Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0280394	**(X3) Date Survey Completed** 08/13/2018
Name of Provider or Supplier Florida Family Laboratory, Inc Dba	**Street Address, City, State** 7290 Southwest 42nd Street, Miami, 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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2017 and 2018, the laboratory did not have successful performance in proficiency testing for the specialty of general immunology. Refer to D2085. Findings include: Review of the American Association of Bioanalysts (AAB) proficiency testing records and the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on August 13, 2018 on or about 3:00 PM, showed that the laboratory had unsatisfactory testing scores for the analyte, anti-nuclear antibodies, ANA for three consecutive testing events in 2017 and 2018 and for the analyte immunoglobulin E, IgE, for two consecutive testing events in 2017 and 2018.

D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful participation in proficiency testing for the specialty of general immunology. Findings include: On August 13, 2018 on or about 3:00 PM the American Association of Bioanalysts (AAB) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the following analytes anti-nuclear antibodies (ANA) and immunoglobulin E (IgE), as shown below. Anti-nuclear antibodies, ANA Event #2, 2017 ANA-0% Event #3, 2017 ANA-0% Event #1, 2018 ANA-0% Immunoglobulin E, IgE Event #3, 2017 IgE-0% Event #1, 2018 IgE-0%
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the specialty of general immunology. Findings include: On August 13, 2018, on or about 3:00 PM, the American Association of Bioanalysts (AAB) proficiency records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for three consecutive testing events for the analyte, anti-nuclear antibodies (ANA) and for two consecutive testing events for the analyte immunoglobulin E (IgE), in the specialty of general immunology. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2085.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing in the specialty of general immunology. Findings include: On August 13, 2018 on or

	about 3:00 PM the American Association of Bioanalysts (AAB) proficiency testing records and the CMS 153 and 155 reports were reviewed on August 13, 2018 on or about 3:00 PM. The review showed that the laboratory failed to achieve satisfactory performance for the following analytes anti-nuclear antibodies (ANA) and immunoglobulin E (IgE), as shown below. Anti-nuclear antibodies, ANA Event #2, 2017 ANA-0% Event #3, 2017 ANA-0% Event #1, 2018 ANA-0% Immunoglobulin E, IgE Event #3, 2017 IgE-0% Event #1, 2018 IgE-0%