

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2134697	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Advanced Dermatology Of Pa	Street Address, City, State 608 Ederer Lane, Ambler, PA	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals and interview with the laboratory director (LD), the laboratory failed to establish a written quality assessment (QA) policy to assess ongoing mechanisms to monitor the laboratory systems from 09/20/2017 to 11/13/2019. Findings Include: 1. On the day of survey, 11/13/2019, review of the laboratory's manuals revealed that the laboratory did not to have a written QA policy to assess the laboratory's pre-analytical to post-analytical systems from 09/20/2017 to 11/13/2019. 2. The LD confirmed the laboratory did not a have quality assessment policy on 11/13/2019 around 09:30 am.</p>
D5805	<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>

This STANDARD is not met as evidenced by:

Based on the review of patient test reports and interview with the laboratory director (LD), the laboratory failed to indicate the name and address of the laboratory's location where the histopathology slides were examined on the test reports (3 of 3 reviewed). Findings Include: 1. On the day of survey, 11/13/2019, a review of some test reports (3 of 3 reviewed) revealed, the top of the reports state "Skin Pathology Associates" and on the bottom, "Advanced Dermatology of PA, 608 Ederer Lane, Ambler PA 19002". 2. The patient test reports did not clearly state the name of the laboratory and address where the histopathology slides were examined (were the slides examined at the Skin Pathology or at Advanced Dermatology of PA). 3. The LD confirmed the findings above on 11/13/2019 around 09:15 am.