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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D1017753 | (X3) Date Survey Completed 11/04/2025 |
| Name of Provider or Supplier Advanced Dermatology And Cosmetic Surgery | Street Address, City, State 1617 Tamiami Trl, Port Charlotte, 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 | An announced CLIA recertification survey was conducted at Advanced Dermatology and Cosmetic Surgery on 11/04/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited were as follows: |
| D5787 | <p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a record system that included the accurate specimen receipt for this laboratory for two of two patient Histology test records (Patient 1 & 2) performed by Testing Person D. Findings included: 1. Testing Person D performed Patient 1 Histology testing on 1/2 /2025 and Patient 2 on 7/10/25. Both Histology test records (Map) documented the testing location was in another city. 2. The Location Manager on 11/04/2025 at 12:30 p.m., confirmed the Histology test records (Maps) documented the testing location was in another city for Patient 1 and 2. There was no evidence the laboratory was aware of the inaccurate location on the patient test records.</p> |
| D6102 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and</p> |

complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patients' specimens, testing personnel received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for one (TP-D) of two (TP-A and TP-D) for Histopathology testing. Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 11/04/25, listed two Testing Personnel (TP-A and TP-D) who performed High Complexity Histology testing. TP-A was the Laboratory Director. 2. The Mohs patient log documented TP-D first performed patient Histopathology testing on 01/02/2025. There was no record presented at the time of the survey of training and competency at this laboratory prior to patient testing on 1/02/2025 for TP-D. 3. The laboratory policy and procedure manual last reviewed by the Laboratory Director on 03/19/2025, included a Policy CP-L#1018 which indicated high complexity testing competency assessments were to be performed upon hire, at 6 months, and annually. There was no policy presented for review regarding training of High Complexity histology testing personnel. 4. The Location Manager on 11/04/2025 at 11:35 a.m., confirmed that TP-D failed to have documentation of training and competency at this laboratory on or prior to 1/02/2025.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that the policy for monitoring testing personnel demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for one (TP-D) of two (TP-A and TP-D) for Histopathology testing. Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 11/04/25, listed two Testing Personnel (TP-A and TP-D) who performed High Complexity Histology testing. TP-A was the Laboratory Director. 2. The Mohs patient log documented TP-D first performed patient Histopathology testing on 01/02/2025 through 11/04/2025. There was no record presented at the time of the survey of 6 months competency as indicated by the lab procedure for TP-D from 7/2025 to 11/2025. 3. The laboratory policy and procedure manual last reviewed by the Laboratory Director on 03/19/2025, included a Policy CP-L#1018 which indicated high complexity testing competency assessments were to be performed upon hire, at 6 months, and annually. 4. The Location Manager on 11/04/2025 at 11:35 a.m., confirmed that TP-D failed to have documentation of 6 month competency at this laboratory from 7/2025 to 11/2025.