

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>39D0195109</p>	<p>(X3) Date Survey Completed</p> <p>12/30/2024</p>
<p>Name of Provider or Supplier</p> <p>Bryn Mawr Skin And Cancer Institute</p>	<p>Street Address, City, State</p> <p>919 Conestoga Road Suite 106 Bldg 2, Bryn Mawr, PA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5209</p>	<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 lack of documentation, review of laboratory procedures, and interview with the Histotech (HT), the laboratory failed to establish and follow written procedures to monitor employee competency 1/6/2023 to 12/30/2024 Findings include: 1. On the day of the survey, 12/30/2024 at 10:00 am, the laboratory failed to provide a written policy for the assessment of competency for laboratory personnel and supervisors for their regulatory responsibilities from 1/6/2023 to 12/30/2024. 2. The HT confirmed the above findings on 12/30/2024 at 10:30 am.</p>
<p>D5217</p>	<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, lack of documentation, and interview with the Histotech (HT), the laboratory failed to verify twice annually the accuracy of Mohs micrographic slide examinations performed in 2023 and 2024. Findings include: 1. The laboratory's procedure "External Quality Control" states the following: "Annually, a Mohs surgeon or Pathologist not affiliated with BMSCI will review at</p>

least ten (10) cases per Mohs surgeon in order to provide external quality control in reference to both laboratory slide preparation, and physician proficiency at histologic interpretation." 2. On the day of survey, 12/30/2024 at 10:00 am, the laboratory could not provide documentation for verification of accuracy for Mohs micrographic slide examinations performed twice annually in 2023 and 2024. 3. The HT confirmed the findings above on 12/30/2024 at 10:15 am.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory temperature records and interview with the Histotech (HT), the laboratory failed to monitor and document room temperature(RT) and humidity to ensure proper operating conditions for 2 of 2 Olympus microscopes, used for Mohs micrographic slide examinations performed from 1/6/2023 to 12/30/2024. Findings include: 1. The Olympus instruction manual states, "Operating and storage environments should be maintained at temperatures between 0 to 40 degrees Centigrade and humidity of 30 to 90%. Failure to do so may lead to microscope malfunction." 2. On the day of the survey, 12/30/2024 at 11:50 pm, the laboratory failed to provide RT and humidity monitoring records to ensure reliable test system operation for 2 of 2 Olympus microscopes(models: Bx45 and Cx41) prior to reporting Mohs micrographic slide examinations from 1/6/2023 to 12/30/2024. 3. The laboratory performed 3,330 histopathology procedures(CMS 116 estimated annual volume) in 2024. 4. The HT confirmed the findings above on 12/30/2024 at 12:00 pm.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Histotech (HT), the laboratory failed to perform and document weekly maintenance per laboratory procedure for 3 of 3 microscopes used to perform MOHS micrographic slide examinations from 1/6/2023 to 12/30/2024. Findings Include: 1. On the day of survey, 12/30/2024, review of policy "Cryostat Temperatures and Daily Maintenance" revealed that "microscopes are to be inspected weekly and recorded on maintenance charts". 2. Review of microscope maintenance logs revealed the laboratory failed to perform and document weekly maintenance performed on 3 of 3 microscopes used for MOHS micrographic

slide examinations from 1/6/2023 to 12/30/2024. 3. The laboratory performed 3,330 histopathology procedures(CMS 116 estimated annual volume) in 2024. 4. The HT confirmed the findings above on 12/30/2024 at 12:15 pm.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's temperature records and interview with the Histotech(HT), the laboratory failed to provide documentation of the corrective actions taken when Cryostat (CT) temperatures were outside of the laboratory's established acceptable ranges of -20 to -30 Celsius (C) for 14 of 158 days in 2024 when Histopathology testing was performed. Findings include: 1. On the day of survey 12/30/2024 at 10:00 am, review of the laboratory's temperature records revealed that 14 of 158 days in 2024 were outside of the laboratory's established acceptable range (-20 to -30C): - February: 3 of 14 days (-37 to -39C) - March: 11 of 11 days (-37 to -38C) - April: 3 of 14 days (-38C) 2. The laboratory could not provide documentation for corrective actions taken when CT temperatures were out of range. 3. The HT confirmed the findings above on 10/19/2023 at 12:10 pm.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on lack of documentation, and interview with the Histotech(HT), the laboratory director (LD) failed to ensure that (Quality Assurance) QA programs were established and maintained to ensure the quality of services provided and to identify failures in quality as they occur for testing performed in dermapathology 1/6/2023 to 12/30/2024. Findings Include: 1. On the day of the survey, 12/30/2024 , the laboratory failed to provide documentation that a QA program was established and maintained to ensure the quality of services provided and to identify failures as they occur for dermapathology testing from 1/6/2023 to 12/30/2024. 2. HT confirmed the findings above on 12/30/2024 at 10:30 am.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

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

(e)(15) 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 Histotech (HT), the Laboratory Director (LD) failed to specify, in writing, the duties and responsibilities of each consultant, supervisor, and testing personnel (TP) involved in the preanalytic, analytic, and postanalytic phases of patient testing from 1/6/2023 to the date of the survey. Findings include: 1. On the date of the survey, 12/30/2024 at 10:45 am, the laboratory could not provide written job responsibilities and duties for LD, clinical consultant (CC), technical supervisor (TS), general supervisor (GS) and TP involved in patient testing. 2. The HT confirmed the findings above on 12/30/2024 at 11:30 am.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 review of competency assessment records, lack of documentation, and interview with the Histotech(HT), the Technical Supervisor (TS) failed to evaluate the annual competency assessment for 1 of 2 Testing Personnel (TP) who performed MOHS Micrographic slides examined from 1/6/2023 to the day of survey. Findings include: 1. On the day of survey 12/30/2024 at 10:15 am, the laboratory was unable to produce documentation for TP#2 (CMS 209) annual competency assessment for 2023 and 2024. 2. The HT confirmed the findings above on 12/30/2024 at 10:15am.