

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2145552	(X3) Date Survey Completed 08/11/2025
Name of Provider or Supplier Simplicity Health	Street Address, City, State 3260 42nd Ave S, Saint Cloud, MN	
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	The Simplicity Health laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the proficiency testing desk review survey performed on August 11, 2025. The following condition-level deficiencies were cited: 493.803 Successful Participation The following standard-level deficiencies were cited: 493.843 Endocrinology .
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the</p>

laboratory failed to successfully participate in Testosterone Testing PT under the specialty of Endocrinology in 2025. Findings are as follows: 1. The CMS CASPER Report 0155D and the API 2025 Chemistry Core - 1st Event Performance Summary and Comparative Evaluation and the API 2025 Chemistry Core - 2nd Event Performance Summary and Comparative Evaluation were reviewed on August 11, 2025. 2. The reports indicated the laboratory failed to achieve satisfactory performance for Endocrinology Testing in two of three consecutive testing events 2025, resulting in unsuccessful performance of the analyte (see D2107). 3. The reports indicated the laboratory failed to submit PT results to the PT program within the time frame specified by the program for one event in 2025, resulting in a score of 0 for the testing event and unsuccessful performance of the analyte (see D2104) .

D2104

ENDOCRINOLOGY
CFR(s): 493.843(d)

(d) 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.

This STANDARD is not met as evidenced by:
. Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API) provider, the laboratory failed to submit Endocrinology PT results to API prior to the submission deadline. Findings are as follows: 1. The laboratory failed to submit PT results for the Testosterone analyte for the 2025 Chemistry Core - 2nd Event. Failure to participate in the testing event resulted in unsatisfactory performance for the analyte. 2. API PT Performance Evaluation listed the following unsatisfactory Testosterone score: 2025 Chemistry Core - 2nd Event Failure to Participate 0% .

D2107

ENDOCRINOLOGY
CFR(s): 493.843(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 a review of Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to achieve successful PT performance for Testosterone. Findings are as follows: 1. The laboratory failed to attain satisfactory Testosterone PT scores in two out of three consecutive PT events. Two out of three consecutive unsatisfactory PT scores for the same analyte constituted unsuccessful performance. 2. API PT Performance Evaluation listed the following unsatisfactory Testosterone scores: - 2025 Chemistry Core - 1st Event: 40% - 2025 Chemistry Core - 2nd Event: 0% .