

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0558842	<b>(X3) Date Survey Completed</b>  10/07/2021
<b>Name of Provider or Supplier</b>  Providence Facey Medical Foundation-	<b>Street Address, City, State</b>  11333 Sepulveda Blvd, Ste 100, Mission Hills, 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>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's 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 ensure that the proficiency testing was performed with regular patient's samples workload by the laboratory personnel who routinely perform testing. Findings included: 1. Based on review of the laboratory's proficiency testing (PT) records, the PT samples testing had been performed by a laboratory staff who did not routinely performs laboratory testing instead of by the 15 testing personnel who routinely perform testing. 2. The TP affirmed on October 7, 2021 at approximately 12:00 p.m., that the laboratory did not include proficiency testing samples in the regular patient workload during routine testing and that the testing was not performed by personnel who routinely perform the testing in the laboratory. 3. The laboratory testing declaration form signed by the laboratory director on 10/05/2021 indicates that the laboratory performed 6,663 tests annually.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:  
Based on the lack of documentation, review of testing personnel competency assessment records, seven (7) randomly chosen patient records review, and interview with the testing personnel (TP) on October 7, 2021 as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency. Findings include: 1. Based on review of the laboratory's policies and procedures, the laboratory failed to establish and follow written policies and procedures for competency assessment of the TP. 2. The laboratory listed in the CMS 209 Form 17 TP. 3. For 17 out of 17 TP from the laboratory personnel report Form CMS-209 and final test reports, the laboratory fail to provide documentation of training or competency assessment for the TP performing testing at the laboratory for the year 2020. 4. This deficient practice was affirmed by interview with the TP on October 7,2021 at approximately 1:00 p.m.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory's reagent materials and testing kits and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to label reagents to indicate the opening, preparation, and expiration dates, when such reagents are used. The findings included: 1. Based on the surveyor's observation during the laboratory tour on October 7, 2021 at approximately 11:40 a. m., the TP indicated that no opening, preparation, or expiration date labels were documented as well as initials of the person preparing the reagents for all the reagents used in the laboratory. 2. The laboratory's TP affirmed in an interview conducted October 7, 2021 at approximately 12:00 p.m., that the reagents currently used to test patients samples were not labeled with opening, preparation, initials, and expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 19,364 samples annually.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on interview with laboratory testing personnel (TP) and review of two (2) randomly chosen patients' reports; it was determined that the laboratory failed to inform the authorized providers of the tests interpretation for the presence or absence of SARS-CoV-2 (Covid19) when samples testing results were reported. The findings included: 1. For two (2) out of two (2) positive and negative testing results for

	<p>Covid19 reviewed on October 7, 2021 at approximately 12:30 p.m. the report submitted to the authorized providers showed no interpretation of the results. 2. The TP affirmed that no interpretation of the results was provided to the sample submitters for Covid-19 in the final reports. 3. The laboratory tests and reports an unknown number of samples for the presence or absence of Covid-19.</p>
<p><b>D6018</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) proficiency testing results, laboratory policies and procedures, proficiency testing records, and interview with the testing personnel (TP); the laboratory director failed to ensure all proficiency testing is performed by TP who routinely perform patients' samples testing, and that the proficiency testing results are received and reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include see D2007.</p>
<p><b>D6026</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(8)</p> <p>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)(8) Ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. The findings included: see D-5807.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on lack of documentation for competency assessments for the year 2020 and interview with the testing personnel; it was determined that the technical consultant /director failed to perform and document the performance evaluation of all testing personnel and assuring that the staff maintained their competency to perform test procedures promptly, accurately, and proficiently. The findings included: see D5209.