

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0975102	<b>(X3) Date Survey Completed</b>  02/20/2025
<b>Name of Provider or Supplier</b>  Main Line Fertility Center	<b>Street Address, City, State</b>  825 Old Lancaster Rd, Suite 170, 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>D6143</b>	<p><b>GENERAL SUPERVISOR QUALIFICATIONS</b> CFR(s): 493.1461</p> <p>(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In</p>

dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).

This STANDARD is not met as evidenced by:

Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records (credentials) and interview with Technical supervisor (TS) #1, the laboratory failed to ensure that 1 of 4 General supervisors (GS) met the requirements to provide supervision of testing personnel who performed hematology testing from 07/07/2023 to the day of survey. 1. The Laboratory General Supervisor Job Description signed by GS #3 (CMS 209 personnel #4) on 07/07/2023 states, "The general supervisor must hold at least a bachelor's degree in biology and/or a medical technology registry from an accredited institution and have at least 2 years of experience in a high complexity area of the laboratory." 2. On the day of survey, 02/20/2025, the laboratory failed to provide personnel qualification records (transcripts) for 1 of 4 GS (CMS 209 GS #3) who provided supervision of high complexity hematology testing (semen analysis) performed by testing personnel from 07/07/2023 to 02/20/2025. 3. TS #1 confirmed the findings above on 02/20/2025 at 12:45 pm.