

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2030445	<b>(X3) Date Survey Completed</b> 08/03/2018
<b>Name of Provider or Supplier</b> South Bay Gi Pathology Lab	<b>Street Address, City, State</b> 23560 Madison St, Ste 217, Torrance, 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>D5817</b>	<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 patient testing records, the final test report, and interview with the laboratory manager and testing personnel, the laboratory failed to notify the ordering physician of the name and address of each laboratory location where the test was performed. The findings include: a. The laboratory does not mention on the patient test report of the name and location where the slide was read. The laboratory's final test report includes the diagnosis which is electronically signed by the clinical consultant, however the test report does not contain the name and location of the laboratory where the slide was read, interpreted and the diagnosis was made. b. On August 3, 2018 at 11:30 am, the laboratory manager affirmed that the slide is read in a hospital lab at a different location, and the test report does not have the hospital's name and location. c. The laboratory's testing declaration form, signed by the laboratory Director on June 28, 2018, stated that the laboratory performs 11,422 tests annually.</p>
<b>D6079</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 patient testing records, and interview with the laboratory manager and testing personnel, the laboratory Director failed to assure the compliance with the applicable regulations. The findings include: a. See D5817