

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0938492	(X3) Date Survey Completed 08/06/2026
Name of Provider or Supplier Uc Health Dept Of Dermatology	Street Address, City, State 3590 Lucille Drive, Suite 1600, Cincinnati, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure titled "Personnel" and interviews with the Clinical Operations Manager (COM) and Testing Personnel (TP) #1, the laboratory failed to follow its policy and procedure for competency assessment. This deficient practice had the potential to affect one out of three TP from the date of the previous inspection on 12/14/2023 through 08/04/2026. Findings Include: 1. Review of the form CMS 209 signed and dated by the Laboratory Director on 07/16/2026 found three staff listed and qualified as testing personnel. 2. Review of the policy and procedure titled "Personnel", approved via signature and date by the LD on 01/03/2024, 01/10/2025, and 01/07/2026, and provided the date of the inspection, found the following statement: "Competency Assessments are performed semi-annually for the first year, and annually thereafter." 3. Review of the laboratory's 2024 and 2025 competency assessment documents did not find any competency records for TP #3. 4. During an interview on 08/04/2026 at 12:55 PM, the COM stated that TP #3 started testing on 03/01/2023, but the laboratory failed to include TP #3 on the previous form CMS 209, which was signed and dated by the Laboratory Director on 12/13/2023. The COM also verified the laboratory did not follow its policy and procedure for competency assessments for TP #3 in 2024 and 2025 and could not provide annual competency assessment records for TP #3. 5. Further document review found 3,446 patient tests in the subspecialty of Histopathology from 12/14/2023 through 08/04/2026
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on a review of the policy and procedure titled "Proficiency Testing" and an interview with Testing Personnel (TP) #1, the laboratory failed to follow its policy and procedure for proficiency testing. This deficient practice had the potential to affect 2,386 patients tested in the subspecialty of Histopathology from 03/28/2024 through the next proficiency test review dated 02/16/2026. Findings Include: 1. Review of the policy and procedure titled "Proficiency Testing", approved via signature and date by the LD on 01/03/2024 and 01/10/2025, and provided the date of the inspection, found the following statement: "Proficiency testing of slides by a consulting dermatopathologist or another Mohs surgeon will be done biannually." 2. Review of the laboratory's 2024 Mohs cases sent out for proficiency testing found one record dated 03/28/2024. 3. Review of the laboratory's 2025 Mohs cases sent out for proficiency testing found one record dated 01/13/2025. 4. During an interview on 08/04/2026 at 1:30 PM, TP #1 verified the laboratory did not follow its policy and procedure for biannual proficiency testing by a consulting dermatopathologist or another Mohs surgeon.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of the policy and procedure titled "Technical Procedure, Wet Mount and/or KOH Preparation" and interviews with the Clinical Operations Manager (COM) and Testing Personnel (TP) #1, the laboratory failed to follow its policy and procedure for KOH preparations. This deficient practice had the potential to affect six out of six KOH patient tests in the subspecialty of Mycology from 12/16/2025 through 05/13/2026. Findings Include: 1. Review of the policy and procedure titled "Technical Procedure, Wet Mount and/or KOH Preparation", approved via signature and date by the LD on 01/10/2025 and 01/07/2026, and provided the date of the inspection, found the following statement: "V. Quality Control For Quality Control Purposes and Test Accuracy Two slides will be obtained by the same provider, read and logged by the same provider, or one slide will be read by two providers." 2. Review of the laboratory's "KOH/WET MOUNT MICROSCOPIC PROCEDURES" patient log sheets failed to show evidence of two prepared slides which were read by the same provider, or that one prepared slide was read by two providers for KOH testing on the following dates: 12/16/2025 01/28/2026 02/25/2026 03/20/2026 04/13/2026 05/13/2026 3. During an interview on 08/04/2026 at 2:00 PM, the COM verified the laboratory did not follow its policy and procedure for KOH preparations and testing. KOH; Potassium Hydroxide