

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2118892	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Vios Fertility Institute Chicago Wicker Park	Street Address, City, State 1455 N Milwaukee Ave, Chicago, IL	
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
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing (PT) records, laboratory policies and procedures, and interview with Technical Consultant (TC) #2, the laboratory failed to perform and document a corrective action for one of one unacceptable PT sample score for follicle stimulating hormone (FSH) in event two of 2025. Findings include: 1. Review of laboratory policy and procedure manual identified the procedure titled, " Proficiency Testing (PT) 161756.642", which stated, "4. All unacceptable proficiency testing results are investigated using 161756.442 CAP PT investigation worksheet. Lab manager/director will work together with the testing personnel on corrective action for failed PT." 2. Review of PT records from the College of America Pathologists (CAP) revealed the laboratory failed to document a corrective action for one of one unacceptable PT sample score for FSH PT in event two of 2025. Specimen / Grade Y-10 / Unacceptable 3. Interview with TC #2 on 12/17/2025, at 12:58 pm, confirmed the laboratory failed to perform or document an investigation or corrective actions for one of one unacceptable PT sample score for FSH in CAP PT event two of 2025.</p>