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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D2286529 | (X3) Date Survey Completed 01/03/2025 |
| Name of Provider or Supplier Phenopath Laboratories, Pllc | Street Address, City, State 30766 Belle Maison, Laguna Niguel, CA | |
| 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 |
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| D3027 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on interview with Laboratory Director (LD) and review of laboratory's patient testing records on January 3, 2025, it was determined that the Laboratory failed to retain any records of test requisitions and patient's records for 2 years. Findings include: 1. It was the practice of the laboratory to perform Histopathology testing and the laboratory utilizes the laboratory information system (LIS) for test requisitions and medical records. 2. On January 3, 2025, at approximately 12:00 pm, the laboratory director was not able to retrieve any test requisitions and patient's medical records from 7/31/2023 to 1/3/2025. 3. The laboratory's testing declaration form, signed by the laboratory director on December 31, 2024, stated that the laboratory had performed 430 histopathology testing annually.</p> |
| D5028 | <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 interview with Laboratory Director (LD) and review of laboratory's histopathology records on January 3, 2025, it was determined that the Laboratory</p> |

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| | <p>failed to meet the requirements specified in 493.1230 through 493.1256. Findings include: 1. The Laboratory failed to retain any records of test requisitions and patient's records. See D3027 2. The Laboratory failed to ensure that the accuracy of the Histopathology testing was verified at least twice annually. See D5217 3. The laboratory director failed to meet the standard requirement to approve, sign, and date all policies and procedures. See D5407 4. The laboratory failed to retain any stained slides. See D5603</p> |
| <p>D5217</p> | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on interview with Laboratory Director (LD) and review of laboratory's Proficiency Testing (PT) records on January 3, 2025, it was determined that the Laboratory failed to ensure that the accuracy of the Histopathology testing was verified at least twice annually for the years 2023 and 2024. The findings include: 1. It was the practice of the laboratory to perform Histopathology testing, which are not listed in the subpart I of the 42 CFR part 493. For the test procedure not listed in subpart I the laboratory must verify the accuracy of the test procedure twice annually. 2. On January 3, 2025, at approximately 11:30 am, the laboratory director affirmed that the laboratory maintained no documentation to show it verified the accuracy of Histopathology testing at least twice annually for 2 of 2 years. 3. The laboratory's testing declaration form, signed by the laboratory director on December 31, 2024, stated that the laboratory had performed 430 histopathology testing annually.</p> |
| <p>D5407</p> | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on interview with Laboratory Director (LD) and review of laboratory's policies and procedures manuals on January 3, 2025, the laboratory director failed to meet the standard requirement to approve, sign, and date all policies and procedures. The findings include: 1. On January 3, 2025, at approximately 12:30 am, the laboratory Director affirmed that the laboratory didn't maintain documentation indicating that written policies and procedures had been approved, signed, and dated by the current laboratory director. 2. The laboratory's testing declaration form, signed by the laboratory director on December 31, 2024, stated that the laboratory had performed 430 histopathology testing annually.</p> |
| <p>D5603</p> | <p>HISTOPATHOLOGY CFR(s): 493.1273(b)(f)</p> <p>(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions</p> |

submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's histopathology records from 7/31/2023 to 1/3/2025, the laboratory failed to retain any stained slides. The findings include: 1. It was the practice of the laboratory to perform Histopathology testing and the laboratory must retain patients' and quality control (QC) slides, as specified in 493.1105. 2. On January 3, 2025, at approximately 12:15 pm, the laboratory director affirmed that the laboratory did not keep slides in-house and that she was not able to provide any patients or QC slides from 7/31/2023 to 1/3/2025. 3. The laboratory's testing declaration form, signed by the laboratory director on December 31, 2024, stated that the laboratory had performed 430 histopathology testing annually.

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 review of the laboratory procedures and performance records on January 3, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings include: 1. The Laboratory director failed to ensure that the laboratory retained records of test requisitions and patient's records. See D3027 2. The Laboratory director failed to ensure that the accuracy of the Histopathology testing was verified at least twice annually. See D5217 3. The laboratory director failed to meet the standard requirement to approve, sign, and date all policies and procedures. See D5407 4. The Laboratory director failed to ensure that the laboratory retain stained slides. See D5603 5. The laboratory's testing declaration form, signed by the laboratory director on December 31, 2024, stated that the laboratory had performed 430 histopathology testing annually. 6. The laboratory director affirmed these deficient practices by interview on January 3, 2025, at approximately 12:30 pm.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedures and performance records on January 3, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings include: 1. The Laboratory director failed to ensure that the laboratory retained records of test requisitions and

patient's records. See D3027 2. The Laboratory director failed to ensure that the accuracy of the Histopathology testing was verified at least twice annually. See D5217 3. The laboratory director failed to meet the standard requirement to approve, sign, and date all policies and procedures. See D5407 4. The Laboratory director failed to ensure that the laboratory retain stained slides. See D5603 5. The laboratory's testing declaration form, signed by the laboratory director on December 31, 2024, stated that the laboratory had performed 430 histopathology testing annually. 6. The laboratory director affirmed these deficient practices by interview on January 3, 2025, at approximately 12:30 pm.