

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2178891	<b>(X3) Date Survey Completed</b>  06/21/2022
<b>Name of Provider or Supplier</b>  Express Gene Molecular Diagnostics Laboratory	<b>Street Address, City, State</b>  9000 Sw 152 St Ste 209, Palmetto Bay, FL	
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 recertification survey conducted on 06/21/2022 found the EXPRESS GENE MOLECULAR DIAGNOSTICS LABORATORY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D2061</b>	<p><b>VIROLOGY</b> CFR(s): 493.831(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to submit the proficiency results for the subspecialty of Virology for the third event of 2021. Findings include: Review of American Proficiency Institute (API) proficiency testing (PT) records revealed that the laboratory had zero percent score for SARS-CoV-2 molecular test resulting in a zero percent score in Virology in the third event of 2021. During an interview on 06/21/2022 at 02:05 PM, the laboratory director explained that the laboratory failed to submit the results because the laboratory was not in operations at the time of the event of reference.</p>