

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0167439	<b>(X3) Date Survey Completed</b> 05/06/2019
<b>Name of Provider or Supplier</b> Medical Arts Gynecology & Infertility Pc	<b>Street Address, City, State</b> 1522 Burrstone Road, Utica, NY	
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 the surveyor's review of the laboratory's competency assessment policies, the personnel records, and an interview with a licensed practical nurse (LPN)/ testing person, the laboratory failed to follow the laboratory's written competency assessment policies and perform an annual competency evaluation for the testing person in the 2017 and 2018 calendar years. <b>FINDINGS:</b> The LPN/testing person confirmed on May 6, 2019 at approximately 11:30 AM, the laboratory failed to follow the laboratory's written competency assessment policies, that requires an annual competency evaluation for all laboratory testing personnel. The laboratory director failed to perform annual competency evaluations for the testing person in the 2017 and 2018 calendar years.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and</p>

procedures and confirmed in an interview with the LPN/testing person, the laboratory failed to follow their established QA policy and perform an annual QA review for the 2017 and 2018 calendar years. FINDINGS: The LPN/testing person confirmed on May 6, 2019 at approximately 11:00 AM, that the laboratory failed to follow their established written QA policies that requires an annual QA review to include all laboratory systems: patient confidentiality; specimen identification and integrity; complaint investigations; communications; personnel competency; and proficiency testing performance/comparison testing. The laboratory director failed to perform annual QA review in the 2017 and 2018 calendar years.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on surveyor's a review of the laboratory QA policy, and interview with the LPN /testing person, the laboratory director failed to follow the laboratory's QA procedure for having an on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for hematology in calendar years 2017 and 2018. Refer to D5209 and D5291.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on the lack of competency assessment documentation and an interview with the LPN/testing person, the laboratory director acting as the technical consultant, failed to perform annual competency evaluation for the only testing person in calendar years 2017 and 2018. Refer to D5209.