

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2169789	(X3) Date Survey Completed 07/27/2021
Name of Provider or Supplier Integrated Dermatology Of North	Street Address, City, State 3809 Computer Drive, Suite 200, Raleigh, NC	
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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing procedures and records, laboratory procedure manual and laboratory director (LD) interview 07/27/21, the laboratory failed to ensure they either participated in a proficiency testing program or participated in a system to verify the accuracy of the Potassium Hydroxide (KOH)/wet prep test results at least twice a year. Findings: Review of the laboratory proficiency testing records revealed no documentation for the participation in a system to verify the accuracy of KOH/wet prep at least twice a year. Review of the laboratory's proficiency testing section in the "Quarterly QA Checklist" states "PT results are available for the prior two years." No documentation was found showing enrollment in a proficiency testing program for KOH/wet prep for 2019, 2020, or 2021. Review of the laboratory's "Proficiency Testing" forms, revealed documentation for "MOHS Micrographic Surgery Form " only, there was no form or documentation for KOH/wet prep proficiency testing. Review of the laboratory's procedure manual revealed there was no procedure for performance of accuracy for KOH/wet prep. Interview at approximately 12:00 p.m. with LD confirmed that the lab did not participate in KOH /wet prep proficiency testing at least twice a year.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for</p>

specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 laboratory procedure manual and interview with the LD 7/27/21, the laboratory procedure manual was not complete and current for the testing performed. 1. The laboratory procedure manual failed to include a procedure for performing KOH/wet prep. Findings: Review of the laboratory procedure manual revealed the procedure manual failed to include a procedure for the performance of KOH/wet prep testing. Interview at approximately 12:00 p.m. with the LD confirmed there was not a procedure for KOH/wet prep testing. 2. The laboratory procedure manual failed to include a procedure for entering test results into the patient medical record. Findings: Review of the laboratory procedure manual revealed the procedure manual failed to include a procedure for entering test results into the patient medical record. Interview at approximately 12:00 p.m. with LD confirmed that there was not a procedure for entering patient test results into the patient medical record.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records, review of "Quality Assurance Manual" and review of "Quarterly QA Checklist" 7/27/21, the LD failed to ensure that 2 of 3 testing personnel (TP) had documented training for Moh's specimen processing and grossing and/or KOH/ wet prep testing. 1. The LD failed to ensure that prior to testing patient specimens TP #1 had documented training for Moh's specimen processing and grossing. Findings: Review of laboratory personnel records revealed no documentation of training for TP #1 for Moh's specimen processing and grossing. Review of the laboratory "Quality Assurance Manual" revealed "New hires will be trained within 30 days of hire and annually thereafter." Review of "Quarterly QA Checklist" revealed "All personnel who perform specimen collection and handling and results reporting have been trained and this training is documented." Interview with the LD at approximately 12:00 p.m. confirmed there was no documentation of

training for TP #1 for Moh's specimen processing and grossing. 2. The LD failed to ensure TP #3 had documented training for the performance of KOH/ wet prep prior to performing patient testing. Findings: Review of laboratory personnel records revealed no documentation of training for TP #3 for the performance of KOH/wet prep testing. Review of the laboratory "Quality Assurance Manual" revealed "New hires will be trained within 30 days of hire and annually thereafter." Review of "Quarterly QA Checklist" revealed "All personnel who perform specimen collection and handling and results reporting have been trained and this training is documented." Interview with the LD at approximately 12:00 p.m. confirmed there was no documentation of training for TP #1 on the performance of KOH/wet prep testing.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of personnel record, review of "Quarterly QA Checklist", and interview with LD 7/27/21, the LD failed to specify, in writing, the testing TP #3 was authorized to perform. Findings: Review of personnel records revealed no documentation of what testing TP#3 was authorized to perform. Review of the "Quarterly QA Checklist" revealed "All lab personnel have been trained to perform the tests that they are authorized to perform." Interview with LD at approximately 12:00 p.m. confirmed TP #3 performed KOH/ wet prep testing.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

This STANDARD is not met as evidenced by:
Based on review of personnel records and "Quarterly QA Checklist" 07/27/21, the Technical Supervisor (LD) failed to evaluate competency of TP#3 in 2020 and 2021 for the performance of KOH/ wet prep testing. Findings: Review of personnel records revealed no documentation of a competency evaluation for TP#3 since 2020. Review of "Quarterly QA Checklist" revealed "Personnel are evaluated as often as stated in our laboratory policies. Personnel evaluations are documented and retained in the appropriate personnel files."