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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0710493 | (X3) Date Survey Completed 10/30/2025 |
| Name of Provider or Supplier Harry J Hurley Md Pc Laboratory | Street Address, City, State 1101 Paoli Pk, West Chester, PA | |
| 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 |
|---------------------------|--|
| 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 lack of documentation and interview with the laboratory director (LD), the laboratory failed to ensure that the verification of accuracy for parasitology microscopic examinations was performed at least twice annually, as required for tests not included in subpart I for 2 of 2 years from 10/05/2023 to the date of the survey. Findings include: 1. On the day of the survey, 10/30/2025 at 11:30 am, the laboratory could not provide documentation that the verification of accuracy for scabies microscopic examinations were performed twice annually for 2 of 2 years from 10/05/2023 to 10/30/2025. 2. The laboratory performed 1 scabies examine in 2025. 3. The LD confirmed the findings above on 10/05/2023 at 12:00 pm. ***Repeat deficiency***</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> |

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Accu3003 microscope used to perform histopathology microscopic slides from 10/05/2023 to 10/30/2025. Findings include:

1. The laboratory's Safety & Maintenance policy stated the following: working temperature: 0-40 degrees Celsius; maximum 85 % relative humidity
2. On the day of the survey, 10/30/2025, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 10/05/2023 to 10/30/2025: - 1 of 1 Accu3003 microscope
3. The laboratory performed 1207 histopathology slide examination in 2024 (CMS 116, estimated annual volume, dated 09/27/2025).
4. The LD confirmed the above findings on 10/30/2025 at 09:30am.