

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>37D2098113</p>	<p>(X3) Date Survey Completed</p> <p>06/16/2022</p>
<p>Name of Provider or Supplier</p> <p>Center For Orthopaedic Reconstruction & Excellence</p>	<p>Street Address, City, State</p> <p>3029 W Main Street, Jenks, OK</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
<p>D0000</p>	<p>The recertification survey was performed on 06/14,15,16/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and testing person #2 during an exit conference performed at the conclusion of the survey.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, ACL Elite manufacturer's maintenance logs, and interview with the laboratory manager, the laboratory failed to perform maintenance procedures as required by the manufacturer for one of 17 months. Findings include: (1) On 06/14/2022 at 11:30 am, the laboratory manager stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) testing using the ACL Elite analyzer; (2) On 06/15/2022, a review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Daily (i) Check Wash R-Emulsion Level (ii) Empty Liquid Waste if Necessary (iii) Perform Needle Cleaning Procedure (iv) Priming (b) Monthly (i) Check and Clean Air Filters (ii) Backup/Archive (3) A review of maintenance logs from January 2021 through May 2022 revealed the following for one of 17 months: (a) The daily maintenance procedures had not been documented as performed for one of 24 days in March 2021. The specific day was 03/29/2021; (b) The monthly maintenance procedures had not been documented as performed during March 2021. (4) The records were reviewed with the laboratory manager who stated on 06/15/2022 01:20 pm, the maintenance as shown above had not been documented as performed.</p>

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 a review of records, Quidel Triage TOX Drug Screen Instructions for Use, and interview with the laboratory manager, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 06/14/2022 at 11:40 am, the laboratory manager stated Urine Drug Screen testing was performed using Quidel Triage Meter Pro and the Quidel Triage TOX Drug Screen test device; (2) On 06/15/2022, a review of the Quidel Triage TOX Drug Screen "Instructions for Use" stated, "This test provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectroscopy (GC/MS), Liquid Chromatography/Mass Spectroscopy/Mass Spectroscopy (LC-MS/MS) and High Performance Liquid Chromatography (HPLC) are common confirmatory methods"; (3) A review of one patient report with Urine Drug Screen test results reported on 06/06/2022 revealed the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the laboratory manager who stated on 06/15/2022 at 03:12 pm, the patient reports did not include the disclaimer.