

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2011319	<b>(X3) Date Survey Completed</b>  07/03/2018
<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 at Envision Pathology - CLIA # 19D2011319 on July 3, 2018. Envision Pathology was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1219 CONDITION: Histopathology. 42 CFR 493.1441 CONDITION: Laboratory Director performing high complexity testing.
<b>D5028</b>	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Histopathology. Findings: 1. The laboratory failed to verify the accuracy of the performance of the reading of Histopathology slides at least twice a year. Refer to D5215. 2. The laboratory failed to ensure that Histopathology Staining Solutions are not used beyond their expiration dates. Refer to D5417. 3. The laboratory failed to perform bi-monthly maintenance for the Grossing Station for eight (8) of thirty two (32) bimonthly periods reviewed. Refer to D5429 I. 4. The laboratory failed to perform monthly maintenance for the Histopathology Refrigerator and Formalin Waste Containers for three (3) of eighteen (18) monthly periods reviewed. Refer to D5429 II. 5. The laboratory failed to perform every 2 weeks maintenance for the Sakura DRS 601-Hematoxylin and Eosin Stainer for six (6) of thirty six (36) 2 week periods reviewed. Refer to D5429 III. 6. The laboratory failed to perform bi-monthly maintenance for the VIP Tissue Tek 2000 Tissue Processor for two (2) of thirty two (32) bimonthly periods reviewed. Refer to D5429 IV. 7. The testing personnel failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&amp;E) Staining utilized for</p>

histopathology slides for sixteen (16) of sixteen (16) patients reviewed. Refer to D5601. 8. The Laboratory's Quality Assurance monitors failed to identify and correct quality control issues in Histopathology. Refer to D5791.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory failed to verify the accuracy of the performance of the reading of Histopathology slides at least twice a year. Findings: 1. Observation by surveyor on July 3, 2018 revealed the laboratory processed Histopathology Samples for the reading and diagnosis performed by the Laboratory Director. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure for verifying the accuracy of the performance of Histopathology Samples for the reading and diagnosis of patients at least twice annually. 3. Interview with the Laboratory Director on July 3, 2018 confirmed he failed to verify the accuracy of the performance of Histopathology Samples for the reading and diagnosis of patients at least twice a year.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(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 observation, and interview with laboratory personnel, the laboratory failed to ensure that Histopathology Staining Solutions are not used beyond their expiration dates. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 3, 2018 revealed the following expired items in place for patient testing: One (1) 125 milliliter (ml) bottle of STAT LAB Methenamine Solution - lot number 33455 with an expiration date July 2016. One (1) 125 ml bottle STAT LAB Gold Chloride Solution - lot number 33374 with an expiration date July 2016. One (1) 125 ml bottle STAT LAB Silver Nitrate Solution - lot number 33095 with an expiration date of June 2016. 2. Interview with the Histotechnologist on July 3, 2018 confirmed by observation the expired items that were in place for patient testing.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

