

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0955128	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Annapolis Dermatology Center	Street Address, City, State 71 Old Mill Bottom Rd North Ste 202 And 300, Annapolis, MD	
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
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 review of the procedure manual, review of proficiency testing (PT) records, and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of potassium hydroxide (KOH) preparations at least twice annually in one of two years reviewed. Findings: 1. The "Proficiency Testing - KOH" procedure stated that "Proficiency Testing for KOH slides by clinical dermatologists at Annapolis Dermatology Center will occur annually via the American Academy of Dermatology approved self-assessment examination." 2. Review of PT records from 2025-2026 showed that PT was performed once in January 2025 and once in January 2026 as of the time of the onsite survey on 08/19/2026. 3. During the exit interview on 08/19/2026 at 12:30 PM, the LD confirmed that accuracy for KOH preparations was not verified at least twice annually in 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains,

and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the laboratory director (LD), the procedure for performing potassium hydroxide (KOH) preparations did not include step-by-step instructions for performing the microscopic examination or how to interpret and report results. Findings: 1. The "Procedure for Skin KOH" stated that the "Provider will review slide under microscope, enter results in patient's chart and in reference book." 2. During the exit interview on 08/19/2026 at 12:30 PM, the LD confirmed that the procedure for performing KOH preparations did not include step-by-step instructions for performing the microscopic examination or how to interpret and report results.

D5417

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

(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, review of the potassium hydroxide (KOH) log, and interview with the laboratory director (LD), the laboratory used the KOH reagent beyond the expiration date for 11 of 11 patients tested between 06/05/2026-08/07/2026. Findings: 1. Observation of the area where KOH preparations were performed determined that the KOH reagent, lot 000519, expired on 05/22/2026. 2. Results of the KOH preparations were documented on the KOH Log. Review of the KOH Log showed that 11 patients were evaluated between 06/05/2026-08/07/2026. 3. During the exit interview on 08/19/2026 at 12:30 PM, the LD confirmed that KOH reagent lot 000519 that expired on 05/22/2026 was used for patient testing between 06/05/2026-08/07/2026.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on review of the procedure manual, review of personnel records, and interview with the laboratory director (LD) who was also the technical consultant for potassium hydroxide (KOH) testing, the LD failed to evaluate the competency for eight of eight testing personnel (TP). Findings: 1. The Laboratory Personnel Report (Form CMS-209) listed eight TP who performed KOH testing. 2. The "Quality Assurance" procedure stated that "The Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." 3. There was no documentation that competency was evaluated for any of the TP that performed KOH testing using the minimum regulatory requirements: 1) Direct observation of routine patient test performance, 2) Monitoring the recording and reporting of test results, 3) Reviewing test results or worksheets, 4) Assessing test performance through testing internal blind testing samples or external proficiency testing samples, and 5) Assessing problem-solving skills. 4. During the exit interview on 08/19/2026 at 12:30 PM, the LD confirmed that competency for eight of eight TP performing KOH testing was not evaluated.