including the number, type and frequency of testing control materials. See D5425 for findings 3. No documentation was presented for review during the survey to indicate the laboratory monitored QC results over time (from 11/01/2022 through 9/26/2024) to identify shifts and trends in QC data and to ensure the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions. 4. The TP-1 interviewed on 9/26/2024 at 3:10 PM confirmed the laboratory failed to have documentation of approved

	QC procedures for the Indiko Plus analyzer and failed to produce documentation showing that QC results were monitored over time to ensure the accuracy and precision of test performance.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records from 11/01/2022 through 9/26/2024, lack of QC lot correlation documentation and interview with the testing personnel (TP-1), the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory began patient testing on 11/01/2022 on the Indiko Plus analyzer, with a reported annual test volume of 30,591. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from 11/01/2022 through the date of the survey on 9/26/2024. 3. The number of QC lots used on the analyzer from 11/01/2022 through the date of the survey could not be determined at the time of the survey. 4. TP-1 interviewed on 9/26/2024 at 3:10 PM stated "I have no idea how many lots of QC have been used on the analyzer" and confirmed the laboratory failed to verify the criteria for acceptability of quality control materials for each lot of QC used on the Indiko Plus analyzer from 11/01/2022 through 9/26/2024.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on lack of policies and procedures for review and interview with the facility personnel, the laboratory failed to establish corrective action policies and procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. Findings include: 1. No documentation was presented for review to indicate the laboratory established corrective action policies and procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test

	results and reports. 2. The testing personnel interviewed on 9/26/2024 at 2:00 PM confirmed the laboratory failed to provide documentation of established corrective action policies and procedures.
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 lack of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through 493.1289. Findings include: 1. No QA documentation was provided for review during the survey conducted on 9/26/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1256 and 493.1281 through 493.1289. 2. The facility personnel interviewed on 9/26/2024 at 3:40 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have an adequate system in place to ensure the accuracy of test results that are electronically interfaced from the Laboratory Information System (LIS) to the patients' Electronic Medical Record (EMR). Findings include: 1. The laboratory performs urine drug screen testing on the Indiko Plus analyzer under the subspecialty of Toxicology, with a reported annual test volume of 30,951. Patient testing began on 11/01/2022. 2. The test results generated from the analyzer are electronically interfaced from the LIS (Paracelsus) to the EMR (e-Clinical). 3. No documentation was presented for review to indicate the laboratory has a system in place to ensure patient test results and other patient-specific data are accurately and reliably sent from the point of data entry (LIS) to final report destination (EMR), in a timely manner. 4. The facility personnel interviewed on 9/26/2024 at 2:15 PM confirmed that the laboratory failed to have a system in place to verify the accuracy of

	the patient test results and other patient-specific data that are electronically interfaced from the LIS to the EMR.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, five out of five test reports failed to include the units of measurement for Creatinine and failed to include the specimen source for the analytes tested on the Indiko Plus analyzer. Findings include: 1. The laboratory began patient testing on 11/01/2022 in the subspecialty of Toxicology, with an annual test volume of 30,591. 2. Five out of five patient test reports (Accession# 010001055, 010001691, 010001403, 010004676 and 010006814) reviewed during the survey failed to include the units of measurement for Creatinine. 3. Five out of five patient test reports (Accession# 010001055, 010001691, 010001403, 010004676 and 010006814) reviewed during the survey failed to include the specimen source. 4. The facilty personnel interviewed on 9/26/2024 at 2:55 PM confirmed that the test reports indicated above were missing the units of measurement for Creatinine and failed to include the specimen source for the analytes reported.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the postanalytic systems specified in 493.1291. Findings include: 1. No QA documentation was provided for review during the survey conducted on 9/26/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. 2. The facility personnel interviewed on 9/26/2024 at 3:40 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the postanalytic systems.
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 the number and severity of deficient practices cited herein, the Condition: Laboratories Performing Moderate Complexity Testing - Laboratory Director was not met. The laboratory director failed to ensure that quality control and quality assessment programs were established and maintained to identify failures in quality as they occur for testing performed in the subspecialty of toxicology (see D6022); the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and training for the type and complexity of services offered (see D6029); the laboratory director failed to ensure that an approved procedure manual was available to all laboratory personnel responsible for urine drug screen testing in the specialty of chemistry (see D6031); and the laboratory director failed to specify, in writing, the duties and responsibilities of all laboratory personnel (see D6029).
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on testing personnel interview on 9/26/2024, lack of established Quality Control (QC) procedures and lack of quality assessment (QA) programs, the laboratory director failed to ensure that quality control and quality assessment programs were established and maintained to identify failures in quality as they occur for testing performed in the subspecialty of toxicology. See D5291, D5391, D5401, D5417, D5421, D5425, D5441, D5469, D5791, and D5891.
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 lack of initial training documentation for one out of one testing personnel (TP-1), lack of academic credentials to qualify TP-1 and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and have the appropriate training for the type and complexity of services offered. Findings include: 1. No evidence of academic credentials was presented for review for TP-1. See D6065 for findings. 2. No initial training documentation was presented for review for one out of one testing personnel (TP-1) who began patient testing in November 2022. 3. The facility personnel interviewed on 9/26/24 at 1:55 PM confirmed the laboratory failed to provide documentation of academic credentials and initial training records for TP-1 as indicated above. 4. The laboratory reports 30,591 urine drug screen tests annually in the specialty of chemistry.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:
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 lack of an approved procedure manual for review and interview with the facility personnel on September 26, 2024, the laboratory director failed to ensure that an approved procedure manual was available to all laboratory personnel responsible for urine drug screen testing in the specialty of chemistry. See D5401 for findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of written documentation for review and interview with the facility personnel, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each person engaged in the performance of the preanalytic, analytic and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. Findings include: 1. No written documentation was presented for review to indicate the laboratory director specified, in writing, the responsibilities and duties of all laboratory personnel engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. 2. The facility personnel interviewed on 9/26/2024 at 3:37 PM confirmed that the laboratory failed to provide evidence of written documentation specifying the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing as indicated above.
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 the number and severity of the deficiencies cited herein, the Condition, Laboratory Performing Moderate Complexity Testing - Technical Consultant was not met. The Technical Consultant failed to provide technical and scientific oversight of the laboratory (see D6036); the Technical Consultant failed to verify the test performance characteristics (see D6040); the Technical Consultant failed to establish a Quality Control program (see D6042); the Technical Consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens (see D6053); and the Technical Consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually (see D6054).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413

