

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2015702	<b>(X3) Date Survey Completed</b>  11/18/2020
<b>Name of Provider or Supplier</b>  Abington Dermatology Assoc	<b>Street Address, City, State</b>  1190 Old York Rd, Warminster, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and interview with the mohs laboratory manager and business manager, the laboratory failed to retain quality control and patient test records (including instrument printouts) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 from 07/18/2018 to 11/18/2020. Findings include: 1. On the day of survey, 11/18/2020, review of the mohs analytical system records revealed, the following documents were missing from 07/18/2018 to 11/18/2020. - Quality control records for H&amp;E stain checks. - Microtom HM 525 temperature records. - Microscope maintenance documents from. - Automatic stain maintenance records from. 2. The mohs laboratory manager and business manager confirmed the findings above on 11/18/2020 around 10:15 am.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory procedure manuals and interview with the mohs laboratory manager and business manager, the laboratory failed to establish a</p>

complete competency assessment procedure to assess the competency of 2 of 4 technical consultants in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 11/18/2020, the laboratory failed to provide a complete written policy to assess the competency for 2 of 4 TC (personnel #4 and #5), listed on the CMS Testing Personnel form 209 as TC. 2. Personnel #4 and #5 reviewed physician peer reviews for KOH and scabies microscopic examinations in 2018, 2019 and 2020. 3. Personnel #4 and #5 were not assessed for competency for their TC roles in 2018, 2019 and 2020. 3. The mohs laboratory manager and business manager confirmed the finding above on 11/18/2020 around 9:15 am. \*\*\* KOH = Potassium Hydroxide.

**D5301**

**TEST REQUEST**  
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the The mohs laboratory manager and business manager, the laboratory failed to document test requests for 3 of 7 patient specimen analyzed for Potassium Hydroxide (KOH) and scabies microscopic examinations performed in 2019. Findings include: 1. On the day of survey, 11/18/2020, review of KOH and scabies microscopic examinations test requests revealed, the laboratory did not document test requests for 3 of 7 patients (1 of 5 for KOH and 1 of 2 for scabies) for KOH and scabies microscopic examinations performed in 2019. 2. The mohs laboratory manager and business manager confirmed the finding above on 11/18/2020 around 09:20 am.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of Potassium Hydroxide (KOH) and scabies microscopic examinations quality control (QC) records, and interview with the mohs laboratory manager and business manager, the laboratory failed to document QC procedures performed for 7 of 7 patient specimens examined for KOH and scabies microscopic examinations performed from 2019 to the date of survey. Findings Include: 1. On the day of survey, 11/18/2020, review of KOH and scabies microscopic examination records revealed, the laboratory did not document QC procedures performed each day of patient testing for KOH and scabies microscopic examinations performed from 01/01/2019 to 11/18/2020. 2. In 2019, the following Microscopic Examination were analyzed: - 4 KOH examination. - 2 Scabies examination. 3. In 2020, the following Microscopic Examination were analyzed. - 1 KOH examination. 4. The mohs laboratory manager and business manager confirmed the finding above on 11/18/2020 around 09:00 am.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of Potassium hydroxide (KOH) and scabies microscopic examination procedures and interview with the mohs laboratory manager and the business manager, the laboratory director failed to assure that quality assessment programs were maintained to assure the quality of laboratory services provided for KOH and scabies microscopic examinations performed from 07/09/2018 to the day of survey. 1. Both the Scabies diagnosis by skin scraping and Fungal Infection by diagnosis by skin scraping standard operating procedures state, "Quality assessment (QA) will be conducted twice annually to conform the diagnosis by the clinical consultant. Scraping will be sent to an outside laboratory (LabCorp, Quest)". "The findings will be compared by the laboratory director and documented". 2. On the day of survey, 11/18/2020, the laboratory could not provide documentation of twice annual QA review for KOH and scabies microscopic examinations performed from 2018, 2019 and 2020. 3. The mohs laboratory manager and the business manager confirmed the findings above on 11/18/2020 around 9:17 am.