

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2228796	(X3) Date Survey Completed 09/28/2022
Name of Provider or Supplier Orion Laboratories, Llc	Street Address, City, State 6300 Corporate Boulevard, Baton Rouge, 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	An initial certification survey was performed on September 26-28, 2022 at Orion Laboratories, LLC - CLIA ID # 19D2228796. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 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.</p> <p>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 laboratory's patient test reports through the laboratory information system revealed the address of the laboratory that performed the testing was not the correct physical address of the laboratory. 2. In interview on September 27, 2022 at 1:48 pm, the technical supervisor confirmed that the final patient report displayed the physical address of the main laboratory, not the satellite address where SARS-CoV-2 testing was performed.</p>
D6098	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p>

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of patient final reports and interview with personnel, the Laboratory Director failed to ensure patient final reports included the physical address where testing is performed. Refer to D5805