

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0558842	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Providence Facey Medical Foundation-	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the testing personnel (TP); it was determined that the laboratory failed to update protocols in place and the effective date and signature of approval by the laboratory director. The findings included: 1. On the day of the survey February 16, 2023, at approximately 12:45 p.m. the procedure manual in place had not been reviewed, approved, signed, and dated by the laboratory director. 2. The TP affirmed on February 16, 2023, that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 8,157 patients test annually.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on direct observation and interview with the laboratory testing personnel; it was determined that the laboratory director failed to ensure that a signed and dated approved written procedure manual is available at all times to all personnel responsible for any aspect of the testing process. See D5407.