

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0686478	(X3) Date Survey Completed 06/13/2019
Name of Provider or Supplier Vandana K Madkan, Md	Street Address, City, State 1821 Wilshire Blvd Ste 550, Santa Monica, 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
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory policy and procedure, test order and patient testing records, and interview with the laboratory Director, the laboratory failed to have corrective action policies and procedures to follow as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. The findings include: a. The laboratory did not have any written policy and procedure for any corrective action that might be necessary for any unacceptable testing events. b. On June 13, 2019 at 11:30 am laboratory Director confirmed that the laboratory did not have any corrective action policy and procedure. c. The laboratory testing declaration form, signed by the laboratory Director on November 17, 2017, indicates that the laboratory performs approximately 1,300 tests annually.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for</p>

acceptability.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory policy and procedure, test order and patient testing records, and interview with the laboratory Director, the laboratory failed to indicate on its test report the address of the laboratory location where the test was performed. The findings include: a. The laboratory performs histopathology test in Dermatology. The laboratory's test report does not have the address of the lab on it. b. On June 13, 2019 at 11:50 am laboratory staff affirmed that the laboratory did not indicate its address on the test report. c. The laboratory testing declaration form, signed by the laboratory Director on June 10, 2019, indicates that the laboratory performs approximately 1,000 tests annually.