Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2329333	03/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sollis Health Florida Inc	2333 Ponce De Leon Suite 302, Coral Gables, FL	

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	An announced CLIA initial survey was conducted at SOLLIS HEALTH FLORIDA INC from 03/16/2026 to 03/30/3036. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to achieve satisfactory performance for the Potassium (K) analyte in the Chemistry specialty for one out of one event reviewed (2026). Findings include: 1-Review of American Proficiency Institute (API) records for Routine Chemistry 2026 (1st event) revealed the following failing score: -1st event 2026: K analyte the laboratory received a 0% score (unsatisfactory analyte performance). 2-During an interview on 03/16/2026 at 11:20 AM, Testing Personnel # 1 confirmed the unsatisfactory analyte performance for K in Routine Chemistry.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have policy with the step-by-step performance procedure for the Sysmex Poch-100i, the Piccolo with cartridge Metlac-12 and Metlyte Plus CRP and the Quidel Triage for D-Dimer and Troponine I. Findings included: 1-Review of the Polices and Procedures signed for by the Laboratory Director on 03/06/2026, revealed that the procedure failed to have a step-by-step performance procedure for the following analyzers: Sysmex Poch-100i, the Piccolo with cartridge Metlac-12 and Metlyte Plus CRP and the Quidel Alere Triage for D-Dimer and Troponine I besides the manufacturer's instructions. 2-The laboratory tested patients the following dates: Complete Blood Cell Count (Sysmex Poch-100i tested three patients following dates (02/27/2026, 03/09/2026 and 03/11 /2026), Piccolo Metlac 12 (tested 8 patient following dates (01/17/2026 (two patients) and one patient (01/20/2026, 02/04/2026, 02/09/2026, 02/11/2026, 02/12/2026, 03/16 /2026), four patient Metlyte Plus CRP (one patient 01/2026, 01/21/2026 02/11/2026, 02/23/2026), Quidel TriageTroponi I (one patient 02/10/2026), 2-During an interview on 03/16/2026 at 11:30 AM, the Technical Consultant confirmed that the procedure manual failed to include the step-by-step performance procedure for the following analyzers: Sysmex Poch-100i, the Piccolo with cartridge Metlac-12 and Metlyte Plus CRP and the Quidel Triage for D-Dimer and Troponine I besides the manufacturer's instructions.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective actions (CA) for 5 days out of 62 days for freezer temperatures that were not within acceptable temperature range as per manufacturer instructions (below -20

	C) for the storage of the Triage Controls level 1 and 2 since 01/14/2026. Findings included: 1-Review of Quality Control records, revealed that the laboratory was using the following controls: Triage Controls Level 1 (Lot C4187AN and Lot C4208AN) and Level 2 (Lot C4189AN and C4192AN). 2-Review of the manufacturer instructions revealed the following statement in the section "Storage and Handling Requirements" "Store frozen at -20C or colder in a non-defrosting freezer." 3-Review of documented temperature logs from 01/14/2026 to 03/16/2026 revealed the following dates the temperature has not reached the requirement of -20C or colder: 01 /22/2026 (-17C), 02/24/2026 (-18C), 02/25/2026 (-19C), 03/10/2026 (-17C) and 03/04 /2026 (-19C). 4-During an interview on 03/16/2026 at 11:55 AM, Testing Personnel #1 confirmed that there was no documentation of CA for the days the temperature was outside of acceptable range.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation that the Laboratory Director (LD) reviewed and approved the Quidel Triage for D Dimer and Troponin I tests. The laboratory tested one patient for Troponin I before LD reviewed and approved the verification. The findings included: 1-Review of the performance and verification study for the Quidel Triage Troponin I and D-Dimer systems, revealed that the study performed on 02/26/2026 failed to have the acceptance signature of the LD. 2- Review of patient reports revealed that the laboratory tested one patient for Troponin I on 02/10/2026, a method that failed to have the documentation of the review and approval of the LD. 3-During an interview on 03/16/2026 at 11:50 AM, Testing personnel #1 confirmed that the laboratory failed to have the documentation that the LD reviewed and signed the verification of performance of the Quidel Triage for D-Dimer and Troponin I and that the laboratory tested one patient on 02/10/2026 for Troponin I when the LD failed to sign the approval of the verification.