

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1047119	(X3) Date Survey Completed 01/18/2018
Name of Provider or Supplier Stephen O Kovacs Md Pc	Street Address, City, State 61 Lincoln Street Ste 307, Framingham, MA	
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
D0000	A CLIA recertification survey was conducted for the Dermatologic Surgery Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain documentation to verify, at least twice annually, procedures it performs that are not included in subpart I of this part as evidenced by the following: The laboratory's procedure for peer review of pathology cases was to pull eight (8) cases (four (4) skin biopsy and four (4) MOHS cases) every six months and re-examined by another pathologist to verify the the accuracy of the diagnoses. A review of calendar years 2016 and 2017 quality assessment records for case review revealed that, for some records, there was no date of review indicated (2016: case numbers for MOHS 16-50, 16-100, 16-156, 16-208, 16-243 and biopsy case numbers BXF16-51, BXF16-99, and BXF16-134; 2017: case numbers for MOHS 17-50, 17-100, 17-148, 17-200 and biopsy case number BXF17-50) making it impossible to determine whether the reviews were performed at least twice annually or all on the same date. The laboratory director interviewed on 1/18/18 at 9:12 am verified that the dates the case reviews for skin biopsy and MOHS cases were performed was not available.</p>