

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403228	(X3) Date Survey Completed 08/26/2025
Name of Provider or Supplier Southdale Obgyn Consultants	Street Address, City, State 3625 W 65th St #100, Edina, MN	
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
D0000	<p>. The Southdale OBGYN laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on August 26, 2025. The following standard-level deficiency was cited: 493.1236 Evaluation of proficiency testing performance .</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate two unacceptable Microbiology proficiency testing (PT) results out of twenty challenges completed by survey date in 2025. Findings are as follows: 1. The laboratory performed Candida and Gardnerella vaginalis testing on the BD Affirm VPIII microbial identification system as confirmed by Testing Personnel 1 during a tour of the laboratory at 1:05 p.m. on 08/26/25. 2. The laboratory performed PT using the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing provider. 3. One of ten Candida PT results and one of ten Gardnerella vaginalis PT results were unacceptable in 2025 as indicated in 2025 AAB-MLE reports received by date of survey, 08/26/25. See below. 2025 - M1 event Test: Candida Sample: 3 Laboratory Result: Positive AAB-MLE expected result: Negative 2025 - M1 event Test: Gardnerella vaginalis Sample: 3 Laboratory Result: Positive AAB-MLE expected result: Negative 4. Investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing procedure located in the General Laboratory Policy and Procedure Manual. 5. Investigation documentation for the unsuccessful Candida and Gardnerella vaginalis scores was not found in laboratory records. The laboratory was unable to provide evidence of PT</p>

result investigation and corrective action records for these unacceptable results upon request. 6. In an interview at 2:20 p.m. on 08/26/25, the Clinic Manager confirmed the above finding. .