

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1080085	(X3) Date Survey Completed 01/17/2024
Name of Provider or Supplier Eli Cohen Md Pa	Street Address, City, State 6290 Linton Blvd Ste 201, Delray Beach, FL	
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	Recertification survey was conducted from 1/9/2024 to 1/17/2024. Eli Cohen Md PA clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with office manager and histotechnician, the laboratory failed to complete their twice annual Mohs (microscopically controlled) surgery verification for 2022 and 2023 and failed to have it reviewed by another qualified Mohs surgeon. Findings Included: Review of Proficiency and Consultation policy read, " it is policy of the Mohs laboratory that Mohs surgeon sends 2 random cases to a qualified consultant for proficiency testing as required by CLIA. The Mohs surgeon may also seek consultation to make an accurate diagnosis in difficult cases. For proficiency testing the Mohs surgeon will select 2 random cases every 6 months." The policy did not include where specimen would be sent for secondary review, and which qualified professional would perform it. Review of 2022-2023 Proficiency Testing (PT) worksheets revealed the following: a. PT was performed on 9/22/22 and with no documentation of Mohs surgeon for case review. b. PT was performed on 12/1/22 and with no documentation from the Mohs surgeon for case review. c. PT was performed on 6/30/23 and with no documentation of Mohs surgeon for case review. d. PT was performed on 12/15/23 and with no documentation from the Mohs surgeon for case review. On 1/9/2024 at 4:04 PM, the office manager and histotechnician confirmed laboratory failed to complete their twice annual Mohs (microscopically controlled) surgery verification for 2022 and 2023 and have it reviewed by another qualified Mohs surgeon.</p>

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to label 14 reagent bottles in use with preparation and expiration dates on Tissue-Tek VIP instrument. Findings Included: On 1/9/2024 at 12:40 PM Tissue-Tek VIP instrument in the laboratory had 14 reagent bottles that were not labeled with preparation and expiration dates. Review of Quality Control Program: Test methods, equipment, reagents materials and supplies read, "All reagents, solutions, culture media, control materials, calibration materials and other supplies will be labeled to indicate: 1. Identity and when significant titer, strength, or concentration. 2. Recommendation storage requirements 3. Preparation and expiration dates 4. Safety data 5. Other pertinent information." On 1/9/2024 at 4:04 PM, office manager and histotechnician confirmed laboratory failed to label 14 reagent bottles in use with preparation and expiration dates on Tissue-Tek VIP instrument.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, The laboratory failed to document positive stain quality control for Periodic Acid Schiff (PAS) and Tissue biopsy Hematoxylin and eosin (H&E) testing in 2022 and 2023 for 3 of 5 patient records reviewed (#3, #4, and #5). Findings included: Review PAS Quality Control signed by Laboratory director on 8/23/23 read, "all PAS stains that are performed will have a known positive control slide stained when patient specimens are processed for the PAS Stain. The positive control slide will be screened by the reading physician prior to screening the patient slides. The doctor will then sign off on the PAS quality control form stating whether the stain is satisfactory or not." Review of Quality Control Policies signed by laboratory director on 8/23/23 read, "before any microscopic slides are reviewed, a control slide is cut and stained for evaluated for section thickness, section completeness and staining quality. This protocol applies to both paraffin embedded tissue as well as Mohs sections. The slides are reviewed by the physician and are signed off on the H&E quality control form." Review of 2022-2023 Histology Test requisition and Report log revealed no documentation of control slides and slide quality for PAS and H&E. Review of Patients' slides revealed the following: A. Patient #3 received H&E biopsy test on 12/30/2022 with no control slide. B. Patient

#4 received H&E biopsy test on 6/16/2023 with no control slide. C. Patient #5 received H&E biopsy and PAS test on 9/30/2022 with no control slide. Review of CMS-116 application for certification revealed 13,001 patients were tested for histopathology. On 1/9/2024 at 4:04 PM, office manager and histotechnician confirmed laboratory failed to document positive stain quality control for Periodic Acid Schiff (PAS) and Tissue biopsy Hematoxylin and eosin (H&E) testing for 2022 and 2023.