| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D0913175 | 09/14/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ocala Dermatology And Skin Cancer Center | 10915 Se 177 Place, Summerfield, 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 |
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| **D0000** | At the time of the announced, on-site recertification survey, Ocala Dermatology and Skin Cancer Center, was found to be NOT in compliance with the CLIA laboratory requirements of 42 CFR 493. |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of material safety data sheets (MSDS), and interview, the laboratory failed to store flammable liquid in an approved flammable liquids storage area for Eosin Y Stain. The findings include: During observations taken on 9 /14/21 at approximately 11:00 AM a one gallon container of Platinum line Eosin Y stain, 1% w/v in alcohol (Lot#1924210 exp. 9/4/2021) was found stored under the sink in a cabinet. Review of the MSDS sheets for the Eosin Y stain states to "Store in approved Flammable Liquids storage area." During an interview on 9/14/21 at approximately 11:30 AM, laboratory personnel confirmed that the flammable liquid was not stored properly. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. |

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| | This STANDARD is not met as evidenced by:<br>Based on observation, and staff interview, the facility failed to ensure the two bottles used for storing Hematoxylin and Eosin on the counter top were labeled with the identity of the stain, preparation, and expiration date. The findings include: During the tour of the laboratory on 9/14/21 at 10:30am, a bottle with an orange liquid was placed next to the fume hood which contained the histopathology stain line. The bottle had no label to indicate the identity of the liquid, when it was prepared, or what the expiration date was. The interview with laboratory personnel on 9/14/21 at 11:00am confirmed the liquid was Eosin and the bottle was not labeled as required. A second bottle with a dark purple liquid was sitting next to the fume hood which contained the histopathology stain line. The bottle was labeled "Hematoxylin". The label contained no information about when the stain was prepared or what the expiration date was. The interview with laboratory personnel on 9/14/21 at 11:00am confirmed the liquid was Hematoxylin and the bottle was not labeled as required. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the facility failed to document corrective action when the Cryostat temperature was out of range for 60 days out of 66 days reviewed in 2020 and 32 days out of 93 days reviewed in 2021. The findings include: Record review of the "Cryostat Temperature" logs showed the acceptable temperature range is" -21 to -30 Celsius (C) ". In 2020, the following dates were out of range: 1. On March 4th, 5th, and 6th, the cryostat temperature was documented at -19C. On March 20th, the temperature was documented at -20C. 2. On April 3rd and 30th, the cryostat temperature was documented at -20C. On April 17th and 20th, the temperature was documented at -19C. 3. On May 4th and 20th, the cryostat temperature was documented at -19C. On May 15th and 18th, the temperature was documented at -20C. 4. On June 1st, 12th, and 29th, the cryostat temperature was documented at -20C. On June 15th and 26th, the temperature was documented at -19 C. 5. On July 9th, the cryostat temperature was documented at -20C. On July 20th and 21st, the temperature was documented at -19C. On July 27th, 28th, and 29th, the temperature was documented at -18C. 6. On August 7th and 26th, the cryostat temperature was documented at -19C. On August 10th, 21st, 24th, and 25th, the temperature was documented at -20C. 7. On September 14th, 15th, 16th, 17th, 18th, and 21st, the cryostat temperature was documented at -20C. On September 29th and 30th, the temperature was documented at -18C. 8. On October 1st, 2nd, 3rd, 13th, 15th, 16th, 28th, 29th, and 30th, the cryostat temperature was documented at -18C. On October 14th, 19th, and 27th, the temperature was documented at -19C. 9. On |

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| | November 2nd and 10th, the cryostat temperature was documented at -18C. On November 11th, 12th, 13th, 16th, 25th, and 30th, the temperature was documented at -19C. 10. On December 11th and 14th, the cryostat temperature was documented at -19C. In 2021, the following dates were out of range: 1. On January 8th, 11th, 12th, 13th, 14th, 15th, 18th, 19th, 20th, 21st, 22nd, and 25th, the cryostat temperature was documented at -19C. 2. On February 5th, 8th, 15th, 16th, and 17th, the cryostat temperature was documented at -19C. On February 24th, the temperature was documented at -20C. 3. On March 2nd, 3rd, 18th, 19th, 22nd, 30th, and 31st, the cryostat temperature was documented at -19C. On March 15th, 16th, and 17th, the temperature was documented at -18C. 4. On April 1st, 5th, 13th, and 14th, the cryostat temperature was documented at -19C. There was no corrective action documented on any day. The policy titled "Cryostat Maintenance" states "The cryostats should be maintained at -21C to no colder than -30C for best Mohs sectioning. Any variance out of range will be recorded and reported to the supervisor immediately. If the range variance cannot be repaired, the console will not be used until serviced." The interview with laboratory personnel on 9/14/21 at 11:45AM confirmed no corrective action was documented. |