

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2107105	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Indigo Dermatology Llc	Street Address, City, State 675 S Babcock St, Melbourne, FL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow their policy to access employees competency. Findings: Review of the laboratory logs and quality assurance documentation showed that there was no documentation of initial training or competency assessment for the Mohs technician from 1/28/17 to 6/19/18. During an interview on 6/19/18 at 11 AM, the Office Manager stated they only had the Mohs technicians resume and a brief typed statement, and that no other training or competency was documented.</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 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</p>

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 record review and interview, the laboratory's procedure manual failed to include step by step instructions for performing blind peer review. Findings: Review of the procedure titled "Mohs Bi-Annual Assessment" showed that the procedure failed to include step by step instructions on performing blind peer review. The procedure states "The slides will be read by the Dermatopathologist first and then read by the Mohs Surgeon." There was no documentation regarding what information is provided to the second reader. Peer review was performed in July 2017, December 2017, and June 2018 showed a copy of a patients Mohs map with a statement of agreement and signature of the reviewing doctor at the bottom for 9 out 9 peer review assessments performed. Competency documentation showed that the laboratory was not perform blind peer review. During an interview on 6/19/18 at 12:30 AM, the Office Manager acknowledged that for peer review she sends copies of the Mohs map to the reviewing doctor and that it was not a blind peer review.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the lot number, expiration date and open dates for reagents used in their Hematoxylin & Eosin (H & E) stains. Findings: Record review of the laboratory's reagent/quality control (QC) slide log showed that the log used for the H & E stain did not include the lot number, expiration date and open date of the reagents. During an interview on 6/19 /18 at 11:18 AM, the Office Manager stated the reagent/QC log was the only log with reagents they had.