

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0938477	(X3) Date Survey Completed 08/13/2025
Name of Provider or Supplier Urology Associates Pc-Cool Springs	Street Address, City, State 1909 Mallory Lane, Suite 110, Franklin, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, laboratory procedure, final patient test reports, and staff interviews, the laboratory failed to follow the procedure for testing personnel competency assessment for one testing person (one of four reviewed) who performed provider performed microscopy (PPM) qualitative semen analysis patient testing in 2024. The findings include: 1. A review of the Form CMS-209 completed for the survey on 08/13/2025 revealed four testing personnel, two of whom performed PPM qualitative semen analysis patient testing. 2. A review of the laboratory's personnel records revealed that testing person four (one of two PPM personnel) did not have an annual competency assessment performed in 2024. 3. A review of the "Training and Competency" laboratory procedure revealed that testing personnel would have initial and six-month competency assessments within the first year of employment and annually thereafter. 4. A review of patient test reports revealed that testing person four performed qualitative semen analysis for the following patients in 2024: Patient number 1966060 reported on 01/22/2024 Patient number 1861640 reported on 04/17/2024 Patient number 2230640 reported on 10/23/2024 5. An interview with the laboratory technical consultant on 08/13/2025 at 1:00 p.m. confirmed the survey findings. Word Key: CLIA- Clinical Laboratory Improvement Amendments</p>