

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2075709	(X3) Date Survey Completed 11/28/2018
Name of Provider or Supplier Southern Marin Dermatology Inc	Street Address, City, State 2330 Marinship Way Ste 370, Sausalito, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient biopsy slides, patient final testing reports (electronic medical records (EMR), slide labeling, and interview with the laboratory personnel, it was determined that from 01/11/2017 through 08/18/2018 for four (4) out of nine (9) random patient testing records reviewed, the laboratory failed to follow written policies and procedures for specimen collection, labeling and biopsy reports for each biopsy specimen. The findings included: a. Review of patient initial biopsy slides found that the unique slide identifier (Accession #) found on the slide did not match the unique slide identifier (Accession #) found in final electronic medical record EMR patient (Path Reg) test report. Date Pt slide ID# EMR Pt slide ID# 01/11/17 SMD16-0192 SMD-16-0912 01/12/17 SMD16-019A SMD-16-915 01/12/17 SMD16-019B SMD-16-916 01/16/17 SMD16-0196 No Acc # recorded 01/16/17 SMD16-0197 SMD-16-0918 b. On 11/28/2018 11:30 AM (survey date), the laboratory personnel confirmed that the unique identifier (Accession #) found on biopsy slide did not match the unique identifier (Accession #) on the EMR final test report. c. Based on the laboratory's annual test volume declaration (10/22/2018) the laboratory performed 1,000 Histopathology patients' testing.</p>