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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0650651 | (X3) Date Survey Completed 04/18/2023 |
| Name of Provider or Supplier Pinkus Dermatopathology Laboratory Pc | Street Address, City, State 1314 N Macomb St, Monroe, MI | |
| 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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| D5209 | <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 record review and interview with the Histology Laboratory Manager, the laboratory failed to establish a competency assessment policy for testing personnel performing tick identification testing for 2 (April 2021 to April 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's personnel competency records revealed a lack of competency assessments for the performance of tick identification testing from April 2021 to April 2023. 2. An interview on 4/18/21 at 3:00 pm with the Histology Laboratory Manager confirmed the laboratory had not established a process for the competency assessment process for testing personnel performing tick identification testing.</p> |
| D5217 | <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 record review and interview with the Histology Laboratory Manager, the laboratory failed to verify the accuracy of its tick identification testing at least twice annually for 2 (April 2021 to April 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's Internal and External Quality Review documentation from</p> |

April 2021 to April 2023 revealed a lack of documentation of verification of accuracy testing for its tick identification testing. 2. An interview on 4/18/21 at 3:00 pm with the Histology Laboratory Manager confirmed the laboratory had not performed verification of accuracy testing for its tick identification testing.