

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2048182	(X3) Date Survey Completed 09/10/2020
Name of Provider or Supplier Alliant Dermatology Pa	Street Address, City, State 8620a E Cr 466, 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
D0000	A recertification survey was conducted on September 10, 2020. Alliant Dermatology PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain Quality Control (QC) records for the histopathology laboratory for 1 (May 2019) out of 21 months (January 2019 to September 2020). Findings: Review of the laboratory's records showed that the "Daily H/E Slide Quality Control" log sheet for May 2019 was missing. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 9/10/20, the laboratory had an estimated annual test volume of 45,000 histopathology tests per year. During an interview on 9/10/20 at 1:51 PM, the Laboratory Consultant stated he was unable to locate the missing log.</p>
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.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to record the temperature for 1 out of 2 Leica CM1850 Cryostats from 9/10/18 to 9/10/20.

Findings: During a tour of the laboratory on 9/10/2020 at 11:00 AM, both Leica 1850 Cryostats were turned on. Review of the laboratory's "Temperature / Humidity / Microscope / AC / H&E" log showed there was only one column with one temperature recorded for the two cryostats. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 9/10/20, the laboratory had an estimated annual test volume of 45,000 histopathology tests per year. During an interview on 9/10/20 at 12:45 PM, the Mohs Assistant stated they used one cryostat for freezing the tissue and the other cryostat for cutting the tissue. During an interview on 9/10/20 at 12:47 PM, the Laboratory Consultant stated they were not recording the temperature of both cryostats.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (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, observation, and interview, the laboratory failed to have negative control slides for recording the negative reactivity for 2 (#1, 2) out of 8 (#1 - 8) histopathology patients. Findings: The laboratory evaluated the following Immunohistochemical (IHC) stained slides: BerEp4 (Epithelial Antigen IHC stain), CD8 (Cluster of Differentiation 8 T cell Lymphocytic IHC stain), CD10 (Cluster of Differentiation 10 Cell Surface Enzyme IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CD31 (Cluster of Differentiation 31 platelet endothelial cell adhesion molecule-1 IHC stain), CD34 (Cluster of Differentiation 34 progenitor cells IHC stain), CD68 (Cluster of Differentiation 68 transmembrane glycoprotein), CK7 (Cytokeratin 7 glandular and transitional epithelial IHC stain), CK20 (Cytokeratin 20 IHC stain), Desmin (Smooth Muscle Tumor IHC stain), EMA (Epithelial Membrane Antigen IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), MART-1 (Melanocytic Marker IHC stain), MITF (Microphthalmia Transcription Factor IHC stain), Pan-Keratin (MCK- muscle creatine kinase antibody IHC stain), and Sox-10 (melanoma marker IHC stain). Review of the final pathology reports showed that patients #1 and #2 had Mart-1 and MITF IHC stains reported on their final pathology report. Observation of the slides for patient #1 and #2 showed that each patient had a Mart-1 and a MITF IHC stained slide, and no negative control slides specific for Mart-1 and MITF IHC stains. During an interview on 9/10/20 at 2:49 PM, Histotech B stated they did not have a negative control slide specific for each IHC stain.

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document corrective actions when temperatures were out of range from 1/2/19 to 9/10/20. Findings: According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 9/10/20, the laboratory had an estimated annual test volume of 45,000 histopathology tests per year. 1. Review of the Venetana reagents used for the Immunohistochemical (IHC) stains showed the storage temperature of 2 to 8 degrees C (Celsius). Review of the "Statistical Limits" procedure noted the refrigerator temperature range as 2 to 8 degrees C. Review of the "Daily Histology Log Book" and the "Instrument QC Sheet" showed the refrigerator temperature was out of range for the following days with no documented corrective action performed. The recorded temperature of 1.9 degrees C was listed for: 8/1/2019, 9/13/2019, 9/24/2019, 9/27/19, 10/1/2019, 10/11/2019, 10/17/2019, 10/22/2019, 10/25/2019, 11/1/2019, 11/18/2019, 12/6/2019, 12/11/2019, 12/17/2019, 12/30/2019, 1/3/2020, 2/5/2020, 2/19/2020, 2/25/2020, 3/5/2020, 3/12/2020, 4/2/2020, 4/24/2020, 4/29/2020, 5/26/2020, 6/1/2020, 6/5/2020, 6/12/2020, 6/17/2020, and 6/26/2020. The recorded temperature of 1.8 degrees C was listed for: 11/25/19, 3/19/2020, 3/26/2020, 4/20/2020, and 6/8/2020. The recorded temperature of 1.7 degrees C was listed for: 10/21/2019, 10/23/2019, 10/28/2019, 11/27/2019, 12/10/2019, 12/20/2019, 12/24/2019, 1/15/2020, 2/6/2020, 2/26/2020, 3/18/2020, 3/24/2020, 4/13/2020, 4/17/2020, 4/27/2020, 5/4/2020, 5/12/2020, 5/14/2020, 5/19/2020, 5/25/2020, 5/28/2020, 6/2/2020, 6/15/2020, 6/19/2020, 6/23/2020, 6/30/2020. The temperature of 1.6 degrees C was recorded for: 3/25/2020, 5/21/2020, and 6/24/2020. The temperature of 1.5 degrees was recorded for: 1/13/2020, 3/6/2020, 3/16/2020, 4/14/2020, 4/15/2020, 5/27/2020, and 6/22/2020. The temperature of 1.4 degrees C was recorded for: 3/9/2020, 5/5/2020, 5/13/2020, 6/16/2020, and 6/25/2020. The temperature of 1.3 degrees C was recorded for: 1/16/2020, 5/22/2020, 6/9/2020, and 6/29/2020. The temperature of 1.2 degrees C was recorded for 5/20/2020. The temperature of 1.1 degrees C was recorded for 5/29/2020. The temperature of 0.4 degrees C was recorded for 1/6/2020. During an interview on 9/10/20 at 11:45 AM, the Laboratory Consultant stated that temperatures were out of range and there was no documentation of corrective action taken. 2. Review of the "Statistical Limits" procedure noted the embedding center temperature range as 57 to 64 degrees C. Review of the "Daily Histology Log Book" and the "Instrument QC Sheet" showed the embedding center temperature was reported as 65 degrees C or greater for 391 out of 422 laboratory testing days. During an interview on 9/10/20 at 11:45 AM, the Laboratory Consultant stated that temperatures were out of range and there was no documentation of corrective action taken.