

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0876744	<b>(X3) Date Survey Completed</b>  08/24/2021
<b>Name of Provider or Supplier</b>  Advanced Women's Care Of Pgh	<b>Street Address, City, State</b>  3928 Washington Rd, Suite 230, McMurray, 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><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 upon a review of proficiency testing records and interview of the Laboratory Coordinator, on 08/24/2021, the Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload for AAFP Affirm VP3.. Findings: The AAFP attestation statement was not signed by the Laboratory Director for 4 of 4 testing events reviewed. 2019 3rd event, 2020 2nd event, 2020 3rd event, and 2021 1st event. During the survey (13:40 08/24/2021), the Laboratory Coordinator confirmed, the above findings.</p>
<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 laboratory personnel interview with the Laboratory Coordinator and review of the personnel records, the Technical Consultant failed to establish written policies and procedures to assess Testing Personnel competency for 9 of 10 Testing Personnel. from 09/11/2019 through the date of the survey. Findings: 1. The laboratory could not produce written policies and procedures to assess Testing Personnel competency for</p>

KOH, and Wet Preps, from 09/11/2019 through the date of the survey 08/24/2021. 2. The Laboratory Director acted as Technical Consultant#1 from 09/11/2019, through the date of the survey. 3. Review of the personnel records revealed no documentation of Testing Personnel competency for 9 of 10 Testing Personnel from 09/11/2019, through the date of the survey. 4. During the survey (13:40 08/24/2021), the Laboratory Coordinator confirmed, the above findings.