

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2146088	<b>(X3) Date Survey Completed</b>  02/21/2019
<b>Name of Provider or Supplier</b>  Yosemite Pathology Medical Group Inc	<b>Street Address, City, State</b>  2303 Camino Ramon Ste 104, San Ramon, 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>D5805</b>	<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 acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's physical address, reviews of CLIA Applications (3/01/17, 2/21/19) and laboratory Pathology Reports and Cytology Reports, and interview with a laboratory person, it was determined that the reports incorrectly stated the laboratory address, failed to specify the Laboratory Director for this CLIA Certificate, and failed to state the name and address of the laboratory performing Grossing. Findings included: a. The CLIA Applications stated the following: 1) Physical Address 2303 Camino Ramon ste 104 San Ramon, CA 94583 2) Laboratory Director Emad Kaabipour, MD b. This CLIA survey on 2/21/19, took place at the aforementioned physical address. c. Twelve out of 12 laboratory reports reviewed from the timeframe May 23, 2018 to February 20, 2019 stated the address as 6001 Norris Canyon Road, San Ramon, CA 94583, and two Medical Directors Emad Kaabipour, MD, and Anthony R Victorio, MD. d. The Pathology Reports included Gross Descriptions of the biopsy samples in terms of number of fragments, color, and measurements, constituting High complexity testing; but failed to disclose the laboratory and address where performed and the responsible Laboratory Director. e. The laboratory person affirmed (2/21/19 at 2pm) the aforementioned address on the reports was incorrect for the professional components of interpreting slides; and that Grossing was performed</p>

at a different laboratory and physical location that was not clearly stated in the reports.  
f. Based on the stated annual estimates (Laboratory Testing Declaration, 2/21/19), the laboratory reported potentially 2,169 reports each month, beginning in May 2018. The reliability and quality of laboratory reports could not be assured when addresses were stated incorrectly or not provided, and the Laboratory Directors were not specified.