Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0280554	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Finlay Clinical Laboratory Inc	330 Sw 27th Ave Ste 101, 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 subspecialty of toxicology. Refer to D2118. Findings include: Review of the American Associates of Bioanalysts (AAB) proficiency testing records and the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on June 20, 2018 on or about 10:00 AM, showed that the laboratory had unsatisfactory testing scores for the analytes, gentamicin and digoxin for two out of three testing events in 2017 and 2018.

D2118	TOXICOLOGY CFR(s): 493.845(f) Failure to achieve satisfactory performance for the same analyte or test in 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 subspecialty of toxicology. Findings include: On June 20, 2018 on or about 10:00 AM 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 analytes, gentamicin and digoxin, as shown below. Event #2, 2017 gentamicin-40% digoxin-20% Event #1, 2018 gentamicin-40% digoxin-20%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 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 subspecialty of routine toxicology. Findings include: On June 20, 2018, on or about 10:00 AM, 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 two out of three testing events for the analytes, gentamicin and digoxin, in the subspecialty of toxicology. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2118.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that 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 scores, 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 subspecialty of toxicology. Findings Include: The review of the American Association of Bioanalysts (AAB) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on June 20, 2018 on or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores as shown below. Event #2, 2017 gentamicin-40% digoxin-20% Event #1, 2018 gentamicin-40% digoxin-20%