

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1013344	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier All Island Dermatology	Street Address, City, State 54 New Hyde Park Road, Garden City, NY	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of the Quality Assessment (QA) policy, the laboratory failed to establish a written policy for monitoring pre-analytic, analytic, and post-analytic systems in the laboratory. Finding: 1. Annual QA review was not performed from 2020 through the survey date. 2. Confirmed above finding on an interview with TP#2 and TP#3 on 2/7/2023 at approximately 12:30 P.M.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the histopathology laboratory humidity log from 2020 through the survey date, the laboratory failed to document humidity as required. Findings: 1.</p>

	<p>Histopathology laboratory humidity log was not available for review from 2020 through the survey date. 2. Confirmed above finding on an interview with TP#3 on 2/7/2023 at approximately 12:00 P.M.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of aliquot bottles in the Mohs laboratory, the laboratory failed to properly identify the reagent, concentration, lot number, expiration date, and storage requirement for the following: Findings: 1. 10% Formalin Fixative vial containing black dye. 2. 10% Neutral Buffer vial containing green dye. 3. 10% Formalin Fixative vial containing red dye. 4. Frozen embedding media vial containing 100% reagent grade alcohol. 5. Sodium hypochlorite vial containing water. 6. Para Gard vial does not identify concentration, lot number, and expiration date. 7. Confirmed above findings on an interview with testing person (TP)#2 on 2/7/2023 at approximately 11 A.M.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Mohs laboratory humidity log from 2020 through the survey date, the laboratory failed to perform corrective action for days which humidity was out of range. Findings: 1. Mohs laboratory humidity log calendar year 2022: a. May - 23, 24, 25. b. June - 2, 7, 8, 9, 14, 15, 20, 21, 27, 28. c. July - 19, 25, 26, 27, 28. d. August - 1, 2, 11, 15, 16, 17, 18, 22, 23, 25, 29, 30. e. September - 19, 20, 22, 27, 28. f. October - 3, 4, 10, 11, 13, 17, 18, 24, 25, 27, 31. g. November - 1, 3, 14, 15, 21, 22, 28, 29. h. December - 1, 5, 6. 2. Confirmed above finding on an interview with TP #2 on 2/7/2023 at approximately 11:15 A.M.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of the laboratory's Quality Assessment (QA) procedure, the laboratory failed to establish written QA for all phases of the general laboratory system. Refer D5291.