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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 17D2007412 | (X3) Date Survey Completed 01/05/2024 |
| Name of Provider or Supplier Kansas Medical Clinic Pa- Dermatology | Street Address, City, State 3511 Clinton Place,Ste C, Lawrence, KS | |
| 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 |
|---------------------------|--|
| D6076 | <p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of competency documentation for TP #2 (see D6079); presence of expired reagents, review of temperature logs with missing data and a lack of thermometer accuracy documents (see D6082); lack of proficiency testing (PT) attestation documents (see D6089); lack of evaluation of failed PT results (see D6091); lack of corrective action for failed PT results (see D6092); failure to have a Quality Assurance (QA) process to ensure amended reports are released (see D6094); and interview with the Director of Operations (DOO), the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445.</p> |
| D6079 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> |

This STANDARD is not met as evidenced by:
 Based on the review of the CMS209 form, lack of 2022 competency documentation for testing personnel (TP) #2, and interview with the DOO, the LD failed to ensure that TP #2 was competent to perform patient testing in 2022. Findings: 1. Based on the review of the CMS 209 revealed the LD was also listed as the clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel #1 (TP#1). There are two TP listed on the 209. 2. Request was made for the 2022 and 2023 competency assessments for TP#2. No documentation for the 2022 competency assessment was made available at the time of survey. 3. Interview with the DOO on 1/5/24 at 10:40 a.m. confirmed, the LD failed to ensure that TP#2 was competent to perform patient testing in 2022.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
 Based on the presence of expired reagents during a tour of the laboratory, review of the "KOH quality control log", review of the storage temperature logs, failure to have a thermometer with proof of accuracy or function checks, and interview with the DOO, the LD failed to ensure the laboratory provided quality laboratory services in the analytic phase of testing. Findings: 1. The surveyor performed a tour of the laboratory and found two bottles of KOH reagent with expiration dates of 7/31/21 and 2/2/23. No other KOH reagents were present at the time of survey. 2. Review of the document "KOH Quality Control Log" revealed: a. The LD (as testing personnel) assessed the KOH reagents for contamination, but failed to identify that the reagents were expired. Dates of assessment were 3/7/23 and 12/5/23. b. The document is signed by the LD on 12/5/23. 3. Review of the "Lawrence Dermatology Storage Temp Log" revealed: a. Temperature readings were not taken daily. Only 28 temperature reading were recorded for the year 2023. b. Recorded dates are: 1/10/23, 1/23/23, 2/8/23, 2/21/23, 3/6/23, 3/22/23, 4/7/23, 4/18/23, 5/11/23, 5/23/23, 6/6/23, 6/21/23, 7/12/23, 7/25/23, 8/9/23, 8/25/23, 9/14/23, 9/25/23, 10/10/23, 10/19/23, 10/31/23, 11/3/23, 11/15/23, 11/29/23, 12/7/23, 12/12/23, 12/19/23 and 12/28/23. b. Reagents were stored in the laboratory that have temperature requirements including KOH reagent and waived testing kits. c. The temperature log is signed by the LD on 1/3/24 with no corrective action (CA) noted. 4. Request was made for thermometer accuracy documentation on the laboratory ambient temperature thermometer. No documentation of accuracy or function checks for one of one thermometers was made available at the time of survey. 5. Interview with the COO on 1/5/24 at 11 a.m. confirmed, the LD failed to ensure the laboratory provided quality laboratory services in the analytic phase of testing.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as

required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) documents from American Academy of Family Physicians (AAFP) for 2022 and Wisconsin State Laboratory of Hygiene (WSLH) for 2023 for attestation statements and interview, the LD failed to ensure that PT samples are tested as required for participation in PT testing for laboratories performing non-waived testing. Findings: 1. Request was made for the 2022 AAFP PT attestation documents for event 2022 B and 2022 C. a. No documentation of attestation for event 2022 B was made available at the time of survey. b. Attestation document for 2022 C was signed by TP #2, but no signature of the LD was present. 2. Request was made for the 2023 WSLH PT attestation documents for events Misc QA POC 1 and MiscQA POC 2. a. No attestation documentation for 2023 PT testing was provided at the time of survey. 3. Interview with the COO on 1/5/24 at 10:55 a.m. confirmed, the LD failed to ensure that PT samples are tested as required for participation in PT testing for laboratories performing non-waived testing.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of PT results from WSLH 2023 MiscQA POC2 results for KOH preparation, skin, and interview with the DOO, the LD failed to ensure all PT results are evaluated to identify any problems that require corrective action (CA). Findings: 1. Review of PT results from WSLH 2023 MiscQA POC2 results for KOH preparation, skin revealed an unacceptable result for specimen PM-4 with no evaluation for the failed result. 2. The document was signed by the LD in 12/2023. 3. Interview with the COO on 1/5/24 at 10:55 a.m. confirmed, the LD failed to ensure all PT results were evaluated to identify any problems that require corrective action.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Review of 2023 WSLH PT performance evaluation records, and interview with the DOO, the LD failed to ensure CA was performed in response to failed PT responses. Findings: 1. Review of 2023 WSLH PT performance evaluation records for KOH preparation, skin revealed sample PM-4 result was listed as "Fail." 2. No documentation of CA was provided at the time of survey. 3. LD signature is present on PT evaluation page with a date of 12/2023. 4. Interview with the COO 1/5/24 at 10:55 a.m. confirmed, the LD failed to ensure CA was performed in response to failed PT responses.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on the review of the 2022 accuracy checks for histopathology, failure to document CA, failure to issue an amended report and interview with the COO, the LD failed to ensure that quality assessment (QA) processes were in place to address failures in quality as they occur. Findings: 1. Request was made to review accuracy check records for 2022 and 2023. Review of the 2022 accuracy checks revealed: a. Disagreement on one of three accuracy checks. b. Notes for the secondary review were: "There is BCC at tip margin. Need to get levels to see if it clears or external to a lateral edge of said tip." BBC is basal cell carcinoma. c. Secondary review is dated 9/26/22. d. LD signature of review is 10/4/22. 2. Surveyor requested documentation which addressed disagreement on accuracy report. A review of the documentation revealed: a. The patient report was amended on 1/3/23 (90 days after LD review of accuracy check) with the following statement: "Additional info - Internal quality review by second dermatopathologist reveals BCC at tip margin." b. The amended report is not signed by the LD. The surveyor asked the COO if the amended report was released. The COO stated the report was not released. 3. Interview with the COO on 1/5/24 at 11:40 a.m. confirmed, the LD failed to ensure that QA processes were in place to address failures in quality as they occur.