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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D1089309 | (X3) Date Survey Completed 02/16/2024 |
| Name of Provider or Supplier Advanced Dermatology And Skin Cancer | Street Address, City, State 7658 Poplar Pike, Germantown, 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 |
|---------------------------|---|
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient records, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of the Mart-1 immunohistochemistry (IHC) stain twice a year in 2022, 2023, and 2024. 1. Observation of the laboratory facility on 02/16/24 at 8:45 am revealed Mart-1 IHC reagents used for staining of tissue removed during Mohs surgical procedures. 2. Patient record review revealed the use of the Mart 1 IHC stain on 12/06/22 for patient MRN 26036, 10/10/23 for patient MRN 35465, and on 01/02/24 for patient MRN 10917. 3. There was no documentation that the Mart 1 IHC stain was verified for accuracy twice a year in 2022, 2023 or 2024. 4. The histotech stated during an interview on 02/16/24 at 11:00 AM that the laboratory did not send the Mart-1 IHC slides for twice a year verification of accuracy. This confirmed the survey findings. Word Key: MRN=Medical Record Number</p> |
| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, patient test records, and staff interview, the laboratory procedure for performing Mart-1 immunohistochemical (IHC) staining was</p> |

not approved, signed or dated by the laboratory director. The laboratory used the Mart-1 stain in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory facility on 02/16/24 at 8:45 AM revealed Mart-1 IHC reagents used for staining of tissue removed during Mohs surgical procedures. Observed taped to the wall were instructions for performing the stain that had not been approved, signed or dated by the laboratory director. There were multiple corrections to the instructions noted with no lab director approval. During the observation, the histotech stated the laboratory used the instructions taped to wall as their procedure. 2. Review of patient test records revealed the use of the Mart 1 IHC stain on 12/06/22 for patient MRN 26036, 10/10/23 for patient MRN 35465, and on 01/02/24 for patient MRN 10917. 3. Interview with the histotech on 02/16/24 at 11:00 AM confirmed the laboratory used the Mart-1 stain in 2022, 2023, and 2024 and did not have an approved procedure for performing the Mart-1 stain.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of patient records, lack of documentation and staff interview, the laboratory failed to retain records of reagent and stain lot numbers and records that showed the acceptability of the stain/reagent lots prior to 08/01/2023. The findings include: 1. Observation of the laboratory on 02/16/24 at 8:45 AM revealed stains (hematoxylin and eosin), reagents, and equipment used for preparing patient tissue removed during Mohs surgical procedure for microscopic examination. 2. Review of patient Mohs case numbers 9713 and 9996 revealed Mohs surgical procedures performed on 12/06/22 and 04/11/23. 3. Reagent/stain lot records were not maintained prior to 08/01/23. 4. During an interview on 02/16/24 at 11 AM, the lead histotech stated that she had the records, but had discarded them. This confirmed the survey findings.

D5475

CONTROL PROCEDURES
CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of patient test records, lack of documentation and staff interview, the laboratory failed to document the results of positive and negative controls for the Mart-1 (IHC) stain for three of three Mohs cases reviewed from 2022, 2023, and 2024, and failed to retain records of the Mart-1 reagent lot numbers and expiration dates. The findings include: 1. Observation of the laboratory facility on 02/16/24 at 8:45 AM revealed Mart-1 IHC reagents used for

staining of tissue removed during Mohs surgical procedures. 2. Review of patient test records revealed the use of the Mart-1 IHC stain on 12/06/22 for patient MRN 26036, 10/10/23 for patient MRN 35465, and on 01/02/24 for patient MRN 10917. The results of the positive and negative controls were not documented for any of the cases selected for review. 3. Historic reagent lot numbers and expiration dates for the reagents used in the Mart-1 IHC stain were not documented. 4. During an interview on 02/16/24 at 11:00 AM, the histotech confirmed the laboratory failed to document the results of the positive and negative controls for the Mart-1 stain in 2022, 2023 and 2024, and failed to retain records of lot numbers and expiration dates of the reagents used for performing the Mart-1 stain.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory's reagent log, the laboratory's monthly quality assessment documents, and staff interview, the laboratory failed to have an effective quality assessment process to ensure reagents were not used past their expiration date in 2023 and 2024. The findings include: 1. Observation of the laboratory on 02/16/24 at 8:45 AM revealed Scott's Tap Water Substitute used in performing staining of slides for histopathology procedures. The observed expiration date was 07/01/23. The received date documented on the container was 10/03/23. 2. Review of the laboratory's reagent log revealed an open date of 11/28/23 for the expired Scott's Tap Water Substitute. 3. Review of the laboratory's monthly quality assessment forms dated 10/3/23, 11/7/23, 12/5/23, 01/02/24 and 02/06/24 revealed the following : "All reagents, controls, kits, etc. that exceeded their expiration date were discarded." The monthly quality assessment documents were signed by both the histotech and laboratory director. 4. Interview with the histotech on 02/16/24 at 11 AM confirmed the laboratory's quality assessment process was not effective in preventing problems with use of expired reagents.