

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0710493	(X3) Date Survey Completed 10/05/2023
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) proficiency testing (PT) records and interview with the laboratory director (LD), the LD/designee and testing personnel (TP) failed to sign 4 of 4 AAFP PT attestation statement documents for parasitology and mycology testing performed in 2021 and 2022. Findings Include: 1. On the day of the survey, 10/05/2023 at 10:00 am, review of the AAFP PT records revealed that the following 4 of 4 AAFP PT attestation statements reviewed were not signed by the LD/designee or TP for parasitology and mycology testing performed in 2021 and 2022: - AAFP-PT 2021-C - AAFP-PT 2022-A - AAFP-PT 2022-B - AAFP-PT 2022-C 2. During an interview, 10/05/2023 at 10:30 am, the LD stated that the office staff submitting the PT results to AAFP would sign the names of the TP and LD for them on the attestation sheets.</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 laboratory director (LD), the laboratory failed to ensure that the verification of accuracy for histopathology,</p>

mycology, and parasitology microscopic examinations were performed at least twice annually, as required for tests not included in subpart I from 01/14/2022 to the date of the survey. Findings include: 1. On the day of the survey, 10/05/2023 at 11:30 am, the laboratory could not provide documentation that the verification of accuracy for histopathology microscopic examinations were performed at least twice annually from 01/14/2022 to 10/05/2023. 2. The laboratory could not provide documentation for the verification of accuracy for Potassium Hydroxide (KOH) and scabies microscopic examinations performed from 01/01/2023 to 10/05/2023. 3. The laboratory could not provide a procedure for performing verification of accuracy for KOH, scabies and histopathology examinations. 4. The LD confirmed the findings above on 10/05/2023 at 12:00 pm.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of the American Academy of Family Physicians (AAFP) proficiency testing (PT) records, and interview with the laboratory director (LD), the LD failed to ensure that AAFP PT reports received were reviewed by the appropriate staff for 4 of 4 AAFP PT results in 2021, and 2022. Findings Include: 1. On the day of the survey, 10/05/2023 at 10:30 am, review of AAFP PT records revealed that the LD failed to ensure that all PT reports were reviewed by the appropriate staff for the following 4 of 4 AAFP PT events for parasitology and mycology microscopic evaluations in 2021 and 2022: - AAFP-PT 2021-C - AAFP-PT 2022-A - AAFP-PT 2022-B - AAFP-PT 2022-C 2. The LD confirmed the finding above on 10/05/2023 at 12:00 pm.