

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2329482	(X3) Date Survey Completed 04/01/2026
Name of Provider or Supplier Sure Cure Labs Llc	Street Address, City, State 29777 Telegraph Road Suite 1200, Southfield, MI	
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with the technical consultant (TC), the laboratory failed to ensure two secondary reagent containers (DI water, 70% Isopropyl Alcohol) were labeled with preparation and expiration dates. Findings include: 1. During the tour of the laboratory on 04/01/2026, at 11:00 am, the surveyor observed two secondary reagent containers labeled DI Water and 70% Isopropyl Alcohol without preparation or expiration dates. 2. An interview on 04/01/2026 at 11:10 am with the TC confirmed the containers were not labeled with preparation or expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with testing personnel #4 (TP4), the laboratory failed to ensure one bottle of CA Clean reagent used in coagulation patient testing was

not used beyond the expiration date. Findings include: 1. On 04/01/2026 at 10:50 am, during the tour of the laboratory, the surveyor observed CA Clean I (Lot# Q5005), on the Sysmex CA-600 Series coagulation analyzer with an expiration date of 02/18 /2026. 2. An interview with TP4 on 04/01/2026 at 10:55 am confirmed CA Clean I was available for use for automated probe cleaning on the analyzer.