Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0856392	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Facey Medical Foundation Valencia	26357 Mcbean Parkway Ste 120, Santa Clarita, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyors' review of patient results, the lack of quality control (QC) documentation and interview with the laboratory's testing personnel (TP) and office manager (OM); it was determined that the laboratory failed to retrieve the original QC records for at least 2 years. The findings included: 1. At the time of the survey on March 7, 2024, at approximately 4:30 p.m. the TP and OM failed to retrieve for one (1) out of five (5) patients for QC documentation records requested. 2. The TP and OM affirmed that QC for the one (1) out of five (5) patients' records requested described in 1 were not retrievable at the time of the survey. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 1,104 tests for routine chemistry.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 laboratory's verification of performance documentation for Hematology and interviews with the testing personnel (TP) and office manager (OM) on March 6, 2024, the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had only documentation for method comparison but no data for accuracy and precision. Per regulation, the laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy (B) Precision (C) Reportable range of test results for the test system (D) Reference range 2. The TP and OM affirmed at the time of the survey on 3/7/2024 at approximately 3:45 p. m. that no documents could be retrieved to show that above performance specifications were performed. 3. Based on the estimated annual tests volumes reported on 3/7/2024; the laboratory performed and reported approximately 3,258 Hematology tests.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (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 surveyors' observation, the lack of standard operating procedures applicable for storage and retention of documents, and interviews with the laboratory staff, it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to 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 postanalytic phase of testing. The findings included: See D3031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the deficiency found last survey on March 5, 2024, the laboratory director is

	herein cited for deficient practice in ensuring test system verification procedures were completed and compliant with the regulations at 493.1253(b)(1) before the laboratory personnel was allowed to test patients' samples without confirming the manufacturer's performance specifications. See D5421.