

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2126890	<b>(X3) Date Survey Completed</b> 07/10/2020
<b>Name of Provider or Supplier</b> Alliance Dermatology Physicians Pc	<b>Street Address, City, State</b> 11 Friends Lane, Suite 115, Newtown, 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>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's procedure manuals and interview with practice manager and mohs technologist, the laboratory failed to follow their competency assessment policy to evaluate 1 of 1 testing personnel (TP) for their mohs micrographic examination competency assessment and 1 of 2 regulatory personnel for their yearly competency assessment in 2018, 2019 and 2020. Findings include: 1. The Competency and CLIA competency policy states, "Evaluation and documenting competency of personnel responsible for testing is requires at least semi annual during the 1st year the individual sees patient specimen. After the first year, competency must be performed at least annually". " Documented competency is required for individuals clinical consultants (CC), technical consultant, technical supervisors (TS), and general supervisors (GS)..." 2. On the day of survey, 07/10/2020, the laboratory could not provide the following documents for 1 of 1 TP who performed mohs micrographic examinations from August of 2018 to July of 2020: - Their semi annual competency performed on February of 2019 and August of 2019. - Their first annual competency performed in 2020. - Their regulatory competency assessment for postions held on the CMS -209, Laboratory Personnel Form (CC, TS and GS) in 2018, 2019 and 2020. 3. The practice manager and mohs technologist confirmed the findings above on 07/10/2020 around 10:25 am.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p>

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of cryostat temperature logs and interview with the practice manager and mohs technologist, the laboratory failed to document temperatures and corrective actions, when temperatures are out of range for 1 of 1 cryostat microtone from 2018 to the day of survey. Findings Include: 1. The Quest Quantum Cryostat temperature logs state, "1. Console temperature is recorded daily". "2. They cryostat should be maintained at -21 to -30 degrees Celsius for best mohs sectioning". "Any variance out of range will be recorded and reported to the supervisor immediately". 1. On the day of survey, 07/10/2020, review of 1 of 1 cryostat temperature logs revealed: - In 2018 (July 2018 to December 2018), 04 of 17 daily cryostat temperatures were not documented on days mohs examinations were analyzed. - In 2018 (July 2018 to December 2018), 01 of 17 daily cryostat temperatures were out of range, and no corrective action was documented. - In 2019 (January 2019 to December 2019), 17 of 42 daily cryostat temperatures were not documented on days mohs examinations were analyzed. - In 2019 (January 2019 to December 2019), 09 of 42 daily cryostat temperatures were out of range, and no corrective action were documented. - In 2020 (January 2020 to July 2020), 02 of 16 daily cryostat temperatures were not documented on days mohs examinations were analyzed. - In 2020 (January 2020 to July 2020), 01 of 16 daily cryostat temperatures were out of range, and no corrective action was documented. 2. The practice manager and mohs technologist confirmed the findings above on 07/10/2020 around 10:45 am.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of the histopathology laboratory and interview with the practice manager and mohs technologist, the laboratory failed to ensure 5 of 5 bottles of Avantik tissue marking dyes were not used beyond their expiration dates of 03/2020. Findings Include: 1. On the day of survey, 07/10/2020, while on tour on the histopathology laboratory, the examiner observed 5 of 5 bottles of Avantik tissue marking dyes (red, blue, green, black and yellow), Lot# 065113, had expired March of 2020. 2. The practice manager and mohs technologist confirmed the findings above on 07/10/2020 around 10:30 am.