

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0706889	(X3) Date Survey Completed 03/13/2024
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 03/13/2024. 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	<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 a review of the Certification and Survey Provider Enhanced Reporting</p>

(CASPER) Reports and American Proficiency Institute (API) records, the laboratory failed to achieve successful performance for two of three consecutive testing events for 2023 and 2024, resulting in unsuccessful performance. Refer to D2096.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(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 and 2024, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of three consecutive proficiency testing (PT) events for the analyte Total Iron. Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. The findings included: 1. A review of the CASPER Report 155 (Individual Laboratory Profile) revealed the following scores for the PT analyte Total Iron: Year Event: Analyte - Score 2023 Event 3: Total Iron - 0 2024 Event 1: Total Iron - 60 2. A desk review of API proficiency testing records for 2023 and 2024 confirmed that the laboratory received a Total Iron score of 0% for the 3rd Event of 2023 and 60% for the 1st Event of 2024.

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 Total Iron 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 Total iron for two of three consecutive events from 2023 to 2024. Refer to D2096.