

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1036910	(X3) Date Survey Completed 01/14/2021
Name of Provider or Supplier Dillon Dermatology	Street Address, City, State 1037 Conneaut, Suite 201, Bowling Green, OH	
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
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 interviews with the Mohs Histotechnician, the laboratory failed to blindly verify the accuracy of the Mohs tissue biopsy and slide interpretation procedures at least twice annually, in the year 2019. This deficient practice had the potential to affect all patients tested in the specialty of histopathology in the year 2019. Findings Include: 1. An offsite review of the laboratory's 'Peer Review' policy and procedure found the following statement: "...Two cases from the previous year are selected and submitted for independent review..." 2. An offsite review of the laboratory's 'Peer Review' documentation for 2019 and 2020 found that only 1 case was submitted for independent review in 2019. Year Submitted Case 2019 19192 2020 20184 2020 20222 3. An interview with the Mohs Histotechnician via video phone call, on 1/14/21 at 1:00 PM, confirmed that only 1 Mohs case was submitted for independent review in 2019; thus, the lab failed to blindly verify the accuracy of the Mohs tissue biopsy and slide interpretation procedures at least twice annually, in the year 2019.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, and an interview with Mohs Histotechnician, the laboratory failed to perform, document and follow QC (quality control) procedures for the potassium hydroxide (KOH) testing performed to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance, for 1 out of 9 patient and QC results reviewed. All patients tested in the subspecialties of mycology and parasitology had the potential to be affected. Findings Include: 1. An offsite review of the laboratory's 'Ectoparasites' and 'KOH' policy and procedure found the following statement: "...Quality Control Procedures...Test each specimen in "duplicate"..." 2. An offsite review of patient KOH and ectoparasite test results and QC found 1 out of 9 patients charts reviewed did not have QC results. Patient Test Date QC Result 1 11/01/2020 'negative' 2 10/29/2020 'negative' 3 10/26/2020 [no result] 4 10/22/2020 'negative' 5 10/22/2020 'negative' 6 07/29/2019 'negative' 7 07/01/2019 'short hyphae...' 8 06/28/2019 'negative' 9 06/13/2019 'negative' 3. An interview with the Mohs Histotechnician, confirmed that the laboratory failed to perform, document and follow KOH and ectoparasites QC procedures for 1 out of 9 patients.