

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2138086	<b>(X3) Date Survey Completed</b> 11/21/2023
<b>Name of Provider or Supplier</b> Bryn Mawr Dermatology, Pc	<b>Street Address, City, State</b> 534 2nd Ave Ste 101, Collegeville, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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:</p> <p>A. Based on lack of documentation, review of laboratories procedures and interview with the Practice Manager (PM), the laboratory failed to verify twice annually the accuracy of Mohs microscopic examinations performed in 2022 and 2023. Findings include: 1. The laboratory's procedure manual "Proficiency Testing Mohs Micrographic Surgery Skin Specimens" states the following: "semi-annually, the tech or Risk Manager will send two cases containing the original slides." 2. On the day of survey, 11/21/2023 at 11:30 am, the laboratory could not provide documentation for verification of accuracy for Mohs microscopic examination twice annually in 2022 and 2023. 3. On the day of survey, 11/21/2021, the laboratory provided: - one peer review for 2022 performed on 1/17/22 - one peer review for 2023 performed 10/23/23 4. The PM confirmed the findings above on 11/21/23 at 11:30 am. B. Based on lack of documentation and interview with the Practice Manager (PM), the laboratory failed to verify twice annually the accuracy of potassium hydroxide (KOH) microscopic examinations performed in 2022 and 2023. 1. On the day of survey, 11/21/23 at 11:40 am, the laboratory could not provide documentation for verification of accuracy for KOH microscopic examination twice annually in 2022 and 2023. 2. The PM confirmed the findings above on 11/21/23 at 11:40 am.</p>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with Practice Manager (PM), the laboratory failed to document a positive and negative quality control every day of patient testing and to provide quality control procedures for potassium hydroxide (KOH) from 1/18/2022 to the day of survey. Findings include: 1. On the day of survey, 11/21/2023 at 11:55 am, PM could not provide quality control procedures for KOH. 2. On the day of survey, 11/21/2023 at 11:55 am, PM could not provide daily quality control records for KOH microscopic examination from 1/18/2022 to 11/21/2023. 3. The laboratory's CMS-116 states that the laboratory performs approximately 15 KOH tests annually. 4. PM confirmed the findings above on 11/21/2023 at approximately 11:55 am.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records and interview with the Practice Manager (PM), the Laboratory Director (LD) failed to specify, in writing, the duties and responsibilities of 5 of 5 testing personnel (TP) involved in the preanalytic, analytic, and postanalytic phases of patient testing in microbiology from 01/18/2022 to the date of the survey. Findings include: 1. On the date of the survey, 11/21/2023 at 10:40 am, the laboratory could not provide written job responsibilities and duties for 5 of 5 TP who perform potassium hydroxide (KOH) microscopic examinations. 2. The PM confirmed the findings above on 11/21/2023 around 10:30 am.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

A. Based on review of the laboratory procedure manual, personnel competency assessment records, and interview with Practice Manager (PM), the Technical

Supervisor (TS) failed to ensure the competency of 1 of 1 testing personnel (TP) performing inking and grossing macroscopic examinations were assessed for competency in 2021, 2022, and 2023. Findings Include: 1. On the day of survey, 11/21/23, the LD could not provide documentation of competency assessments performed for 1 of 1 TP who performed inking and grossing macroscopic examinations in 2021, 2022, and 2023. 2. The PM confirmed the findings above on 11/21/23 around 11:00 am. B. A. Based on review of the laboratory procedure manual, personnel competency assessment records, and interview with Practice Manager (PM), the Technical Supervisor (TS) failed to ensure the competency of 5 of 5 testing personnel (TP) performing potassium hydroxide (KOH) microscopic examinations were assessed for competency in 2021, 2022, and 2023. Findings Include: 1. On the day of survey, 11/21/23, the LD could not provide documentation of competency assessments performed for 5 of 5 TP who performed KOH microscopic examinations in 2021, 2022, and 2023. 2. The PM confirmed the findings above on 11/21/23 around 11:00 am.