

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2187340	(X3) Date Survey Completed 04/12/2024
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 290 Clear Sky Court, Clarksville, TN	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), the laboratory procedure manual, Mohs data logs, review of testing personnel records and a lack of records, and review of an electronic mail communication, the laboratory failed to follow the policy for performing initial, six-month, and annual competency assessments for two of three testing personnel who performed inking of tissue removed during Mohs micrographic surgical procedures. The findings include: 1. A review of the FORM CMS-209 revealed three testing personnel who inked tissue removed during Mohs micrographic surgery. 2. A review of the procedure titled "POLICY FOR PERSONNEL COMPETENCY" revealed the following: "Personnel must not report test results for patient specimens until training is complete and competency is verified for each test procedure they perform. Competency assessments should occur every six months for the first year and annually thereafter for all testing personnel." 3. A review of Mohs data logs revealed the initials of testing persons three and four (TP3, TP4) as follows: TP3 and TP4 in January 2023, TP4 in February 2023, TP3 in April 2023, and TP3 in July 2023. 4. A review of testing personnel records revealed no documented initial training or six-month competency for TP3 in 2023 and no annual competency assessment for TP4 in 2023. 5. A review of an electronic mail communication with testing person two on 04/19/24 at 12:51 p.m. revealed that competency assessments are not usually performed for the Mohs histotechs that fill in for the full-time histotechs. This confirmed the survey findings.</p>

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's twice a year verification of accuracy (alternative proficiency testing) reports and staff interview, the laboratory failed to document review for four of four alternative proficiency testing reports from 2022 and 2023.

The findings include: 1. Review of the laboratory's twice a year verification of accuracy (alternative proficiency testing) reports revealed no documented review after the results were received for the following events: January-June 2022, July-December 2022, January-June 2023, July-December 2023. 2. Testing person number two confirmed the findings during interview on 04/12/24 at 10:45 a.m.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient Mohs's surgical report, laboratory quality records, and staff interview, the laboratory failed to document the quality assessment of hematoxylin and eosin stain for one of four dates selected from 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 04/12/24 at 8:25 a.m. revealed reagents and equipment used for processing and staining of tissue removed during Mohs micrographic surgery. Stains observed were hematoxylin and eosin (H&E). 2. Review of patient identification number A9236737 revealed Mohs surgical procedure performed on 11/10/2022. 3. Review of the H&E stain quality log revealed no documentation that stain quality was evaluated on 11/10/22. 4. Testing person number two confirmed the survey findings during interview on 04/12/24 at 10:45 a.m.