

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0864255	(X3) Date Survey Completed 11/05/2021
Name of Provider or Supplier Iowa Dermatology Clinic	Street Address, City, State 6000 University Avenue, Suite #350, West Des Moines, IA	
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
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by the Chief Operating Officer at approximately 2:00 pm on 11/05/2021, the laboratory director failed to meet responsibility requirements including ensuring that prior to testing patients' specimens, all personnel have the appropriate education and experience and receive the appropriate training for the type and complexity of the services offered as specified in D6102.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by the Chief Operating Officer at approximately 3:30 pm on 11/05/2021, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.</p>

<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A. Based on review of the Laboratory Personnel Report and confirmed by the Chief Operating Officer at approximately 2:00 pm on 11/05/2021, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing high complexity testing (histopathology specimen grossing) have the appropriate education for one out of three testing personnel. Refer to D6171. B. Based on review of the Laboratory Personnel Report and confirmed by the Chief Operating Officer at approximately 2:30 pm on 11/05/2021, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing high complexity testing (histopathology specimen grossing) received the appropriate training for two out of two new testing personnel (laboratory personnel identifiers #5 and #7) hired since the last survey on 10/30/2019. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #5 and #7.</p>
<p>D6168</p>	<p>TESTING PERSONNEL 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 review of laboratory personnel records and confirmed by the Chief Operating Officer at approximately 2:00 pm on 11/05/2021, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform high complexity testing as specified in standard D6171.</p>
<p>D6171</p>	<p>TESTING PERSONNEL QUALIFICATIONS 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 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</p>

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 review of laboratory personnel records and confirmed by the Chief Operating Officer at approximately 2:00 pm on 11/05/2021, the laboratory failed to have a diploma and/or transcripts to qualify one out of three testing personnel (personnel identifier #7, refer to the Laboratory Personnel Report) who perform high complexity testing.