I. Based on record review and interview with personnel, the laboratory failed to perform bi-monthly maintenance for the Grossing Station for eight (8) of thirty two (32) bimonthly periods reviewed. Findings: 1. Review of the Equipment Maintenance Log revealed the laboratory is required to "Clean grossing station" on a bimonthly basis for the Grossing Station: Further review of the Equipment Maintenance Log from January 2017 through June 2018 revealed the laboratory failed to document the performance of the bimonthly cleaning of the Grossing Station for the following eight (8) periods. June 1, 2017 - June 14, 2017. June 15, 2017 - June 28, 2017. June 29, 2017 - July 12, 2017. July 13, 2017 - July 26, 2017. July 27, 2017 - August 3, 2017. November 17, 2017 - November 30, 2017. December 1, 2017 - December 14, 2017. December 15, 2017 - December 28, 2017. 2. Interview with the Histotechnologist on July 3, 2017 confirmed the laboratory failed to document the bimonthly maintenance for the Grossing Station for the eight (8) bimonthly periods cited above. II. Based on record review and interview with personnel, the laboratory failed to perform monthly maintenance for the Histopathology Refrigerator and Formalin Waste Containers for three (3) of eighteen (18) monthly periods reviewed. Findings: 1. Review of the Equipment Maintenance Log revealed the laboratory is required to do the following monthly maintenance: a) Clean Fridge. b) Check Formalin Waste Containers and process according to directions. Further review of the Equipment Maintenance Log from January 2017 through June 2018 revealed the laboratory failed to document the performance of the monthly maintenance for the following three (3) months. June 2017. July 2017. May 2018. 2. Interview with the Histotechnologist on July 3, 2017 confirmed the laboratory failed to document the monthly maintenance for the three (3) months cited above. III. Based on record review and interview with personnel, the laboratory failed to perform every 2 weeks maintenance for the Sakura DRS 601-Hematoxylin and Eosin Stainer for six (6) of thirty six (36) 2 week periods reviewed. Findings: 1. Review of the Sakura DRS 601-Hematoxylin and Eosin Stainer Log revealed the laboratory is required to do the following 2 week maintenance: a) Rotate Position 1: Xylene. b) Rotate Position 3: 100% ETOH. c) Rotate Position 5: 95% ETOH. d) Rotate Position 6: 95% ETOH. e) Rotate Position 12: 95% ETOH. f) Rotate Position 14: 100% ETOH. g) Rotate Position 15: 100% ETOH. h) Rotate Position 17: Xylene. i) Rotate Position 18: Xylene. Further review of the Sakura DRS 601-Hematoxylin and Eosin Stainer Log from January 2017 through June 2018 revealed the laboratory failed to document the performance of the 2 week maintenance for the following six (6) 2 week periods. April 4, 2017 - April 11, 2017. June 15, 2017 - June 19, 2017. July 27, 2017 - August 8, 2017. November 28, 2017 - December 3, 2017. January 23, 2018 - February 4, 2018. March 29, 2018 - April 9, 2018. 2. Interview with the Histotechnologist on July 3, 2017 confirmed the laboratory failed to document the 2 week maintenance for the six (6) 2 week periods cited above. IV. Based on record review and interview with personnel, the laboratory failed to perform bi-monthly maintenance for the VIP Tissue Tek 2000 Tissue Processor for two (2) of thirty two (32) bimonthly periods reviewed. Findings: 1. Review of the VIP Tissue Tek 2000 Tissue Processor Maintenance Log revealed the laboratory is required to do the following bimonthly maintenance: a) Fluid Rotation. b) Wax Purity Test. Further review of the VIP Tissue Tek 2000 Tissue Processor Maintenance Log from January 2017 through June 2018 revealed the laboratory failed to document the performance of the bimonthly cleaning of the Grossing Station for the following two (2) periods. December 26, 2017 - January 2, 2018. May 1, 2018 - May 13, 2018. 2. Interview with the Histotechnologist on July 3, 2017 confirmed the laboratory failed to document the bimonthly maintenance for the VIP Tissue Tek 2000 Tissue Processor for the two (2)

bimonthly periods cited above.

**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 with personnel, testing personnel failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for sixteen (16) of sixteen (16) patients reviewed. Findings: 1. Review of a random selection of Histopathology patient reports from July 6, 2017 through June 4, 2018, Testing Personnel failed to perform and document H&E quality control for the following sixteen (16) patients. On June 6, 2017 patient 1 (D17-432) was collected on July 6, 2017, Received in the laboratory on July 6, 2017 and reported on July 10, 2017. On June 6, 2017 patient 2 (DN17-1018) was collected on July 6, 2017, Received in the laboratory on July 7, 2017 and reported on July 11, 2017. On October 10, 2017 patient 3 (D17-666) was collected on October 10, 2017, Received in the laboratory on October 10, 2017 and reported on October 13, 2017. On October 10, 2017 patient 4 (DN17-1646) was collected on October 10, 2017, Received in the laboratory on October 12, 2017 and reported on October 16, 2017. On January 2, 2018 patient 5 (D18-2) was collected on January 2, 2018, Received in the laboratory on January 2, 2018 and reported on January 12, 2018. On January 2, 2018 patient 6 (DN18-9) was collected on January 2, 2018, Received in the laboratory on January 3, 2018 and reported on January 8, 2018. On February 12, 2018 patient 7 (D18-112) was collected on February 12, 2018, Received in the laboratory on February 12, 2018 and reported on February 14, 2018. On February 12, 2018 patient 8 (DN18-171) was collected on February 12, 2018, Received in the laboratory on February 13, 2018 and reported on February 18, 2018. On March 5, 2018 patient 9 (D18-112) was collected on March 5, 2018, Received in the laboratory on March 5, 2018 and reported on March 8, 2018. On March 5, 2018 patient 10 (DN18-264) was collected on March 5, 2018, Received in the laboratory on March 6, 2018 and reported on March 8, 2018. On April 6, 2018 patient 11 (D18-290) was collected on April 6, 2018, Received in the laboratory on April 6, 2018 and reported on April 10, 2018. On April 6, 2018 patient 12 (DN18-430) was collected on April 6, 2018, Received in the laboratory on April 10, 2018 and reported on April 12, 2018. On May 10, 2018 patient 13 (D18-414) was collected on May 10, 2018, Received in the laboratory on May 10, 2018 and reported on May 13, 2018. On May 10, 2018 patient 14 (DN18-568) was collected on May 10, 2018, Received in the laboratory on May 14, 2018 and reported on May 17, 2018. On June 4, 2018 patient 15 (D18-477) was collected on June 4, 2018, Received in the laboratory on June 4, 2018 and reported on June 12, 2018. On June 4, 2018 patient 16 (DN18-657) was collected on June 4, 2018, Received in the laboratory on June 5, 2018 and reported on June 8, 2018. 2. Interview with the Laboratory Director (personnel 1) on July 3, 2018 revealed the laboratory did not have a system in place for tracking patient samples from received time through the processing, staining then reporting of the results. The Laboratory Director stated samples are usually processed the date the samples are

