

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0953867	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier Ou Health Partners Dermatology	Street Address, City, State Nicholson Tower, Oklahoma City, OK	
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	The recertification survey was performed on 06/18/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse at the conclusion of the survey.
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 a review of records, written policies and procedures, and interview with the clinic manager, the laboratory failed to have a written policy to assess the competency of the technical supervisor and technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical supervisor and technical consultant, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of September 2023 through the current date identified competencies, based on job responsibilities, had not been performed as follows: (a) One of one person listed as the technical supervisor (not performed after 09/14/2023); (b) One of one person listed as the technical consultant (not performed after 09/14/2023). (3) The findings were reviewed with the clinic manager who stated on 06/18/2025 at 02:00 pm, a policy had not been written, and competencies had not been performed for the positions as stated above.</p>
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse, the laboratory failed to verify the accuracy of two of four test systems at least twice annually during the review period of August 2023 through the current date. Findings include: (1) On 06/18/2025 at 09:20 am, clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse stated the laboratory performed the following: (a) KOH test on skin scraping; (b) Ectoparasites testing. (2) A review of records from August 2023 through the current date identified the testing had not been verified for accuracy at least twice annually; (3) The records were reviewed with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse who stated on 06/18/2025 at 03:15 pm, the laboratory had not verified the accuracy of the testing twice annually during the review period.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of written policies and procedures and interview with the clinic manager, registered nurse, and histotechnician, the laboratory failed to have a written procedure for the Mart-1 staining procedure. Findings include: (1) On 06/18/2025 at 09:39 am, the clinic manager, registered nurse and histotechnician stated the laboratory performed Mohs surgical procedures which included Mart-1/Melan-A Immunohistochemical staining for patients with previously diagnosed melanoma; (2) A review of the laboratory policies and procedures identified no evidence of a written procedure for the Mart-1 staining procedure; (3) The findings were reviewed with the clinic manager and registered nurse who stated on 06/19/2025 at 3:08 pm, the laboratory did not have a written procedure.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse, the laboratory failed to ensure patient test reports included the name, as stated on the CLIA certificate and address of the laboratory location where the testing was performed for nine of nine reports reviewed. Findings include: (1) On 06/18/2025 at 09:25 am, the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse stated the laboratory performed microscopic interpretations of H&E (Hematoxylin and Eosin) stained slides from frozen section of tissues removed during Mohs surgery. The tissue would then be observed microscopically; (2) A review of the following patient reports identified the laboratory name, as stated on the CLIA certificate and address of the laboratory location where testing was performed were not included: (a) Patient # M25-029 testing performed on 01/07/2025 (b) Patient # M25-086 testing performed on 01/20/2025 (c) Patient # M25-143 testing performed on 01/29/2025 (d) Patient # M25-173 testing performed on 02/03/2025 (e) Patient # M25-230 testing performed on 02/12/2025 (f) Patient # M25-286 testing performed on 02/27/2025 (g) Patient # M25-342 testing performed on 03/10/2025 (h) Patient # M25-426 testing performed on 03/27/2025 (i) Patient # M25-454 testing performed on 04/02/2025 (3) The findings were reviewed with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse, who stated on 06/18/2025 at 04:00 pm, the laboratory name and address had not been included on the patient test reports.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for six of six testing persons during the review period of 01/01/2024 through the current date. Findings include: (1) A review of personnel records for six persons (testing person #2, testing person #3, testing person #4, testing person #5, testing person #6, and testing person #8) performing moderate complexity testing from 2024 through the current date identified no evidence annual competency evaluations had been performed during the review period; (2) The records were reviewed with the clinic manager, regulatory compliance manager, regulatory compliance program manager, and registered nurse, who stated on 06/18/2025 at 12:24 pm, the annual competency evaluations had not been performed as stated above.