Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0646644	(X3) Date Survey Completed 12/06/2021
Name of Provider or Supplier Simple Laboratories	Street Address, City, State 7444 W Wilson Ave, Harwood Heights, IL	

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 CASPER Report 0155D and interview with a College of American Pathologists (CAP) representative the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte Triiodothyronine (T3) during events 1 and 3 of 2021. See D2107.
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 review of CASPER Report 0155D (Individual Laboratory Profile) and interview with a College of American Pathologists (CAP) representative the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte Triiodothyronine (T3) in PT events 1 and 3 of 2021. Findings include: 1. Review of the CASPER 0155D report revealed that the initial unsuccessful PT performance occurred during CAP PT event 1 and 3 of 2021, as listed below. ENDOCRINOLOGY EVENT -1, 2021 T3 - 0% Unsatisfactory EVENT -3, 2021 T3 - 0% Unsatisfactory 2. Interview via phone with the CAP representative on 12-6-21 at 10:56 am confirmed the initial unsuccessful PT performance for T3 in events 1 and 3 of 2021.