

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0280554	(X3) Date Survey Completed 05/20/2026
Name of Provider or Supplier Finlay Clinical Laboratory Inc	Street Address, City, State 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
D0000	A desk review survey of the laboratory's proficiency test results was performed on 05 /20/2026 for Finlay Clinical Laboratory Inc. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2016 493.803(a)(b)(c) Condition: Successful Participation D6000 493.1403 Condition: Moderate Complexity Laboratory Director
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 surveyor proficiency testing (PT) desk review, review of the laboratory's College of American Pathologists (CAP) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email

	communication with the CAP PT program, the laboratory failed to successfully participate in the Subspecialty of General Immunology for the analyte of Immunoglobulin M (IgM) for 2 out of 2 testing events in 2025. Findings included: Review of the CAP proficiency testing records and the review of the CMS 153 and 155 reports, on 04/02/2026 at 11:21 PM, the laboratory had unsatisfactory testing scores for the IgM for 2 out of 3 testing events in 2025 (See D2084).
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) (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 surveyor proficiency testing (PT) desk review, review of the laboratory's College of American Pathologists (CAP) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email communication with the CAP PT program, the laboratory failed to successfully participate in the Subspecialty of General Immunology for the analyte of Immunoglobulin M (IgM) for 2 out of 2 testing events in 2025. Findings included: Review of the laboratory's CAP proficiency testing (PT) records review of the CMS CASPER 153 and 155 reports, and email communication with the CAP PT program, the laboratory failed to successfully participate in the Subspecialty of General Immunology for the analyte IgM for 2 out of 3 testing events in 2025. 1. Event #2 2025 IgM- 40% 2. Event #3 2025 IgM- 40%
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 surveyor Proficiency Testing (PT) desk review, a review of the Centers for Medicare & Medicaid Services (CMS) Casper 155 and 155, the laboratory's College of American Pathologists (CAP) PT records, email communication with the CAP PT program, the Laboratory Director failed to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT in the Subspecialty of General Immunology for the analyte of Immunoglobulin M (IgM) for 2 out of 3 testing events in 2025, resulting in initial unsuccessful PT participation (See D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor Proficiency Testing (PT) desk review, a review of the Centers for Medicare & Medicaid Services (CMS) Casper 155 and 155, the laboratory's College of American Pathologists (CAP) PT records, email communication with the CAP PT program, the Laboratory Director failed to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT in the Subspecialty of General Immunology for the analyte of Immunoglobulin M (IgM) for 2 out of 3 testing events in 2025, resulting in initial unsuccessful PT participation (See D2084).