Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0706889	12/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sml Inc Dba Solis Medical Laboratory	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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of the laboratory's API proficiency testing record, and confirmed in an interview, the laboratory failed to have documentation of attestation statement for 1 of 14 proficiency testing events: 2024 Hematology/Coagulation 2nd Event. The findings were: 1. Review of the laboratory's proficiency testing from API revealed no documentation of attestation statement for 1 of 14 proficiency testing events. 2024 Hematology/Coagulation 2nd Event 2. An interview on 12/11/2024 at 10:1 am in the office, the technical consultant #2 (as indicated on the 209 form) confirmed the above findings. Key: API= American Proficiency Institute
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on the manufacturer's package insert, the laboratory's HIV worksheet, patients results from 08/16/2024-11/04/2024, and confirmed in an interview, the laboratory failed to follow the manufacturer's instructions for 6 of 25 patient samples to perform the patient samples within 7 days of collection. The findings were: 1. Review of the manufacturer's package insert titled Abbott Determine HIV-1/2 Ag/Ab Combo under SPECIMEN STORAGE revealed "Serum and plasma specimens may be stored at room temperature (15- 30C) for up to two days before testing. If testing will not be performed within two days of sample collection, serum and plasma specimens should be stored at 2- 8C if the test is to be run within 7 days of collection." 2. Review of the laboratory's HIV worksheet revealed "EXT (External) Controls run per day of Testing" 3. Review of the patient results from 08/16/2024-11/04/2024 revealed 6 patients samples were not within 7 day collection. QC date: 08/23/2024 7 collection day period: 08/16/2024-08/23/2024 Patient specimen ID: 2688947 Collection date and time: 08/15/2024 at 04:50 am Elapsed days from collection to QC date: 8 days Patient specimen ID: 2688966 Collection date and time: 08/15/2024 at 07:32 pm Elapsed days from collection to QC date: 8 days QC date: 10/10/2024 7 collection day period: 10/03/2024-10/10/2024 Patient specimen ID: 2698087 Collection date and time: 09/29 /2024 at 05:56 am Elapsed days from collection to QC date: 11 days Patient specimen ID: 2698441 Collection date and time: 09/30/2024 at 05:04 am Elapsed days from collection to QC date: 10 days QC date: 11/04/2024 7 collection day period: 10/28 /2024-11/04/2024 Patient specimen ID: 2702035 Collection date and time: 10/17 /2024 at 12:57 pm Elapsed days from collection to QC date: 18 days Patient specimen ID: 2702332 Collection date and time: 10/18/2024 at 03:30 pm Elapsed days from collection to QC date: 17 days 4. An interview on 12/12/2024 at 10:25 am in the office, the technical consultant #2 and the testing personnel #2 (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: I. Based on the manufacturer's manual, direct observation of the surveyor, the laboratory's calibration verification records from 2023 to 2024, and confirmed in an interview, the laboratory failed to have total 12 of 12 documentation of calibration verification every 6 months for iSTAT analyzer (SN: 350079) for 3 of 3 cartridges. The findings were: 1. Review of the manufacturer's manual titled iSTAT System Manual (Rev. Date: 18-OCT-2021 Art: 714336-00R) under Chapter 15 Overview revealed "it is the responsibility of the laboratory to determine when and how this procedure should be performed." (Rev. Date: 18-OCT-2021 Art: 714377-00U) 2. Direct observation of the surveyor on 12/11/2024 at 3:10 pm in the lab revealed the laboratory performed CHEM8+ cartridges Creatinine (CREA) cartridges and Troponin I (cTnI) on i-STAT analyzer. 2. Review of the laboratory's calibration verification records from 2023 to 2024 revealed the laboratory failed to have 12 of 12 documentation of calibration verification every 6 months for 3 of 3 cartridge performed on iSTAT analyzer. 3. An interview on 12/11/2024 at 3:12 pm in the office, the testing personnel #2 (as indicated on the CMS 209 form) confirmed the above findings. II. Based on the laboratory's calibration verification records from 2023 to 2024, and confirmed in an interview, the laboratory failed to have 4 of 4 documentation of calibration verification every 6 months for Beckman Coulter DxC-700 Chemistry analyzer for 1 of 31 analytes: Lithium. The findings were: 1. An interview on 12/11/2024 at 3:05 pm in the office, the testing personnel #2 (as indicated on CMS 209 form) confirmed there was only 1 calibrator for the analyte Lithium, performed on DxC-700 chemistry analyzer. 2. Review of the laboratory's calibration verification records from 2023 to 2024 revealed the laboratory failed to have 4 of 4 documentation of calibration verification every 6 months for 1 of 31 analytes, Lithium, performed on Beckman Coulter DxC-700 Chemistry analyzer. 3. An interview on 12/11/2024 at 3:12 pm in the office, the testing personnel #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's QC records from January, 2024 to June, 2024, In-house test lists, and confirmed in an interview, the laboratory failed to have documentation of monitoring QC values over time for 3 of 3 cartridges performed on iSTAT analyzer for 6 of 6 months reviewed. The findings were: 1. Review of the iSTAT analyzer QC records from January, 2024 to June, 2024 revealed 3 cartridges were performed on iSTAT (SN: 350079): CHEM8+ cartridge Creatinine (CREA) cartridge Troponin I (cTnI) cartridge 2. Further review of the iSTAT analyzer QC

