Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1080085	02/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Eli Cohen Md Pa	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	An announced CLIA recertification survey was conducted at Eli Cohen MD PA on February 24, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6076 493.1441 Condition: Laboratory Director
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, interview, review of the laboratory procedure manual, and safety data sheets (SDS), the laboratory failed to ensure protection from chemical hazards used in their Vacuum Infiltration Processor (VIP) and Hematoxylin and Eosin (H&E) stain from 01/17/2024 to 02/24/2026. Findings Included: A1. During a tour of the laboratory on 02/24/2026 at 9:44 AM, two containers used to store the chemical waste used in their H&E stain and in the VIP was seen on the floor of the laboratory. A2. Review of the VIP 3000 Tissue Processor log noted the laboratory used the following chemicals in their VIP:10% Buffered Neutral Formalin, 75% Alcohol, 95% Alcohol 100% Alcohol, and Xylene Substitute. A3. Review of the H&E Stain Line log noted the laboratory used the following chemicals in their H&E stain: Xylene Substitute, 100% Alcohol, 95% Alcohol, Hematoxylin, Bluing reagent, and Eosin A4. Review of the SDS for 10% Neutral Buffered Formalin, XS-3, Xylene Substitute, and Avantik Eosin Working Solution showed the symbol for flammable reagents. A5. Review of the SDS for 10% Neutral Buffered Formalin noted "Store locked up." A6. Review of the SDS for Stat Lab XS-3, Xylene Substitute noted, "Keep in fireproof place." A7. Review of the SDS for Avantik Eosin Working Solution noted, "Store locked up." A8. During an interview on 02/24/2026 at 9:40 AM, the Mohs Technician

	A acknowledged the chemical waste had been stored on the floor of the laboratory. B1. During a tour of the laboratory on 02/24/2026 at 10:00 AM, no fume hood was observed in the laboratory and the Mohs Technician B was not wearing a respirator. B2. Review of the H&E Flow Chart for Mohs surgical procedures noted the laboratory used the following chemicals in their H&E stain: 100% Reagent Alcohol, Hematoxylin, Bluing reagent, Eosin and Histo-Clear. B3. Review of the SDS for Stat Lab 100% Reagent Alcohol noted, "Do not breathe mist, spray, vapors, gas" and "Use NIOSH (National Institute for Occupational Safety and Health) approved full phase negative pressure respirator equipped with approved cartridges or canisters within the use limitations of the device." B4, Review of the SDS for Avantik Harris Hematoxylin noted, "If ventilation hood not available wear respirator." B5. Review of the SDS for Stat Lab Bluing reagent noted, "Use NIOSH-approved air-purifying or supplied air respirator where airborne concentrations of vapor or mist are expected to exceed exposure limits." B6. Review of the SDS for Avantik Eosin Working Solution noted, "Do not breathe mist, vapors spray" and "Where exposure through inhalation may occur from use, respiratory protection equipment is recommended." B7. Review of the SDS for 100% Reagent Alcohol, Hematoxylin, Bluing reagent, and Eosin showed the symbol for respiratory health hazard. B8. During an interview on 02/24/2026 at 3:35 PM, the Mohs Technician A acknowledged there was no fume hood in the Mohs laboratory. C1. Review of the H&E Flow Chart for Mohs surgical procedures noted the laboratory used the following chemicals in their H&E stain: 100% Reagent Alcohol, Hematoxylin, Bluing reagent, Eosin and Histo-Clear. C2. Review of the SDS for Stat Lab 100% Alcohol and Stat Lab Vintage Bluing noted, "Disposal of waste material in accordance with all local, regional, national, provincial, territorial, and international regulations" and "Avoid release to the environment. This material is hazardous to aquatic environments. Keep out of sewers and waterways." C3. Review of the SDS for Avantik Harris Hematoxylin noted, "Do not dispose of in drains, check with local waste authorities." C4. Review of the SDS for Stat Lab Vintage Bluing noted, "Disposal of waste material in accordance with all local, regional, national, provincial, territorial, and international regulations." C5. Review of the SDS for Avantik Eosin Working Solution noted, "Disposal in safe manner in accordance with local/national regulations. Disposal of contents/container to comply with local, state, and federal regulations" and "Avoid release to the environment." C6. Review of the SDS for Avantik Histo-Clear noted, "This material and its container must be disposed of as hazardous waste. Avoid release to the environment" and "Observe all national state and local regulations regarding disposal." C7. In accordance with Rule 62-730, Florida Administrative Code Hematoxylin & Eosin (H&E) stain reagents, which often contain hazardous chemicals like Xylene, Alcohols, and Formalin, must be managed as hazardous waste in accordance with Rule 62-730, Florida Administrative Code. Dumping these reagents down the drain, on the ground, or in regular trash is prohibited; they must be collected in properly labeled, sealed containers and disposed of by a licensed hazardous waste transporter. C8. During an interview on 02/24/2026 at 3:25 PM, the Mohs Technician A stated Mohs Technician B dumped the H&E reagent used for the staining of the slides for the Mohs surgical procedures down the sink drain.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the

	overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to label 14 reagent bottles with preparation and expiration dates for reagents used on the Tissue-Tek Vacuum Infiltration Processor (VIP) instrument. (See D5415)
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(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 with preparation and expiration dates for reagents used on the Tissue-Tek Vacuum Infiltration Processor (VIP) instrument. This is a repeat deficiency from the recertification survey on 01/17/2024. Findings Included: 1. During a tour of the laboratory on 02/24/2026 at 9:44 AM, revealed the VIP instrument in the laboratory had 2 reagent bottles that were not labeled with preparation and expiration dates, 11 reagent bottles used were not labeled with expiration dates, and one reagent bottle had no label on it. 2. During a tour of the laboratory on 02/24/2026 at 9:48 AM, revealed the flammable cabinet did not contain any 75% Alcohol or 95% Alcohol. 3. Review of the procedure title Quality Control Program, signed and date by the Laboratory Director on 09/01/2025, noted "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." 4. Review of the labels on 13 bottles showed no dates were recorded for Date Changed and the Reagent Expiration listed only the year the reagent expired. Review of one bottle showed there was no label on the bottle. 5. Review of the VIP 3000 Tissue Processor log noted the laboratory used the following chemicals in their VIP:10% Buffered Neutral Formalin, 75% Alcohol, 95% Alcohol, 100% Alcohol, and Xylene Substitute. 6. Review of Plan of Correction signed and dated by the Laboratory Director on 02/05/2024, stated "The histotechnologist will be responsible to put a sticker on the reagent containers in the tissue processor. The labels will provide the following information and be updated each time the tissue processors reagents are changed and or rotated to be effective on 01/25/2024." The date changed, reagent, lot number, expiration were listed on the labels. 7. During an interview on 02/24/2026 at 9:44 AM, the Mohs Technician A confirmed laboratory failed to label 14 reagent bottles completely with preparation and expiration dates on VIP and the 75% Alcohol and 95% Alcohol were made in the laboratory
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease

	nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have a log documenting the preparation of the reagents used in the Vacuum Infiltration Processor (VIP), failed to list the opened dates on their Reagent Log and failed to list all the reagent used in the laboratory in their reagent log from 01/17/24 to 02/24/2026. Findings Included: A1. During a tour of the laboratory on 02/24/2026 at 9:30 AM, no 75% Alcohol or 95% Alcohol was observed in the laboratory's flammable cabinets. A2. Review of the VIP 3000 Tissue Processor log noted the laboratory used the following chemicals in their VIP:10% Buffered Neutral Formalin, 75% Alcohol, 95% Alcohol, 100% Alcohol, and Xylene Substitute. A3. Review of the laboratory's quality control logs showed there was no log documenting the preparation of the 75% Alcohol or 95% Alcohol A4. During an interview on 02/23/2026 at 11:17 AM, the Mohs Technician A stated there was no log documenting the preparation of the 75% Alcohol and 95% Alcohol.. B1. Review of the Reagent Q/A (Quality Assurance) Log, showed the log contained columns for the Reagent, Manufacturer, Lot Number, Date Received, Expiration, Date Opened, and Initials. B2. Review of the reagent log showed there was nothing listed in the Date Opened column for reagents received between 03/08/2023 to 2/10/2026. B3. During an interview on 02/24/2026 at 10:32 AM, the Mohs Technician A confirmed laboratory failed to label 14 reagent bottles completely with preparation and expiration dates on VIP and the 75% Alcohol and 95% Alcohol were made in the laboratory. C1, Observations on 02/24/2026 at 9:44 AM, revealed the two bottles of 10% Neutral Buffered Formalin lot number 237763 were listed on the labels on the bottles loaded in the VIP. C2. Observations on 02/24 /2026 at 9:44 AM, revealed one bottle of 75% Alcohol, one bottle of 95%. and one bottle of 100% Alcohol all listed lot # 246469 on the labels on the bottles loaded in the VIP. C3. Observations on 02/24/2026 at 9:44 AM, revealed one bottle of 100% Alcohol listed lot #235330 on the label on the bottle loaded in the VIP. Observations on 02/24/2026 at 9:44 AM, revealed four bottle of XS-3, Xylene Substitute listed lot #242459 on the label on the bottle loaded in the VIP. C4. Review of the Reagent Q/A Log showed, 10% Neutral Buffered Formalin lot number 237763, 100% Alcohol all listed lot # 246469 and lot #235330 , and XS-3, Xylene Substitute lot #42459 were not listed on the Reagent QA Log.
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 review of the histopathology reports and interview, the laboratory failed to list where the technical component was performed for three (#1 - #3) of seven (#1 -

