

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1044719	(X3) Date Survey Completed 03/21/2019
Name of Provider or Supplier Florida Dermatologic Surgery & Aesthetics	Street Address, City, State 11950 Cr 101 Suite 230, The Villages, 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
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 record review and interview, the laboratory failed to record the temperature and humidity of the room where testing was performed from 3/21/17 to 3/21/19. Findings: The laboratory has one Leica CM1510S cryostat, two Leica CM1850 cryostats, and one Leica CM1850UV cryostat. The manuals for all the cryostats noted that the room temperature of the laboratory should have a maximum room temperature of 35 degrees C and that the relative humidity should be a maximum of 60%. A review of the laboratory's logs showed that the laboratory failed to record the temperature and humidity of the room where testing was performed. On 3/21/19 at 11: 20 AM, the General Supervisor stated that they did not record the room temperature or the humidity of the laboratory.</p>
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to document all quality control (QC) procedures performed from 3/21/17 to 3/21/19. Findings: 1. The laboratory performed the following special stains: Periodic Acid Schiff (PAS), Mucicarmine, Colloidal Iron, Mast Cell, and Prussian Blue Fe. Review of the "Daily Special Stain/Recut QA" form showed that the columns labeled "Accept" and "Not Accept" for the special stains performed from 1/18/18 through 8/22/18 and 1/1/19 through 2/26/19 were not check off . The bottom of the "Daily Special Stain/Recut QA" forms was signed by the laboratory director on 9/16/18 and 2/28/19. There was no indication that the special stains were examined on the days when the special stains were performed. No documentation showing special stains quality control from 3/21 /17 through 12/31/17 were not available for review. During an interview on 3/21/19 at 11:12 AM, the General Supervisor acknowledged that the acceptability of the special stains were not checked off, that the laboratory director signs when the form is completed, and she did not know where the forms for 2017 were located. 2. Record review of the laboratory's "Antibodies/Reagents" showed that the laboratory failed to record the open dates for the antibodies and reagents for the Immunohistochemistry (IHC) stains, special stains, and Hematoxylin and Eosin stain. The "Antibodies /Reagents" form for 2018 and 2019 failed to have the open date and the forms from 3 /21/17 through 12/31/17 were not available for review. During an interview on 3/21 /19 at 12:43 AM, the General Supervisor acknowledged that the laboratory did not record open dates for antibodies and reagents, and she did not know where the forms for 2017 were located.

D5805

TEST REPORT
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory's final reports did not include all of the required information for 8 out of 8 sampled patients (#1, 2, 3, 4, 5, 6, 7 & 8). Findings: Review of the surgical pathology reports for patients #1, #2, #3, #4 and #5 showed that the address of the laboratory was not listed on the surgical pathology report. Patient #1 - 1/17/19 Patient #2 - 10/17/18 Patient #3 - 4/06/18 Patient #4 - 4/06 /18 Patient #5 - 8/03/17 The laboratory uses their Mohs map for the final patient report for their Mohs procedures. Review of the Mohs map showed that the name and address was not listed on the Mohs map for patients #6, #7, and #8. Patient #6 - 1/09 /19 Patient #7 - 9/18/18 Patient #8 - 11/07/17 During an interview on 3/21/18 at 1:25 PM, the General Supervisor acknowledged that the address was missing from the surgical pathology report, and that the name and address was missing from the Mohs map.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(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 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 record review and interview, the laboratory failed to provide verification of the education for the histology technician who performed high complexity testing.

Findings: An attempt to verify the educational requirements of the histology technologist who performs tissue grossing was made. The laboratory failed to provide the histology technician's college degree and transcripts. During an interview on 3/21 /19 at 1:15 PM, the General Supervisor stated that the laboratory did not have a copy of the histology technician's college degree or transcripts.