	records from January, 2024 to June, 2024 revealed no documentation of the laboratory monitoring the QC values over time for 3 of 3 cartridges QC for iSTAT analyzer for 6 of 6 months reviewed. 3. Review of the In-house testlist provided by the laboratory on 12/11/2024 revealed 88 patients performed CHEM8+ testing, 116 patients performed CREA testing, and 148 patients performed Troponin I testing on iSTAT analyzer from January, 2024 to June, 2024. 4. An interview on 12/11/2024 on 3:12 pm in the office, the testing personnel #2 (as indicated on CMS 209 form) confirmed the above findings. Key: QC=Quality Control CMS=Center of Medicare and Medicaid Services
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on the direct observation of the surveyor, the review of the manufacturer's package inserts, the review of the laboratory's test menu, the laboratory's records from 2023 to 2024, and confirmed in an interview, the laboratory failed to have documentation of performing instrument comparison for 8 of 8 analytes. The findings were: 1. Direct observation of the surveyor on 12/11/2024 at 3:10 pm in the lab revealed the laboratory performed CHEM8+ cartridges and Creatinine (CREA) cartridges. 2. Review of the manufacture's package insert titled i-STAT CHEM8+ cartridge (Art: 765859-01 Rev. B Rev. Date: 06-Nov-2020) revealed CHEM8+ cartridge performed Sodium (Na), Potassium (K), Chloride (CL), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN/UREA), Creatinine (Crea), Hematocrit (Hct), and Total Carbon Dioxide (TCO2) analytes. 3. Review of the manufacture's package insert titled i-STAT CREA cartridge (Art: 765859-01 Rev. B Rev. Date: 06-Nov-2020) revealed CREA cartridge performed Creatinine (Crea) 4. Review of the laboratory's test menu provided on 12/11/2024 revealed the laboratory performed Sodium (Na), Potassium (K), Chloride (CL), Glucose (Glu), Blood Urea Nitrogen (BUN/UREA), Creatinine (Crea), and Total Carbon Dioxide (TCO2) analytes on Beckman coulter DxC-700 Chemistry analyzer (SN: 61591425) and Hematocrit (Hct) on Beckman Coulter DxH690T Hematology analyzer. 5. Review of the laboratory's records from 2023 to 2024 revealed no documentation of comparison study for 8 of 8 analytes for the instrument between iSTAT and DxC 700 chemistry analyzer and iSTAT and DxH 690T hematology analyzer. Na, K, CL, Glu, BUN /UREA, Crea, and TCO2 analytes: Performed on DxC-700 chemistry analyzer and i-STAT CHEM8+ cartridge and CREA cartridge. Hct analyte: Performed on DxH690T Hematology analyzer and i-STAT CHEM8+ cartridge. 6. An interview on 12/11/2024 at 3:34 pm in the office, the technical consultant #2 and the testing personnel #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records, and confirmed in an interview, the Technical consultant failed to have documentation of testing personnel Initial training and 6 month competency assessment for 1 of 10 testing personnel performing moderate complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 10 testing personnel performing moderate complexity tests. 2. Review of the laboratory's personnel competency records revealed the technical consultant failed to have documentation of Initial training and 6 month competency assessment documentation for 1 of 10 testing personnel performing moderate complexity testing. Testing personnel #5 Re-hired date: 01/16/2024 3. An interview on 12/11/2024 at 1:54 pm in the office, the technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records, and confirmed in an interview, the Technical consultant failed to have documentation of testing personnel annual competency assessment for 2023 for 1 of 10 testing personnel performing moderate complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 10 testing personnel performing moderate complexity tests. 2. Review of the laboratory's personnel competency records revealed the technical consultant failed to have documentation of annual competency assessment documentation for 2023 for 1 of 10 testing personnel performing moderate complexity testing. Testing personnel #4 Hired date: 02/10/2022 3. An interview on 12/11/2024 at 1:54 pm in the office, the technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records, and confirmed in an interview, the Technical Supervisor failed to have documentation of testing personnel Initial training

	and 6 month competency assessment for 2 of 13 testing personnel performing high complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 13 testing personnel performing high complexity tests. 2. Review of the laboratory's personnel competency records revealed the technical supervisor failed to have documentation of Initial training and 6 month competency assessment documentation for 2 of 13 testing personnel performing high complexity testing. Testing personnel #5 Re-hired date: 01 /16/2024 Testing personnel #13 Hired date: 09/28/2022 (Hired as needed. The testing personnel#13 did not work in 2023 and 2024) 3. An interview on 12/11/2024 at 1:54 pm in the office, the technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records, and confirmed in an interview, the Technical Supervisor failed to have documentation of testing personnel annual competency assessment for 2023 for 1 of 13 testing personnel performing high complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 13 testing personnel performing high complexity tests. 2. Review of the laboratory's personnel competency records revealed the technical supervisor failed to have documentation of annual competency assessment documentation for 2023 for 1 of 13 testing personnel performing high complexity testing. Testing personnel #4 Hired date: 02/10/2022 3. An interview on 12/11/2024 at 1:54 pm in the office, the technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services