

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D0624961	<b>(X3) Date Survey Completed</b> 01/08/2026
<b>Name of Provider or Supplier</b> Women's Healthcare Associates Llc	<b>Street Address, City, State</b> 7650 Sw Beveland St Suite 210, Portland, OR	
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 laboratory personnel records and interview with the Technical Supervisor (TS), the laboratory failed to ensure that persons delegated by the Laboratory Director (LD) to a federal position, including Technical Supervisor (TS), General Supervisor (GS) and Clinical Consultant (CC) listed on the current CMS 209 form, were assessed at least annually. Findings include: 1. Upon request for the laboratory's policy on assessment of laboratory personnel that hold the title of TS, GS and CC, none could be produced. 2. Upon request for competency assessments by the LD for personnel listed as the TS, GS and CC on the current CMS 209 form, none could be produced. 3. Interview with the TS at 09:30 am on 01/08/2026 confirmed that annual competency assessment for personnel delegated as TS, GS and CC were not performed. 4. The laboratory reports performing 232,991 tests annually.</p>
<b>D6107</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(15)</p> <p>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory personnel records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to create and maintain a current list with delegation of duties for all persons listed to a federal position as TS, General Supervisor (GS) and Clinical Consultant (CC) on the current CMS 209 form. Findings include: 1. Upon request for a current delegation of duties form, none could be produced. 2. Interview with the TS at 09:30 am on 01/08/2026 confirmed that there was no current delegation of duties. 3. The laboratory reports performing 232,991 tests annually.