	#7) Patient reports reviewed, the laboratory failed to list where the immunohistochemical (IHC) stains were performed for one (#7) of six (#1 - #7) Patient reports reviewed, and failed to report where the professional component was performed from 05/23/2026 to 02/24/2026. Finding Included: A1. Review of the histopathology reports that were reported out by a reference laboratory failed to include the name and address of where the technical component was performed. A2. During an interview on 02/24/2026 at 11:35 AM, the Mohs Technician acknowledged the name and address of the laboratory of the technical component was not listed on the reports. B1. Review of histopathology reports showed, Patient #7 had the interpretation of the following IHC stained slides reported: CK34 - Cytokeratin 34 - Squamous Cell Carcinoma IHC stain) Melan-A (Melanocytic Marker IHC stain), PRAME (Melanoma IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), and SOX-10 (Melanoma IHC stain). B2. Review of the histopathology reports revealed the reports failed to list the name and address of the laboratory of where the IHC staining was performed. B3. During an interview on 02/24/2026 at 11:35 AM, the Mohs Technician acknowledged the name and address of the laboratory where the IHC staining was performed was not listed on the histopathology report. C1. Review of the histopathology reports showed Patients #1 - #3 histopathology biopsies were reported out at reference laboratory by Pathologist (Testing Personnel B). C2. During an interview on 02/24/2026 at 11:30, the Pathologist stated she reads the biopsy slide at either this laboratory, the reference laboratory, or her home laboratory which has a CLIA certificate.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the quality assessment program was established and maintained to ensure the quality of laboratory services provided and to identify failures in the laboratory from 01/17/24 to 02/24/2026. (See D6093)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 record review and interview, the Laboratory Director failed to ensure that the quality assessment program was established and maintained to ensure the quality of laboratory services provided and to identify failures in the laboratory from 01/17 /2024 to 02/24/2026. Findings included: 1. The Laboratory Director failed to ensure protection from chemical hazards used in their Vacuum Infiltration Processor (VIP) and Hematoxylin and Eosin (H&E) stain from 01/17/2024 to 02/24/2026. (See D3011) 2. Laboratory Director failed to ensure the laboratory labeled the 14 reagent

	bottles with preparation and expiration dates for reagents used on the VIP instrument. This is a repeat deficiency from the recertification survey on 01/17/2024. (See D5415) 3. The Laboratory Director failed to ensure the laboratory have a log documenting the preparation of the reagents used in the Vacuum Infiltration Processor (VIP), list the opened dates on their Reagent Log, and list all the reagent used in the laboratory in their reagent log from 01/17/2024 to 02/24/2026. (See D5609) 4. The Laboratory Director failed to ensure the laboratory listed where the technical component was performed for three (#1 - #3) of seven (#1 - #7) patient reports reviewed, the laboratory failed to list where the immunohistochemical (IHC) stains were performed for one (#7) of six (#1 - #7) patient reports reviewed, and failed to report where the professional component was performed from 05/23/201. 26 to 02/24/2026. (See D5805) 5. During an interview on 02/24/2026 at 4:10 PM, the Laboratory Director stated he thought the labeling of the bottles on the VIP was corrected and was not aware of the other issues.