

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2331444	(X3) Date Survey Completed 02/26/2026
Name of Provider or Supplier Discover Dermatology Institute, Llc	Street Address, City, State 225 E City Ave Ste #225, Bala Cynwyd, PA	
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
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the laboratory director (LD), the laboratory failed to establish and maintain a policy to ensure all complaints and problems reported to the laboratory were documented and investigated when needed for 1 of 1 month from 02/03/2026 to date of initial survey. Findings include: 1. On the day of initial survey, 02/26/2026 at 09:20 am, the laboratory could not provide a policy to ensure all complaints and problems reported to the laboratory were documented and investigated as needed for 1 of 1 month from 02/03/2026 to 02/26/2026. 2. The LD confirmed the above findings on 02/26/2026 at 09:25 am.
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 laboratory's procedure manual, and interview with the Laboratory Director (LD), the laboratory failed to provide a complete procedural manual for dermatopathology (MOHS) testing performed for 1 of 1 month from 02/03/2026 to the date of initial survey. Findings include: 1. On the day of the initial survey, 02/26/2026 at 09:15 am, review of the laboratory's MOHS procedure manual revealed the laboratory failed to include the following applicable requirements under 493.1251 (b) in the test procedures for MOHS micrographic examinations performed for 1 of 1 month from 02/03/2026 to 02/26/2026: - (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 interpretation of results. - (b)(13) The laboratory's system for entering results in the patient record and reporting patient results. 2. The LD confirmed the findings on 02/26/2026 at 09:40 am.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation and interview with the Laboratory Director (LD), the LD failed to ensure that quality assessment (QA) programs were established and maintained to ensure the quality of services provided for dermatopathology microscopic examinations performed for 1 of 1 month from 02/03/2026 to the date of initial survey. Findings include: 1. On the day of initial survey, 02/26/2026 at 9:47 am, the laboratory could not provide a written QA policy for monitoring, assessing and identifying failures in quality as they occurred for dermatopathology microscopic examinations performed from 02/03/2026 to 02/26/2026. 2. The laboratory could not provide documentation of the ongoing assessment used to evaluate and assess the laboratory's pre-analytical, analytical, and post-analytical processes for 1 of 1 month from 02/03/2026 to 02/26/2026. 3. Review of the laboratory's test logs revealed the laboratory performed 1 dermatopathology microscopic examination from 02/03/2026 to 02/26/2026. 4. The LD confirmed the findings above on 02/26/2026 at 9:56 am.