

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0881910	<b>(X3) Date Survey Completed</b>  01/25/2022
<b>Name of Provider or Supplier</b>  Main Line Fertility And Repro Med	<b>Street Address, City, State</b>  11 Industrial Blvd Suite 100, Paoli, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of the laboratory's Quality Assessment (QA) Policies, competency assessment records review, and interview with the Technical Consultant (TC)#1, the laboratory failed to have a competency assessment (CA) policy for the 1 of 1 Clinical Consultant (CC), 2 of 2 Technical Consultants (TC), 1 of 1 Technical Supervisor (TS), and 1 of 1 General Supervisor (GS) for their supervisory responsibilities in 2020 and 2021. Findings include: 1. On the day of survey, 01/25/2022 at 09:28 a.m., the TC#1 could not provide a CA policy to assess the competency of 1 of 1 CC (CMS-209 personnel #2) , 2 of 2 TC (CMS-209 personnel #3 and #4), 1 of 1 TS ( CMS-209 personnel #4), and 1 of 1 GS (CMS-209 personnel #3) for their supervisory responsibilities in 2020 and 2021. 2. The TC#1 could not provide a competency assessment records for 1 of 1 CC from 01/25/2020 to 01/25/2022. 3. The TC#1 confirmed the findings above on 01/25/2022 around 12:00 p.m.</p>