Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0706889	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Sml Inc Dba Solis Medical Laboratory	**Street Address, City, State** 4200 Twelve Oaks Place, Houston, TX	
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 following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company on 07/15/2024. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: 493.803 D2016 Condition: Successful participation [proficiency testing] 493.1403 D6000 Condition: Laboratories performing moderate complexity testing; 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 a desk review of proficiency testing records obtained from the Certification

	and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with American Proficiency Institute (API), the laboratory failed to attain successful performance for two of three consecutive testing events in specialty of Endocrinology Testing for the analyte of Thyroxine for 2023 and 2024, resulting in unsuccessful performance. Refer to D2096.
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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Reports and the American Proficiency Institute (API) testing records for 2023 Chemistry Core 3rd Event and 2024 Chemistry Core 2nd Event, the laboratory failed to attain of a score of 80% in two out of three consecutive proficiency testing (PT) events for the analyte Thyroxine. The findings included: 1. Review of the CASPER Report 155 (Individual Laboratory Profile) revealed the following: 2023 Chemistry Core 3rd Event laboratory received unsatisfactory score of 0% for the analyte Thyroxine. 2024 Chemistry Core 2nd Event laboratory received unsatisfactory score of 60% for the analyte Thyroxine. 2. Review of the laboratory's API proficiency testing records for each event revealed the following results: API 2023 Chemistry Core 3rd Event: 0% for the analyte of Thyroxine due to failure of participate. API 2024 Chemistry Core 2nd Event: 60% for the analyte of Thyroxine. Sample: CH-07 Report Result: 5.7 (ug/dL) Expected Result: 6.0-9.1 (ug/dL) Performance: Unacceptable Sample: CH-09 Report Result: 4.8 (ug/dL) Expected Result: 5.2-7.8 (ug /dL) Performance: Unacceptable
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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Reports and the American Proficiency Institute (API) testing records, the laboratory director failed to ensure successful participation in an CMS approved proficiency testing program for the analyte of Thyroxine for two of three consecutive events from 2023 to 2024. Refer to D6016.
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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Reports and the American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in a CMS approved proficiency testing program for the analyte of Thyroxine for two of three consecutive events from 2023 to 2024. Refer to D2107.