received, then stained with the routine H&E Stain the following date. Reporting differs for each sample based on the microscopic review and if additional cuts or stains are need to put out a final report for the patient. The Laboratory Director confirmed he failed to have a system in place to track patient samples with the quality control of H&E staining. The Laboratory Director also confirmed he failed to document the H&E Quality Control each day of patient testing. to track when samples had just begun patient testing on February 21, 2017. Personnel 1 stated that she performs a control slide of known reactivity for the Hematoxylin and Eosin Staining utilized for histopathology slides. However, personnel 1 confirmed that she failed to document the performance and the acceptability of the reactivity for the Hematoxylin and Eosin stain. Personnel 1 confirmed that patients were tested and reported without documenting the performance and the acceptability of the reactivity for the Hematoxylin and Eosin stain.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Histopathology. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to verify the accuracy of the performance of the reading of Histopathology slides at least twice a year. Refer to D5215. b) The laboratory failed to ensure that Histopathology Staining Solutions are not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to perform bi-monthly maintenance for the Grossing Station for eight (8) of thirty two (32) bimonthly periods reviewed. Refer to D5429 I. d) The laboratory failed to perform monthly maintenance for the Histopathology Refrigerator and Formalin Waste Containers for three (3) of eighteen (18) monthly periods reviewed. Refer to D5429 II. e) The laboratory failed to perform every 2 weeks maintenance for the Sakura DRS 601-Hematoxylin and Eosin Stainer for six (6) of thirty six (36) 2 week periods reviewed. Refer to D5429 III. f) The laboratory failed to perform bi-monthly maintenance for the VIP Tissue Tek 2000 Tissue Processor for two (2) of thirty two (32) bimonthly periods reviewed. Refer to D5429 IV. g) The testing personnel failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for sixteen (16) of sixteen (16) patients reviewed. Refer to D5601. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with the Laboratory Director on July 3, 2018 confirmed the above findings.

**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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Please refer to D6087. 2. The Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6094. 4. The Laboratory Director failed to ensure the establishment and documentation of maintenance procedures as required. Refer to D6095.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of the performance of the reading of Histopathology slides at least twice a year. Refer to D5215. 2. The laboratory failed to ensure that Histopathology Staining Solutions are not used beyond their expiration dates. Refer to D5417.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 review of laboratory policy and procedure manual, quality control and patient test records and interview with personnel, the Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Findings: 1. The testing personnel failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for sixteen (16) of sixteen (16) patients reviewed. Refer to D5601. 2. The Laboratory Director confirmed the above statement on July 3, 2018.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to verify the accuracy of the performance of the reading of Histopathology slides at least twice a year. Refer to D5215. b) The laboratory failed to ensure that Histopathology Staining Solutions are not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to perform bi-monthly maintenance for the Grossing Station for eight (8) of thirty two (32) bimonthly periods reviewed. Refer to D5429 I. d) The laboratory failed to perform monthly maintenance for the Histopathology Refrigerator and Formalin Waste Containers for three (3) of eighteen (18) monthly periods reviewed. Refer to D5429 II. e) The laboratory failed to perform every 2 weeks maintenance for the Sakura DRS 601-Hematoxylin and Eosin Stainer for six (6) of thirty six (36) 2 week periods reviewed. Refer to D5429 III. f) The laboratory failed to perform bi-monthly maintenance for the VIP Tissue Tek 2000 Tissue Processor for two (2) of thirty two (32) bimonthly periods reviewed. Refer to D5429 IV. g) The testing personnel failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for sixteen (16) of sixteen (16) patients reviewed. Refer to D5601. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with the Laboratory Director on July 3, 2018 confirmed the above findings.

**D6095**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:  
 Based on record review and interview with personnel, the Laboratory Director failed to ensure the establishment and documentation of maintenance procedures as required. Findings: 3. The laboratory failed to perform bi-monthly maintenance for the Grossing Station for eight (8) of thirty two (32) bimonthly periods reviewed. Refer to D5429 I. 4. The laboratory failed to perform monthly maintenance for the Histopathology Refrigerator and Formalin Waste Containers for three (3) of eighteen (18) monthly periods reviewed. Refer to D5429 II. 5. The laboratory failed to perform every 2 weeks maintenance for the Sakura DRS 601-Hematoxylin and Eosin Stainer for six (6) of thirty six (36) 2 week periods reviewed. Refer to D5429 III. 6. The laboratory failed to perform bi-monthly maintenance for the VIP Tissue Tek 2000 Tissue Processor for two (2) of thirty two (32) bimonthly periods reviewed. Refer to D5429 IV.