Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2178891	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Express Gene Molecular Diagnostics Laboratory	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial survey conducted on 09/10/2020 found that the Express Gene Molecular Diagnostics Laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Condition level deficiency: -D3000
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the Florida Emergency Rule 64DER20-18 (64D-3.029) to report all COVID 19 tests results immediately to the Florida Department of Health (DOH) from 6/05/2020 to 09/10 /2020 . See 3009
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to meet the Florida Emergency Rule 64DER20-18(64D-3.029). The laboratory failed to report Coronavirus 19 (COVID-19) negative results from 6/5/2020 to 9/10/2020. Findings include: -Record review revealed that the laboratory received EUA for their method

	on 5/22/2020. -The laboratory started reporting real Time Polymerase Chain reaction (RT-PCR) COVID-19 results on 6/5/2020. -Review of FDOH Emergency Rule 64DER20-26 (64D-3.029) of April 10th 2020, revealed for COVID-19; the timeframe is immediately and had special reporting requirements. Results should be reported and accompanied by any testing conducted (positive and negative). For laboratories performing electronic laboratory reporting as described in subsection 64D-3.031 (5). F. A.C., all test results (positive and negative) are to be submitted, including screening test results (positive and negative). -Review of reports sent to the Department of Health from 8/4/2020 to 9/09/2020 revealed that the laboratory reported 137 RT-PCR COVID-19 positive cases but failed to report 1367 RT-PCR COVID-19 negative cases for the period of reference. During an interview on 09/10/2020 at 1:30 PM, the laboratory director confirmed that the laboratory only sent the COVID-19 positive results, he explained that during phone conversation with County Health personnel, he received instructions over the phone, to report only positive cases, he could not provide documentation of this instruction.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (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. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to document the quality assurance (QA) for 3 months during year 2020. Findings include: - Laboratory record review, revealed that the laboratory failed to document the QA activity from June to August 2020. During an interview on 09/10/2020 at 1:00 PM, the laboratory director confirmed that the laboratory failed to document the QA for the period of reference.