Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0561012	09/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cedars-Sinai Medical Care Foundation	18133 Ventura Blvd, Ste 201, Tarzana, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the incomplete verification of performance specifications for the Erythrocyte Sedimentation Rate (ESR) test and interviews with the technical consultant (TC), administrators, and laboratory assistant (LA) on September 17, 2025; it was determined that the laboratory failed to provide a complete document for the verification of performance specifications when a new instrument was obtained. The findings include: 1. Surveyor's review of the verification of performance specifications for Alcor iSED analyzer used for the ESR test showed that the documentation lacked the accuracy and reportable range studies. 2. The binder presented on September 17, 2025, containing the verification of performance specifications was reviewed, approved, and signed by the previous laboratory director. 3. The TC, administrators, and LA affirmed by interviews on September 17, 2025, at approximately 9:30 a.m., that the validation documentation missed the accuracy and reportable range portion of the study as mentioned on statement #1. 4. According to the testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 2,263 tests annually for ESR during the time when the verification performance was incomplete.
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 the surveyor's review of the laboratory's documentation for the verification of performance specifications for the Alcor iSED analyzer and interviews with the technical consultant, administrators, and laboratory assistant; the laboratory director is herein cited for failure to ensure that the verification of performance specifications was complete and valid prior to patient testing. See D5421.