| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D2028816 | 07/11/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dermatology And Skin Cancer Consultants, Pllc | 701 Medical Park Drive, Humboldt, TN | |

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** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of the 2017, 2018 and 2019 laboratory temperature records and interview with the laboratory director, the laboratory failed to document the temperature of the cryostat, in 2017, 2018 and 2019. The findings include: 1) Observation on July 11, 2019 at 10:00 a.m. of the laboratory revealed two cryostat instruments in use for patient sample preparation. 2) Review of the 2017, 2018 and 2019 laboratory temperature records revealed one temperature recording for a cryostat. 3) Interview on July 11, 2019 at 11:15 a.m. with the laboratory director confirmed the second cryostat instrument temperature documentation was not performed in 2017, 2018 and 2019. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. |

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| | This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and interview with the supervisor of the laboratory, the laboratory failed to ensure expired potassium hydroxide (KOH) was not in use past the expiration date, in 2019. The findings include: 1) Observation on July 11, 2019 at 10:10 a.m. of the laboratory revealed a bottle of KOH lot number 1816506 expiration date June 14, 2019. 2) Interview on July 11, 2019 at 11:45 a.m. with the laboratory director confirmed the KOH expired on June 14, 2019 with patient testing in use from June 15, 2019 to current survey date. |