Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0563772	07/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sun Clinical Laboratories	9349 Telstar Ave Ste A & B, El Monte, CA	

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 the surveyor's observation during the Cytology laboratory's tour and interviews with the testing personnel (TP), the laboratory failed to label staining reagents used in the laboratory to indicate the received date, opening, preparation, and expiration dates when such materials are used. The findings include: 1. Based on the surveyor's observation during the Cytology laboratory tour on July 9, 2025, at approximately 4:15 p.m. no received date, opening date, and preparation labels were used or documented Cytology staining reagents: alcohols, OG-6, EA-50, D-Limonene, Cytoseal, etc. 2. The laboratory's TP affirmed in an interview conducted on July 9, 2025, at approximately 4:20 p.m. that the Cytology reagents mentioned in statement #1 were not labeled properly with the received date, opening, preparation, and/or expiration date. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 33,599 tests for Cytology using staining reagents not labeled properly.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic,

	and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's direct observation during the tour of the Cytology laboratory, it was determined that the laboratory director failed to provide effective preanalytical direction of the Cytology laboratory. See D5415.