

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0856392	<b>(X3) Date Survey Completed</b> 03/11/2021
<b>Name of Provider or Supplier</b> Facey Medical Foundation Valencia	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Sodium Chemistry analyte for the second event in 2018 (Q2-2018). The finding included: 1. Based on review of PT records for 2018, the API reported the following unsatisfactory scores for Sodium: Sample CH-06 Reported 144, Expected Result 145-154 Unacceptable Sample CH-07 Reported 130, Expected Result 130-139 Acceptable Sample CH-08 Reported 157, Expected Result 159-168 Unacceptable Sample CH-09 Reported 125, Expected Result 126-135 Unacceptable Sample CH-10 Reported 155, Expected Result 155-164 Acceptable 2. Based on the laboratory testing declaration submitted at the time of the survey on March 11, 2021 the laboratory analyzed and reported approximately 853 Routine Chemistry tests for the year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TP affirmed on 03/11 /2021 at approximately 12:30 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:  
Based on the lack of laboratory written policies and procedures and interview with the testing personnel (TP), it was determined that the laboratory failed to have available and follow written policies and procedures for Hematology, Routine Chemistry test procedures, and SARS2-CoV reporting of results; performed in the laboratory. The findings included: 1. On the day of the survey 03/11/2021 at approximately 1:30 p.m. the laboratory failed to provide written policies and procedures for Hematology, Routine Chemistry, and reporting test results for SARS2-CoV performed in the laboratory. 2. For ten (10) out of ten (10) random patient test results reviewed covering period from 05/14/2018 to 1/13/2021, all the patients had tests ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The TP confirmed on 03/11/2021 at approximately 1:30 p.m. that the laboratory did not have written policies and procedures available for Hematology, Routine Chemistry, and SARS2-CoV result reporting tests performed in the laboratory.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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 the surveyors' observation, examination of laboratory reagents, and interview with the testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, 03/11/2021 at approximately 11:00 a.m., the examiner found BD vacutainer tubes Lot number 0043763 Expiration date 01/31/2021 currently being used beyond its expiration date. 2. The TS and TP affirmed on 03/11/2021 at approximately 11:15 a.m. using the BD vacutainers tubes listed in (1) beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 5,973 tests annually.

**D5433**

MAINTENANCE AND FUNCTION CHECKS  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on the surveyor's observation, lack of maintenance protocol and documentation, and interview with the testing personnel (TP); it was determined that the laboratory failed to establish and document a maintenance protocol for the

centrifuge (Van Guard V6500), vortex, and thermometers, that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. The laboratory uses small equipment such as centrifuge and vortex for processing samples for various procedures used in the laboratory. 2. Based on surveyor observation during tour of the laboratory on March 4, 2021 at approximately 11:00 a. m. the equipment described above used in the laboratory had no records of maintenance. 3. The TP affirmed that the laboratory failed to establish a maintenance protocol the small equipment described in 1. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 5,973 samples annually.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on the lack of all laboratory personnel competency evaluation, the lack of laboratory written policies and procedures for assessing individual performances, and interview with the testing personnel the Laboratory Director failed to ensure that policies and procedures are established and followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5401 and D6046.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on lack of documentation for competency assessments and interview with the testing personnel (TP), it was determined that the technical consultant/director failed to perform and document the performance of all testing personnel and assuring that the staff maintained their competency to perform test procedures promptly, accurately, and proficiently. The findings included: 1. There was no documentation to show that all testing personnel were evaluated. 2. The procedures for evaluation of the competency of the staff must include, but are not limited to: Direct observation of the

testing performed (including sample handling, processing and testing). Monitoring the recording and reporting of results. Direct observation of instrument maintenance. Review of intermediate worksheets, quality controls. Assessment of testing previously analyzed specimens (external QC and proficiency testing). Assessment of problem solving skills. 3. On the survey date 03/11/2021 at 2:00 p.m. the TP confirmed that no competency assessments were performed and documented for 23 TP performing CBCs in the Horiba instrument.