

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2004607	<b>(X3) Date Survey Completed</b>  08/29/2018
<b>Name of Provider or Supplier</b>  Optimum Labs Inc	<b>Street Address, City, State</b>  34 Welby Rd, Suite 202, New Bedford, MA	
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>D0000</b>	A CLIA recertification survey was conducted for Optimum Labs Inc. pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. ,
<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 record review and interview, the laboratory failed to indicate the address of the laboratory location where reference testing was performed as evidenced by the following: a) A review of 21 test reports for testing performed between 3/10/17 and 5/24/18 was conducted. b) The review revealed the fact that, for reports where reference laboratory testing was performed, the address of the reference laboratory was not indicated on the final report for eight (8) out of eight (8) final reports reviewed (accession numbers - 371408, 378435, 378458, 380510, 415651, 413097, 396400, and 398990). c) The technical consultant confirmed in an interview on 8/29/18 at 11:35 AM that the address of the reference laboratory, when applicable, was not included on final reports.</p>