

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0560567	(X3) Date Survey Completed 12/07/2021
Name of Provider or Supplier Charles E Weidmann Md	Street Address, City, State 15243 Vanowen St Ste 306, Van Nuys, 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
D5817	<p>TEST REPORT CFR(s): 493.1291(i)</p> <p>If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patients' testing documents, test reports and interview with the laboratory technical consultant on December 7, 2021 at 2:34 pm, the laboratory failed to retain and was unable to produce an exact duplicate of send out laboratory's report for Vitamin D test of 1 patient out of 10 patients, reviewed. The findings include: 1. The laboratory reported Vitamin D test result for the patient # 54012 as 41, sample collection date: 1/12/2021. The technical consultant said that the Vitamin D test was a send out test and the laboratory staff entered the results from the send out laboratory's report and then discarded the report. However, the laboratory failed to produce an exact duplicate of send out laboratory's report. In addition, the laboratory failed to mention the name and address of the send out laboratory location where the test was performed. Therefore, the accuracy of the reported Vitamin D result can not be assured and thus may have caused patient harm. 2. The laboratory technical consultant on December 7, 2021 at 2:34 pm, affirmed that the laboratory had entered the send out laboratory's Vitamin D test result into their own LabDaq LIS system and discarded the original report received from the send out lab. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/6/2021, stated that the laboratory performs approximately 37,340 tests, annually.</p>

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's patients' testing documents, test reports and interview with the laboratory technical consultant on December 7, 2021 at 2:34 pm, the laboratory director failed to ensure compliance with the applicable regulations.

The findings include: See D5817.