

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2193242	(X3) Date Survey Completed 11/18/2025
Name of Provider or Supplier Elise C Deluke, Md, PLLC	Street Address, City, State 353 Kenmore Avenue - Ste 2, Buffalo, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's package insert instructions as well as interview with the Laboratory Director (LD), the laboratory failed to follow waived test manufacturer's instructions. FINDINGS: 1. There was no documentation of Quality Control (QC) performance for the Consult Diagnostics Human Chorionic Gonadotropin (hCG) urine tests dipstick kits. 2. There was no documentation of date received or in-use date for the Consult Diagnostics hCG urine tests dipstick kit lot numbers. 3. This is contrary to instructions included in the manufacturer's package insert. 4. The LD confirmed the findings on November 18, 2025, at approximately 3:30 P.M.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of analytic system records, Standard Operating Procedures (SOPs), as well as interview with the LD, the laboratory failed to retain QC and records</p>

	<p>documenting all analytic systems activities. FINDINGS: 1. There was no documentation of Avantik QS12 cryostat, Avantik G30 fume hood, Thermo Scientific Linistat automated stainer, and Olympus BX46 microscope service and annual preventive maintenance for 2024 and 2025. 2. The current, approved SOPs did not include instructions for retention of service and maintenance records for all laboratory equipment located in the Mohs processing laboratory. 3. The LD confirmed the findings on November 18, 2025, at approximately 3:30 P.M.</p>
<p>D5209</p>	<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 review of personnel training and competency assessment records, SOPs, as well as interview with the LD, the laboratory failed to establish and approve written policies and procedures to assess employee training and competency. FINDINGS: 1. There was no documentation of Mohs laboratory Testing Personnel (TP) initial training and six-month competency assessment. 2. It was noted that annual competency assessments were performed, documented for 2025. 3. The current, approved SOPs did not include instructions for performing and documenting such activity. 4. The LD confirmed the findings on November 18, 2025, at approximately 3:30 P.M.</p>
<p>D5219</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, lack of Proficiency Testing (PT) records, as well as interview with the LD, the laboratory failed to at least twice annually verify the accuracy of Provider Performed Microscopy (PPM) Procedures. FINDINGS: 1. There was no documentation of minimum twice annual Potassium Hydroxide (KOH) prep verification performance for 2024 and 2025. 2. The current, approved SOPs did not include instructions for performing and documenting such activity. 3. Seven patient KOH preps were performed in 2024 and five in 2025. 4. The LD confirmed the findings on November 28, 2025, at approximately 3:30 P.M.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-</p>

step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on direct observation, review of SOPs, lack of thermometer calibration records, as well as interview with the LD, the laboratory failed to draft and approve procedures for thermometer calibration and certificate retention. FINDINGS: 1. There was no documentation of calibration for the following thermometer used to monitor ambient room temperature and humidity in the Mohs laboratory: a. Thomas Scientific digital thermometer, SN: 200111562, Calibration due: February 17, 2022. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The LD confirmed the findings on November 18, 2025, at approximately 3:30 P.M.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observations, review of the Safety Data Sheets (SDS), reagent manufacturer's storage requirements, approved SOPs, temperature logs, as well as interview with the LD, the laboratory failed to comply with manufacturer's instructions for conditions that are essential for proper storage of reagents as well as monitor and document temperatures in the area where waived test kits were stored and on-site waived patient testing performed. FINDINGS: 1. The surveyors' observations in the Mohs processing laboratory confirmed on November 18, 2025, at approximately 10:00 A.M., the following reagents and processing materials were not stored in the flammable materials storage cabinet as required by the SDS and the reagent manufacturer's storage requirements: a. Avantik Ultra Clear Xylene Substitute, lot: 2335206, expiration: December 12, 2025, one unit, was retained in a cabinet beneath the sink in the Mohs processing laboratory. b. Avantik 100% Reagent Alcohol, lot: 2519201, expiration: July 11, 2028, three units, was stored in a cabinet

beneath the sink in the Mohs processing laboratory. c. Bottle labelled "waste" containing discarded flammable reagents and solutions utilized for patient tissue processing was retained in a cabinet beneath the sink in the Mohs processing laboratory. 2. This is contrary to instructions in the Mohs Procedure Manual SOP, "Reagent Storage, Use, and Handling." 3. There was no documentation of acceptable temperature or humidity ranges on the log sheets utilized to record daily cryostat temperature, ambient room temperature, and humidity in the Mohs laboratory. 4. There was no documentation of ambient room temperature in the area where the Consult Diagnostics hCG urine tests dipstick kits were stored and testing performed. a. The retained manufacturer's package insert stated to store the tests at 36-86F/2-30? C. 5. The LD confirmed the findings on November 18, 2025, at approximately 3:30 P. M.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) 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.

This STANDARD is not met as evidenced by:
Based on direct observations, review of current, approved SOPs, training documents, as well as interview with the LD, the laboratory failed to remove from inventory expired reagents in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on November 18, 2025, at approximately 9:33 A.M., the following reagents were not removed from inventory as required by the Mohs Procedure Manual SOP, "Reagent Storage, Use, and Handling" and the "Personnel Training Checklist" for processing of tissue. a. Avantik Eosin Working Solution, lot: 43090129, expiration: September 19, 2025, was stored in the flammable storage cabinet in the Mohs processing laboratory. b. Avantik Ultra Clear Xylene Substitute, lot: 230383U, expiration.: March 2025, was stored in the flammable storage cabinet in the Mohs processing laboratory. c. Avantik Bluing Reagent, lot: 106213, expiration.: September 30, 2023, was stored in a cabinet beneath the sink in the Mohs processing laboratory. 2. The LD informed the surveyor that the expired reagents were utilized for patient specimen processing. Approximately 23 patient specimens were processed utilizing the expired Avantik Eosin Working Solution, 124 patient specimens processed utilizing the expired Avantik Ultra Clear Xylene Substitute, and an unknown number of patient specimens processed utilizing the expired Avantik Bluing Reagent. 3. The LD confirmed the findings on November 18, 2025, at approximately 3:30 P.M.