

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2055652	<b>(X3) Date Survey Completed</b>  02/25/2021
<b>Name of Provider or Supplier</b>  Broad Clinical Laboratories, Llc	<b>Street Address, City, State</b>  27 Blue Sky Drive, Burlington, MA	
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>	A complaint investigation of the Clinical Research Sequencing Platform laboratory was performed on 2/18/21 and 2/22/21. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
<b>D5821</b>	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to indicate the fact that the report was a corrected report. This Standard is not met as evidenced by: 1. The surveyor reviewed one corrected report on 2/18/2021 for an invalid COVID-19 result from test dates 01/25/2021 to 02/05/2021. The review revealed that the laboratory's corrected report failed to indicate the fact that the report is a corrected report. 2. The associate director of the laboratory confirmed in an interview on 02/18/2021 at 3:20 PM that all the corrected reports issued did not indicate that they were corrected reports and only indicated "C" as the status. 3. The laboratory issued 2,538 corrected reports for COVID-19.</p>