

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1055452	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Bryn Mawr Dermatology, Pc	Street Address, City, State 775 E Lancaster Ave, Suite 200, Villanova, 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, review of the laboratory's proficiency testing manual, and interview with the practice manager (PM), the laboratory failed to verify twice annually the accuracy of dermatopathology microscopic examinations performed in 2023. Findings include: 1. The laboratory's Proficiency Testing manual stated, "Semi-annually, the tech or risk manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist." 2. On the day of survey, 04/30/2024 at 11:36 am, the laboratory could not provide documentation of the semiannual verification of accuracy of dermatopathology microscopic examinations performed in 2023. 3. According to CMS 116 the laboratory reported 247 dermatopathology microscopic examinations performed in 2023. 4. The PM confirmed the findings above on 04/30/2024 at 01:45 pm.</p>
D6125	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the practice</p>

manager (PM), the Technical Supervisor (TS) (CMS 209 personnel #1) failed to assess the competency for 1 of 3 testing personnel (TP) through external proficiency testing samples or internal blind testing samples for histopathology macroscopic examinations performed in 2022 and 2023. Findings include: 1. The laboratory's competency testing manual states, "The following procedures are requirements for assessment of competency for all personnel performing laboratory testing -5. Assessment of test performance through testing previously testing samples." 2. On the day of survey, 04/30/2024 at 11:53 am, review of competency assessment records revealed annual competencies performed in 2022 and 2023 did not include the assessment of external proficiency testing samples or internal blind testing samples for 1 of 3 TP (CMS 209 TP #3) who performed macroscopic examinations in histopathology in 2022 and 2023. 3. The PM confirmed the findings above on 04/30/2024 at 01:45 pm.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on lack of documentation, review of the laboratory's competency evaluation policy, and interview with the practice manager (PM), the technical supervisor (TS) (CMS 209 Personnel #1) failed to assess and document annual competency assessment for 1 of 3 Testing Personnel (TP) who performed dermatopathology microscopic examinations in 2022 and 2023. Findings include: 1. The laboratory's Competency evaluation policy states, "After the first year, competency assessment must be performed at least annually." 2. On the day of survey, 04/30/2024 at 01:00 pm, the laboratory could not provide competency assessment records for 1 of 3 TP (CMS 209 TP #2) who performed dermatopathology microscopic examinations in 2022 and 2023. 3. The PM confirmed the findings above on 04/30/2024 at 01:45 pm.