

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2011319	<b>(X3) Date Survey Completed</b>  01/25/2023
<b>Name of Provider or Supplier</b>  Envision Pathology, Llc	<b>Street Address, City, State</b>  806 North Ave K, Suite 101, Crowley, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification survey was performed on January 25, 2023 at Envision Pathology, LLC, CLIA ID 19D2011319. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D3039</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records and interview with personnel, the laboratory failed to retain the 2022 (QA) records for at least two (years) as required. Findings: 1. Review of the laboratory's monthly QA records revealed the laboratory did not retain the records for 2022. 2. In interview on January 25, 2023 at 1:08 pm the Laboratory Director stated he was unable to find the 2022 QA records.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have complete polices and procedures for Histopathology testing.</p>

Findings: 1. Review of the laboratory's retrospective review policy revealed the laboratory did not include a procedure for documentation of findings. 2. In interview on January 25, 2023 at 11:00 am, the Laboratory Director confirmed the laboratory did not include how findings of retrospective reviews would be documented.

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of the laboratory's policies, quality control logs, patient final test reports, and interview with personnel, the laboratory failed to establish complete quality control procedures for special stains utilized for Histopathology testing. Findings: 1. Review of the laboratory's policies revealed the laboratory did not specify where documentation of the quality control for special stains would be located; i.e. patient final report, quality control log, or both. 2. Review of the laboratory's quality control (QC) logs and random selection of patient final test reports revealed the laboratory documented the special stain quality controls on the patient test reports and occasionally on the (QC) log. 3. In interview on January 25, 2023 at 11:48 , the Laboratory Director confirmed the laboratory's policy for special stains did not include where the quality controls would be documented.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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:

	<p>Based on observation by surveyor, review of manufacturer's requirements, and interview with personnel, the laboratory failed to ensure the Periodic Acid solution was stored per manufacturer's requirements. Findings: 1. Observation by surveyor on January 25, 2023 at 12:36 pm revealed a frozen one (1) liter bottle of 0.5% Periodic Acid solution (lot 145204) stored in the refrigerator. 2. Review of the manufacturer's requirements revealed the storage requirement was 15-30 degrees Celsius. 3. In interview on January 25, 2023 at 12:36 pm the Laboratory Director and staff member confirmed the identified solution was not stored per manufacturer's requirements.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: **Repeat Deficiency from survey on March 16, 2021 ** Based on observation by surveyor and interview with personnel, the laboratory failed to ensure supplies and test kits had not exceeded their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on January 25, 2023 at 9:41 am revealed the following expired items: a) QuantiFERON TB Gold Tubes: QuantiFERON Nil, Lot A18053LP, Expiration date: 2019-08-31, Quantity: one (1) tube QuantiFERON mitogen, Lot A1804398, Expiration date: 2019-07-31, Quantity: one (1) tube QuantiFERON TB Antigen, Lot A180439X, Expiration date: 2019-07-31, Quantity: one (1) tube b) Discover Plus Drug Card Test, Lot DOA1807109, Expiration date: 2020-06, Quantity: one (1) card c) Consult Diagnostics Strep A Dipstick, Lot STA0112020, Expiration date: 2022-10-31, Quantity: one (1) box d) 1% Safranin O stain, Lot 135701, Expiration date: 2022-12-31, Quantity: one (1) bottle e) Acrymount mounting media, Lot 0087, Expiration date: 2022-03-27, Quantity: thirteen (13) bottles 2. In interview on January 25, 2023 at 10:07 am, the laboratory staff confirmed the identified items were expired.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: **Repeat Deficiency from survey on March 16, 2021 ** Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to retain the 2022 (QA) records for at least two (years) as required. Refer to D3039. 2. The laboratory failed to ensure the Periodic Acid solution was stored per manufacturer's requirements. Refer to D5413. 3. The laboratory failed to ensure supplies and test kits had not exceeded their expiration dates. Refer to D5417.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p>

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to have complete policies and procedures for Histopathology testing. Refer to D5401. 2. The laboratory failed to establish complete quality control procedures for special stains utilized for Histopathology testing. Refer to D5403.