

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1070086	(X3) Date Survey Completed 05/31/2024
Name of Provider or Supplier Cotton O'Neil Dermatology	Street Address, City, State 2902 Sw Asbury Drive, Topeka, 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
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 the review of the CMS-209 personnel form, lack of competency documentation, and interview with the clinic nurse manager, the laboratory failed to assess the competency of one of two clinical consultants (CC), one of two technical consultants (TC), one of two general supervisors (GS), and one of two technical supervisors (TS) for 2023, and to date of survey 2024. Findings: 1. Review of the Form CMS-209 revealed one CC, one TC, one TS and one GS listed who was not the laboratory director (LD). 2. The surveyor requested the competency assessments for the CC, TC, TS, and GS for 2022, 2023 and to date of survey 2024. No competency documentation for one of two CC, one of two TC, one of two GS, and one of two TS was made available for 2023, and to date of survey 2024. 3. Interview with interview with the clinic nurse manager on 5/31/24 at 10:40 a.m. confirmed, the laboratory failed to assess the competency of one of two CC, one of two TC, one of two GS, and one of two TS for 2023, and to date of survey 2024.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting</p>

and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based upon the review of the CMS 209 personnel form, a lack of written responsibilities and delegated duties for six of eight delegated positions, and interview with the clinic nurse manager, the laboratory director (LD) failed to specify in writing the written responsibilities and duties of each consultant and supervisor as well as each person performing patient testing. Findings: 1. The surveyor requested documentation of written responsibilities and duties delegated to the clinical consultant, technical consultant, technical supervisor, general supervisor, and testing personnel. a. The laboratory provided documentation for the delegation to one general supervisor (GS) and one clinical consultant (CC) dated 7/25/22. b. No documentation was provided at survey for the remaining six positions: three testing personnel (TP), two technical consultants (TC) and one technical supervisor (TS) 2. Interview with the clinic nurse manager on 5/31/24 at 10:40 a.m. confirmed, the LD failed to specify in writing the written responsibilities and duties of each consultant and supervisor as well as each person performing patient testing.

D6151

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

Based on the review of the CMS 209 personnel form, GS delegation form, lack of TP annual competency documentation, CMS 116 application and interview with the clinic nurse manager, the GS failed to perform the annual competency assessment for four of four TP for 2022, 2023 and to date of survey 2024. Findings: 1. Review of the CMS209 personnel form revealed that four of four TP had performed high complexity testing for more than one year. 2. Review of the "Medical Director Delegation and Assessment" form revealed the GS had been delegated: "Annually personnel training and competency". This form was signed by the LD 7/25/22. 3. Request was made for the annual competencies for four of four TP. The documents provided were the proficiency testing scores for 2022 and 2023. No documentation of competency assessment for four of four TP for 2022, 2023 and to date of survey 2024 was made available at the time of survey. The CMS 116 application revealed that this laboratory performs approximately 8,509 patient tests annually. 4. Interview with the clinic nurse manager on 5/31/24 at 10:50 a.m. confirmed, the GS failed to perform the annual competency assessment for four of four TP for 2022, 2023 and to date of survey 2024.