	The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the CMS-209, Laboratory Personnel Form, lack of evidence to support the Technical Consultant's involvement with the laboratory and interview with the testing personnel (TP-1), the technical consultant failed to provide technical and scientific oversight of the laboratory from 11/01/2022 through the date of the survey, 9/26/2024. Findings include: 1. The CMS-209, Laboratory Personnel Form presented for review during the survey conducted on 9/26/2024 listed one individual as the Technical Consultant (TC) for the specialty of Chemistry. 2. No evidence was presented for review during the survey to indicate the TC provided technical and scientific oversight of the laboratory from 11/01/2022 through 9/26/2024. 3. No documentation was available for review to indicate the TC provided consultation and spent time in the laboratory sufficient to supervise the technical performance of the staff for testing performed in the specialty of Chemistry from 11/01/2022 through 9/26/2024. 4. TP-1 interviewed on 9/26/2024 at 2:50 PM acknowledged there was no documented evidence of the TC's involvement with the laboratory.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (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 review of test verification documentation for urine drug screen testing performed on the Indiko Plus analyzer, and interview with the facility personnel, the technical consultant (TC) failed to ensure performance specification documentation for the Indiko Plus analyzer included the verification of the laboratory's reportable range and reference intervals, and the TC failed to ensure the accuracy and precision study performed for the Indiko Plus analyzer was signed and approved prior to the start of patient testing. Findings include: 1. The performance specification documentation for urine drug screen testing performed on the Indiko Plus analyzer failed to include the laboratory's reportable range and reference intervals, and the TC failed to ensure that the accuracy and precision studies were performed prior to reporting patient test results. See D5421 for specific findings. 2. The accuracy and precision study reviewed during the survey for testing performed on the Indiko Plus analyzer lacked any type review of the data as evidenced by the lack of signature and approval by the laboratory director and/or technical consultant. 3. The facility personnel interviewed on 9/26/2024 at 1:10 PM confirmed the urine drug screen performance specification documentation failed to include verification of the laboratory's reportable range and reference intervals, and failed to include the approval and signature of the laboratory director or technical consultant prior to the start of patient testing. 4. The laboratory's annual test volume under the specialty of Chemistry is 30,591.
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 lack of established quality control policies and procedures for reveiw and interview with the facility personnel on September 26, 2024, the technical consultant failed to establish a quality control program appropriate for the testing performed and failed to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process. See D5425, D5441 and D5469 for findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation from 2023 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel (TP-1) who began patient testing in November 2022. 2. The facility personnel interviewed on 9/26/24 at 1:55 PM confirmed the technical consultant failed to perform and document a semiannual competency evaluation during 2023 for the testing personnel indicated above. 3. The laboratory reports approximately 30,591 urine drug screen tests annually in the specialty of Chemistry.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review from 2023 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one individual responsible for moderate complexity testing at least annually. Findings include: 1. No annual competency evaluation documentation from 2023 was presented for review for one out of one testing personnel (TP-1) who began patient testing on the Indiko Plus analyzer in November 2022. 2. The facility personnel interviewed on 9/26/2024 at 1:55 PM confirmed the technical consultant failed to evaluate and document the performance of TP-1 at least annually during 2023.

D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the facility personnel, the laboratory failed to have academic credentials required to qualify one of one testing personnel for moderate complexity testing in the specialty of Chemistry. (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on lack of personnel records and interview with the facility personnel, the laboratory failed to have documentation of academic credentials to qualify one of one testing personnel (TP) for moderate complexity testing. Findings include: 1. Review of the personnel records for one of one testing personnel for the speciality of routine chemistry revealed the laboratory failed to have academic credentials to qualify TP #1. 2. Interview with facility personnel on 9/26/2024 at 1:20 PM confirmed the laboratory failed to have the required documentation to qualify TP #1 for moderate complexity testing. 3. The laboratory reports approximately 30,591 urine drug screen tests annually in the specialty of Chemistry.