

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D2177187 | (X3) Date Survey Completed 10/07/2024 |
| Name of Provider or Supplier Springfield Clinic - Mohs/ Attn Labo Director | Street Address, City, State 1025 S 6th St, Springfield, IL | |
| 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 |
|---------------------------|---|
| 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: Based on lack of documentation, laboratory policy and procedure manual, and interview with testing personnel (TP) #2; the laboratory failed to establish policies and procedures to assess employee competency for Mohs histopathology testing. Findings Include: 1. Review of the laboratory's policy and procedure manuals found the laboratory lacked a competency assessment policy for Mohs histopathology testing. 2. On survey date 10-07-2024, at 11:30 am, TP#2 confirmed the laboratory failed to establish a competency assessment policy for Mohs histopathology testing.</p> |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of laboratory testing supplies and interview with laboratory testing personnel (TP) #2; five of ten lots of marking dyes for the inking /grossing of Mohs histopathology specimens were expired. Findings Include: 1. During a tour of laboratory on 10-07-24 at 11:53 am the surveyor observed five of ten marking dye reagents that had exceeded the expiration date. a. Avantik Red Marking</p> |

Dye Lot #:133856 EXP date: 12-31-23 b. Avantik Blue Marking Dye Lot #:141560 EXP date: 02-29-24 c. Avantik Black Marking Dye Lot #:139190 EXP date:01-31-24 d. Avantik Green Marking Dye Lot #:135894 EXP date: 12-31-23 e. Avantik Yellow Marking Dye Lot #:136800 EXP date: 12-31-23 2. On survey date 10-07-24, at 11:54 am TP#2 confirmed the marking dyes identified were expired.

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 review of laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory director failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems for Mohs histopathology testing. Findings Include: 1. No documentation of a written quality assessment plan was available for review by surveyors on date of survey 10-07-24. 2. On survey date 10-07-24, at 09:30 am TP#2 confirmed the laboratory director failed to establish a quality assessment plan for Mohs histopathology testing.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's competency assessment records and interview with laboratory testing personnel (TP) #2; the technical supervisor failed to evaluate and document problem solving skills as part of the competency assessment for Mohs histopathology testing for four of four competency assessments reviewed. Findings Include: 1. Review of the laboratory's records identified the competency assessment form titled, "Mohs competency assessment Springfield clinic", which included 15 skills to be assessed for TP competency but failed to include assessment of problem-solving skills. 2. Review of four of four competency assessment records from 2022 through 2024 for TP #2 failed to include an assessment of problem solving skills. 3. Interview with TP #2 at 11:30 am on 10-07-2024 confirmed the lab failed to assess personnel problem solving skills as part of the competency assessments.