

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0931182	(X3) Date Survey Completed 01/03/2024
Name of Provider or Supplier Colorado Springs Dermatology Clinic, Pc	Street Address, City, State 170 Parkside Dr, Colorado Springs, CO	
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
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on an observation of the laboratory and an interview with the histopathology lead and the office administrator, the laboratory failed to ensure patient pathology specimens were not contaminated in the laboratory where the laboratory space was also used for staff and patient food and drinks since the last survey on 8/23/2021. Findings include: 1. An observation on 1/3/2024, at 11:45 a.m., revealed that a corner of the laboratory near the primary cryostat had a coffee machine, coffee supplies, personal refrigerator, drinks, water cooler, and supplies such as utensils. 2. An observation on 1/3/2024, at 11:45 a.m., revealed only one sink in the laboratory, which was used for the emergency eyewash, handwashing, and dirty eating utensils. 3. An interview on 01/03/2024, at 12:30 p.m., with the histopathology lead and office administrator confirmed that the laboratory space was used to store and prepare personal food and drink.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a record review and an interview with the histopathology lead, the laboratory failed to follow the laboratory's competency policies when assessing the competency of testing personnel for pathology slide reviews and potassium hydroxide (KOH) slides since the last survey 8/23/2021. Findings include: 1. A review of the laboratory's QA policy showed that the current policy required testing personnel competency to be evaluated every six months. 2. A review of the laboratory's 2023 competency records revealed that pathology competencies were missing for one of eight testing personnel and KOH competencies were missing for one of eight testing personnel. 3. A review of the laboratory's 2022 competency records revealed that pathology competencies were missing for six of eight testing personnel. 4. The laboratory performed approximately 13,013 histopathology tests and 97 KOH tests annually. 5. An interview with the histopathology lead on 01/03/2024, at 1:30 p.m., confirmed that the missing competencies were not performed.

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the office administrator, the laboratory failed to follow the laboratory's Quality Control (QC) policy, which required testing personnel to document lot numbers and expiration dates for the stains used in the hematoxylin and eosin (H&E) staining procedure used for histopathology slides since the last survey on 8/23/2021. Findings include: 1. A review of the QC policy revealed that the laboratory testing personnel failed to follow the instructions for documenting lot numbers and expiration dates for the reagents used in the H&E staining procedure. 2. A review of the laboratory's quality control log for H&E stains revealed the laboratory did not write the lot numbers and expiration dates since the last survey on 8/23/2021. 3. The laboratory performed approximately 13,000 histopathology tests per year. 4. An interview with the office administrator on 01/03 /2024, at 2:00 p.m., confirmed that the laboratory did not document the dates and lot numbers for staining reagents.