

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2142238	(X3) Date Survey Completed 06/17/2022
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 on June 17, 2022 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.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and quality control records as well as interview with personnel, the laboratory failed to retain records of quality control troubleshooting for at least two (2) years for urine drug screen testing. Findings: 1. Review of the laboratory's quality control (QC) records and instrument records for urine drug screen testing revealed Benzodiazepine QC with the expected result of "positive" resulted negative on November 23, 2021. Further review of QC records resulted in no additional troubleshooting. 2. Interview with testing personnel on June 17, 2022 at 10:05am confirmed there was no record of quality control rerun with the expected Benzodiazepine result of positive. Testing Personnel also stated any out of range QC would be repeated prior to patient testing, but that record could not be produced at the time of the survey.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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 random selection of patient test reports and interview with personnel, the laboratory failed to include the address of the laboratory where testing was performed. Findings: 1. Review of the following laboratory's patient test reports which is generate by the urine drug screen analyzer revealed the address of the laboratory that performed the testing was not the correct physical address of the laboratory. 2. In interview on June 17, 2022 at 9:45 am, the testing personnel stated the laboratory had relocated in March of 2022 to a new office. The laboratory was unable to change the physical address generated by the instrument upon relocation. The testing personnel confirmed the street address on the report was not correct.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included the address of the laboratory. Refer to D5805.