

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1074192	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Kuchnir Dermatology And Dermatologic Surgery	Street Address, City, State 1 Maple Street, Milford, 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 Kuchnir Dermatology and Dermatologic Surgery 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 verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: The surveyor reviewed the laboratory's procedure for twice annual peer slide review of pathology cases on 1/8/2020. The review revealed that laboratory's procedure for peer slide review of pathology cases stated that four (4) to eight (8) cases would be twice annually reviewed by another dermatopathologist to verify the accuracy of the diagnoses. A review of calendar years 2018 and 2019 quality assessment records for pathology revealed that there was no documentation available to verify that the laboratory performed twice annual peer slide reviews for pathology cases for calendar year 2019. The documented reviews were performed on 7/1/18, 12/15/18 and 1/7/2020. The histotechnician interviewed on 1/8/2020 at 1:11 P. M. verified that the twice annual peer slide review for calendar year 2019 was not performed in 2019. The histotechnician stated it was performed on 1/7/2020 for eight (8) cases from calendar year 2019. This is a repeat deficiency that was cited at the survey performed on 1/6/2016. .</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory director did not ensure that the proficiency testing samples were tested as required under Subpart H of this part as evidenced by the following:. The surveyor reviewed the laboratory's twice annually peer slide review documentation of pathology cases for calendar years 2018 and 2019 on 1/8/2020. The review revealed that the laboratory director failed to ensure that the laboratory performed twice annual peer slide reviews for pathology cases for calendar year 2019. The histotechnician interviewed on 1/8/2020 at 1:11 P.M. verified that the laboratory director did not ensure that twice annual peer slide review of pathology cases was performed for calendar year 2019.