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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2052984 | (X3) Date Survey Completed 07/13/2021 |
| Name of Provider or Supplier Dermatology Specialists Of America | Street Address, City, State 5236 W University Dr Suite 2200, Mckinney, TX | |
| 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 | An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Academy of Family Physicians (AAFP) proficiency testing (PT) records (3 Urinalysis events in 2020) the submitted Centers for Medicare and Medicaid (CMS) 116 form, and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for 3 or 3 Urinalysis KOH (Potassium Hydroxide) PT events in 2020. Findings Included: 1. Review of AAFP proficiency testing for 2020 revealed the laboratory participated in 3 Urinalysis KOH events in 2020. Further review of AAFP proficiency testing results revealed the laboratory director failed to document their review of PT results for the following 3 of 3 KOH events in 2020: a. 2020-A Urinalysis KOH (Potassium Hydroxide) b. 2020-B Urinalysis KOH (Potassium Hydroxide) c. 2020-C Urinalysis KOH (Potassium Hydroxide) 2. Review of laboratory's submitted CMS-116 form revealed the laboratory performed 175 KOH tests annually. 3. In an interview with the laboratory director at 11:35 AM on 7/13/2021, in the office, the laboratory director confirmed the above findings.</p> |

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, random review of laboratory environmental logs (01/2021-06/2021), and staff interview, the laboratory failed to define an acceptable room humidity range in accordance with Leica CM1510-S Cryostat manufacturer's specifications for 6 of 6 months in 2021. Findings Included: 1. Review of Leica CM1510-S instructions (Version V 1.8 04/2010) stated the following: "3.2 Technical Data Operating Cryostat General Information Relative Humidity- max 60 percent non-condensing" 2. Random review of the laboratory's environmental logs from 01/2021 through 06/2021 revealed the laboratory failed to define a room humidity range within manufacturer's acceptable operating conditions for 6 of 6 months in 2021. 3. In an interview with the laboratory director at 11:32 AM on 7/13/2021, in the office, the laboratory director confirmed the above findings.