| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 32D1073594 | 05/09/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dermatology & Skin Cancer Center Of Nm | 5120 Masthead St Ne, Albuquerque, NM | |

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 |
|---|---|
| **D0000** | An onsite recertification survey conducted on May 09, 2024, at Dermatology & Skin Cancer of NM found the laboratory to be in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CMS 209, General Laboratory Quality Systems procedure, and interview, the laboratory failed to establish and follow polices to assess competencies for personnel appointed in leadership roles for 3 of 3 technical supervisors and 1 of 1 general supervisors in 2023. Findings included: 1. Review of CMS 209 form revealed the following leadership roles appointed by the facility, 3 technical supervisors (SI 2, SI 3, and SI 4 as listed on staff identifier list) and 1 general supervisor (SI 3). 2. Review of the General Laboratory Quality Systems procedure under the "Personnel Competency Assessment" section stated, "The following competencies will be evaluated: Mohs frozen section, grossing, tissue processing of a blind sample, embedding/microtomy, IHC (immunohistochemical staining), and special stain." No mention of competencies being performed to assess leadership roles or responsibilities. 3.Interview on 05/09/2024 at 1:30 pm with SI 1 (as listed on staff identifier list) stated, they do not currently perform any competencies to evaluate the personnel in their leadership roles. This confirmed the above findings. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a) |

| | |
|---|---|
| | Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy , laboratory's Refrigerator QC Log, direct observation, and staff interview, the laboratory failed to follow the manufacturer's acceptable temperature ranges for 4 of 4 months from January 2024 through April 2024. Findings included: 1. Review of laboratory policy titled "Equipment Quality Control (QC)" stated, "1 ... Optimum temperature for the refrigerator is 1C to 4C..." 2. Review of the laboratory's "2024 Refrigerator QC Log" stated, "Acceptable range 1C to 4C" 3. During a tour of the laboratory on 05/09/2024 at 11:00 am, the following reagents were found in refrigerator storage: a. 2 boxes of Bio SB Tinto SOX-10 Lot 2211TNE22. Expiration 04/2026 Manufacturer's storage requirements: 2C to 8C b. 1 cartridge BOND CD7 LP15 Lot 71874. Expiration 07/15/2024 Manufacturer's storage requirements: 2C to 8C c. 1 cartridge BOND Cytokeratin 7 RN7 Lot 74714. Expiration 01/15/2026 Manufacturer's storage requirements: 2C to 8C 4. During an interview on 05/09/2024 at 11:30 am, after review of the above records, SI 1 (as listed on the staff identifier list) confirmed the findings. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of laboratory policy, laboratory's In House Slide QC (Quality Control) log, and staff interview, the laboratory failed to define the intended reactivity of Hematoxylin and Eosin (H&E) quality control stain characteristics for 31 events from August 17, 2023 through October 16,2023. Findings included: 1. Review of the laboratory's policy titled "Mohs Surgery" stated, "The Mohs surgeon will read the slide and record if the stain is acceptable/not acceptable." The laboratory's policy failed to define the intended reactivity for H&E stains. 2. Review of the laboratory's In House Slide QC log revealed 31 H&E QC slides were screened from 08/17/2023 through 10/26/2023. 3. During an interview on 05/09/2024 at 11:30 am, after review of the above records, SI 1 (as listed on the staff identifier list) confirmed the findings.<br>II. Based on review of laboratory policy and staff interview, the laboratory failed to define the intended quality control reactivity for 6 of 7 special stains in 2024. Findings included: 1. Review of the laboratory's policy titled "Special Stains" revealed the following 7 special stains in use in 2024: Periodic acid-Schiff stain (PAS) Grocott's methenamine silver stain (GMS) Fite's stain Iron stain Trichrome stain Fontana stain Giemsa stain 2. A request was made for documentation of the intended quality control stain reactivity for the following 6 special stains: Periodic acid-Schiff stain (PAS) Grocott's methenamine silver stain (GMS) Fite's stain Iron stain Fontana stain Giemsa |

| | |
|---|---|
| | stain No documentation was provided. 3. During an interview on 05/09/2024 at 11:30 am, after review of the above records, SI 1 (as listed on the staff identifier list) confirmed the findings. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, laboratory patient records, and staff interview, the laboratory failed to document special stain quality control results for 12 days in December 2023. 1. Review of the laboratory's policy titled "Special Stains" stated, "Each day that these staining procedures are performed, a positive and a negative control sample will be analyzed in exactly the same manner as patient samples ... QC results will be documented on RH-QC-016." 2. Review of laboratory patient (PT) records revealed the following dates special stains were performed: a. Patients on 12 /01/2023 PT: DC23-0466 A. Stain: Melan-A PT: DC23-0467 A. Stain: SOX-10 PT: DC23-0467 B. Stain: SOX-10 b. 12/04/2023 PT: DC23-0468 A. Stain: SOX-10 PT: DC23-0468 A. Stain: Step Levels c. 12/05/2023 PT: DC23-0467 A. Stain: Factor XIIIa PT: DC23-0467 A. Stain: CD34 PT: DC23-0470 A. Stain: Periodic acid-Schiff stain (PAS) d. 12/07/2023 PT: DC23-0472 A. Stain: Step Levels PT: DC23-0472 E. Stain: PAS PT: DC23-0473 A. Stain: Preferentially expressed Antigen in Melanoma (PRAME) PT: DC23-0473 A. Stain: SOX-10 PT: DC23-0473 A. Stain: Melan-A PT: DC23-0473 B. Stain: Step Levels c. 12/12/2023 PT: DC23-0478 A. Stain: CD10 PT: DC23-0478 A. Stain: Pan Keratin PT: DC23-0478 A. Stain: Melan-A PT: DC23-0478 B. Stain: CD10 PT: DC23-0478 B. Stain: Pan Keratin PT: DC23-0478 B. Stain: Melan-A PT: DC23-0480 A. Stain: SOX-10 d. 12/13/2023 PT: DC23-0485 A. Stain: SOX-10 e. 12/15/2023 PT: DC23-0486 A. Stain: Melan-A PT: DC23-0486 A. Stain: SOX-10 PT: DC23-0486 A. Stain: Fontana Masson f. 12/19/2023 PT: DC23-0492 A. Stain: PAS g. 12/21/2023 PT: DC23-0498 A. Stain: Pan Keratin PT: DC23-0498 A. Stain: SOX-10 PT: DC23-0498 A. Stain: Melan-A PT: DC23-0500 A. Stain: SOX-10 PT: DC23-0500 A. Stain: Fontana Masson PT: DC23-0501 D. Stain: SOX-10 h. 12/22 /2023 PT: DC23-0502 A. Stain: Melan-A PT: DC23-0504 A. Stain: SOX-10 i. 12/26 /2023 PT: DC23-0482 A. Stain: CD4 PT: DC23-0482 A. Stain: CD20 j. 12/27/2023 PT: DC23-0504 A. Stain: SOX-10 3. A request was made for documentation that positive and negative stain quality control results were recorded. No documentation was provided. 4. During an interview on 05/09/2024 at 11:35 am, SI 1 (as listed on the staff identifier list) stated quality control slides were reviewed each day of use, but the results were not recorded. This confirmed the above findings. |