

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2132556	(X3) Date Survey Completed 09/09/2026
Name of Provider or Supplier Center For Dermatology	Street Address, City, State 19236 Meadow View Drive, Hagerstown, 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
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 potassium hydroxide (KOH) patient logs and interview with testing personnel #2 (TP#2), the laboratory failed to have a written procedure for performing KOH microscopic examinations. Findings: 1. Review of the KOH patient logs determined that the laboratory performed KOH microscopic examinations from 2024-2026. 2. The procedure manual did not include

	a procedure for performing KOH microscopic examinations. 3. During the exit interview on 09/09/2026 at 12:26 pm, TP#2 confirmed that the laboratory did not have a written procedure for performing KOH microscopic examinations.
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 personnel records and interview with testing personnel #2 (TP#2), the laboratory director (LD), who was also the technical consultant for potassium hydroxide (KOH) testing, failed to evaluate the competency for two of two TP performing KOH microscopic examinations. Findings: 1. The Laboratory Personnel Report (Form CMS-209) listed two TP who performed KOH microscopic examinations. 2. 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. 3. During the exit interview on 09/09/2026 at 12:26 pm, TP#2 confirmed that competency for two of two TP performing KOH testing was not evaluated.