

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2209001	<b>(X3) Date Survey Completed</b>  06/18/2021
<b>Name of Provider or Supplier</b>  Ocean Biosciences Llc	<b>Street Address, City, State</b>  1369 Spring Street, Atlanta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on June 18, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) records, and interview with Technical Supervisor(TS) and General Supervisor(GS), the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Th findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems. Corrective actions are being performed in the laboratory, but are not documented to reflect all phases of the QA policy. 2. During an interview with the (TS) TP#4(CMS 209) and (GS) TP#3 (CMS 209) on June 18, 2021 at approximately 11:59 AM in the review office, confirmed that the laboratory is performing corrective actions but not documenting them.</p>