

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2222313	<b>(X3) Date Survey Completed</b> 10/14/2021
<b>Name of Provider or Supplier</b> Integrated Dermatology Of Reston Llc	<b>Street Address, City, State</b> 1886 Metro Center Dr Suite 650, Reston, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced initial CLIA survey was conducted at Integrated Dermatology of Reston, LLC on October 13, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on September 17, 2021 and virtual record review conducted on October 12, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6168 - 42 C.F.R. 493.1487 Condition: Testing Personnel.
<b>D6168</b>	<p><b>TESTING PERSONNEL</b> CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, observation and interviews, the laboratory failed to ensure one (1) of two (2) TP qualified to perform high complexity testing from July 15, 2021 up to October 13, 2021. (Cross reference D6171.)</p>
<b>D6171</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1489(b)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned</p>

an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Personnel Report Form (CMS 209), personnel files, histology logs, lack of documentation, observation and interviews, the laboratory failed to ensure one (1) of two (2) testing personnel were qualified to perform high complexity testing while testing/processing

twenty-three (23) Mohs specimens from July 15, 2021 until October 13, 2021. Findings include: 1. Review of the laboratory's CMS 209 form revealed 2 TP (see Personnel Code Sheet) performing high complexity testing. 2. Review of the laboratory personnel file for TP B revealed a lack of evidence of the required education documentation for high complexity testing (inking) of Mohs specimens. The inspector requested to review additional education documentation for Testing Personnel B. No additional documentation was available. 3. During a tour of the laboratory at approximately 9:15 AM on October 13, 2021, the surveyor observed the delivery of a Mohs specimen to the laboratory by the Mohs surgeon/TP A. The surveyor observed the Mohs surgeon map the specimen and leave the laboratory. The surveyor inquired with the Mohs Technician/TP B who performed the inking of the specimen. The Mohs technician stated, "I perform the inking of specimens. I have 10 years of experience. I am taking classes toward my degree." 4. Review of the laboratory Mohs logs from 7/15/2021 to 10/13/2021, revealed the following number of patients were processed on: 07/15/2021 - 12 patients; 09/01/2021 - 11 patients. A total of 23 patients. 5. In an exit interview with the Laboratory Director (LD) on October 14, 2021 at approximately 5:00 PM, the findings were confirmed.