Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2142238	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Orthopedics And Sports Medicine	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 on February 22, 2024 at Advanced Orthopedics and Sports Medicine, CLIA ID # 19D2142238. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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: Based on review of the laboratory's policies and twice per year verification records as well as interview with laboratory personnel, the laboratory failed to ensure proficiency testing samples were tested in the same manner as patients for two (2) of three (3) testing events. Findings: 1. Review of the laboratory's "Proficiency Testing Procedure" policy revealed "All proficiency testing samples will be tested in the same manner as patient samples." 2. Review of the laboratory's American Proficiency Institute (API) testing records revealed the laboratory tested the following samples twice: a) 2022 Chemistry - Miscellaneous - 2nd Event - UDS-04, UDS-05, UDS-06 b) 2023 Chemistry - Miscellaneous - 2nd Event - UDS-04, UDS-05, UDS-06 3. In interview on February 22, 2024 at 10:13 a.m., Testing Personnel stated the laboratory did not routinely test patient samples twice and the proficiency samples identified above were tested twice to ensure correct results.

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 observation; review of the laboratory's test menu, manufacturer's package inserts and the laboratory's policies; as well as interview with laboratory personnel, the laboratory failed to establish a policy for storage of Toxicology specimens that followed the manufacturer's storage limits. Findings: 1. Observation by surveyor during the laboratory tour on February 22, 2024 at 9:05 a.m. revealed the laboratory utilized the Siemens Viva-ProE and Viva-E analyzers for Toxicology testing. 2. Review of the laboratory's test menu revealed the laboratory performed the following Toxicology testing: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, THC, Opiates, Phencyclidine, and Methadone. 3. Review of the manufacturer's package inserts revealed "...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." 4. Review of the laboratory's policy "Urine Collection with Patient Instructions" revealed "After proper collection, the concentration of the following drugs in urine will not change significantly for at least ten (10) days at room temperature..." which exceeded the room temperature storage limits of the manufacturer. 5. In interview on February 22, 2024 at 12:23 p.m., Testing Personnel confirmed the laboratory's room temperature storage limits exceeded the room temperature storage limits of the manufacturer.
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 observation, review of validation records, and interview with personnel, the laboratory failed to have complete performance specification studies for the Viva-ProE analyzer. Findings: 1. Observation by surveyor during the laboratory tour on February 22, 2024 at 9:05 a.m. revealed the laboratory utilized the Viva-ProE analyzer serial number 22-1354. 2. Review of the laboratory's validation records revealed the laboratory did not include a validation plan and/or review for the

	following studies: a) Accuracy b) Precision - to include day to day and run to run 3. In interview on February 22, 2024 at 11:40 a.m., Testing Personnel confirmed the above studies were not included in the validation records.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the operator's manuals and the laboratory's maintenance logs, as well as interview with laboratory personnel, the laboratory failed to perform quarterly maintenance procedures for the Toxicology analyzers were performed as required by the manufacturer for two (2) of four (4) quarters reviewed in 2023. Findings: 1. Observation by surveyor during the laboratory tour on February 22, 2024 at 9:05 a.m. revealed the laboratory utilized the Siemens Viva-ProE and Viva-E analyzers for Toxicology testing. 2. Review of the operator's manual for the Siemens Viva-ProE revealed the following required quarterly maintenance: - Replace the drying block 3. Review of the operator's manual for the Siemens Viva-E revealed the following required quarterly maintenance: a) Replace mixer belts. b) If not done by the service technician during preventative maintenance: - Replace water filter. - Replace drying block on wash arm. 4. Review of the laboratory's 2023 maintenance records for the Siemens Viva-ProE and Viva-E analyzers revealed the laboratory did not perform quarterly maintenance as follows: a) First quarter - not performed January through March 2023 b) Third quarter - not performed when due July 2023 5. In interview on February 22, 2024 at 11:40 a.m., Testing Personnel stated maintenance was being performed every four (4) months. She confirmed the maintenance identified above was not performed quarterly.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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: 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. Findings: 1. Review of the laboratory's "Centrifuge Operation" policy revealed "The timer will be checked every three months...The findings will be documented and the timer findings tagged on the centrifuge." 2. Observation by laboratory personnel during the laboratory tour on February 22, 2024 at 9:05 a.m. revealed the laboratory utilized a centrifuge for

	spinning turbid specimens, but the centrifuge did not have documentation of a timer check. 3. In interview on February 22, 2024 at 11:50 a.m., Testing Personnel confirmed timer checks were not being performed on the centrifuge.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, laboratory failed to have Quality Assurance (QA) monitors in place to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to have complete performance specification studies for the Viva-ProE analyzer. Refer to D5421. 2. The laboratory failed to perform quarterly maintenance procedures for the Toxicology analyzers were performed as required by the manufacturer for two (2) of four (4) quarters reviewed in 2023. Refer to D5429. 3. The laboratory failed to perform function checks as required by the laboratory for the laboratory's centrifuge timer. Refer to D5435.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5311.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2006.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(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, review of laboratory policies and records, as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to perform quarterly maintenance procedures for the Toxicology analyzers were performed as required by the manufacturer for two (2) of four (4) quarters reviewed in 2023. Refer to D5429. 2.

	The laboratory failed to perform function checks as required by the laboratory for the laboratory's centrifuge timer. Refer to D5435.
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 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 testing samples were testes in the same manner as patients for two (2) of three (3) testing events. Refer to D2006. 2. The laboratory failed to establish a policy for storage of Toxicology specimens that followed the manufacturer's storage limits. Refer to 5311. 3. The laboratory failed to perform quarterly maintenance procedures for the Toxicology analyzers were performed as required by the manufacturer for two (2) of four (4) quarters reviewed in 2023. Refer to D5429. 4. The laboratory failed to perform function checks as required by the laboratory for the laboratory's centrifuge timer. Refer to D5435.
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 observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.