

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1040519	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Bryn Mawr Medical Specialists Association	Street Address, City, State Palmer Medical Building, Wynnewood, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with Testing Personnel (TP)#2, the laboratory failed to perform and document maintenance on the 1of 2 Cryostat instruments from 04/08/2021 to date of survey. Findings Include: 1. Observation of the laboratory on 05/16/2023 at 09:47 am, revealed maintenance for the Leica CM 1510s cryostat was due in November of 2021 and the laboratory did not perform and document maintenance at least yearly as specified by the manufacturer. 2. Interview with TP #2 confirmed the Leica CM 1510s cryostat had not been used and was kept as a backup instrument only. 3. TP #2 confirmed findings above on 05/16/2023 around 10:00am .</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 Testing Personnel (TP)#2, the Technical Supervisor (TS) failed to include assessment of test performance in the competency evaluation of 1 of 2 testing personnel who performed</p>

gross examinations and specimen inking of frozen sections from 04/08/2021 through date of survey. Findings include: 1. On the day of the survey 05/16/2023 at 9:34am, review of competency assessments for Gross examinations and specimen inking of frozen sections, revealed the TS did not include assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples from 04/08/2021 to 05/16/2023. 2. The laboratory reported an annual test volume of 2505 for Histopathology. (CMS-116) 3. TP #2 confirmed the above findings on 05/16/2023 around 10:00am.