

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0960814	<b>(X3) Date Survey Completed</b>  07/26/2023
<b>Name of Provider or Supplier</b>  Main Line Fertility Bryn Mawr	<b>Street Address, City, State</b>  Bryn Mawr Medical Arts Pavilion, Bryn Mawr, 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>D2009</b>	<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 Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director/designee and testing personnel failed to sign 4 of 4 AAB-MLE PT attestation statements for Embryology/Andrology testing in 2022 and 2023. Findings Include: 1. On the day of the survey, 07/26/2023 at 9:58 am, the laboratory could not provide the following 4 of 4 AAB-MLE PT signed attestation statements for Embryology/Andrology testing in 2022 and 2023: - AAB-MLE Embryology/Andrology: - 2022: Event #1 and Event #2. - 2023: Event #1 and Event #2. 2. The TC confirmed the findings above on 07/26/2023 around 11:00 am.</p>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor record review (CMS-116) and interview with the technical consultant (TC), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests are being performed. Findings Include: 1. The</p>

PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. Review of the CMS-116 signed by the laboratory director on 7/18/2023, hours of laboratory testing indicates the laboratory is operating Monday - Friday from 8:00 AM to 5:00 PM and Saturday - Sunday from 8:00 AM through 11:00 AM. 3. On the day of the survey, 07/26/2023 at 11:00 am, during an interview, the TC stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing as required by the State of PA.