

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0403228	<b>(X3) Date Survey Completed</b> 05/04/2023
<b>Name of Provider or Supplier</b> Southdale Obgyn Consultants	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<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 one unacceptable Microbiology proficiency testing (PT) result out of fifteen challenges completed in 2022. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 1:05 p.m. on 05/04/23. 2. The laboratory performed PT using the American Association of Bioanalysts (AAB) proficiency testing provider. 3. The laboratory received one unacceptable PT result of fifteen Gardnerella vaginalis testing challenges completed in 2022 as indicated in AAB reports. See below. 2022 - Q3 Non-Chemistry event Test: Gardnerella vaginalis Sample: 13 Laboratory Result: Positive AAB 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 Gardnerella vaginalis score was not found in laboratory records. The laboratory was unable to provide evidence of PT result investigation and corrective action records for this event upon request. 6. In an interview at 2:43 p.m. on 05/04/23, TP1 confirmed the above finding. .</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where</p>

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of three test results reviewed on date of survey were entered into the patient electronic medical record (EMR) in 2022. Findings are as follows: 1. The laboratory performed Rupture of Fetal Membranes testing under the General Immunology specialty as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:05 p.m. on 05/04/23. 2. Clinical Innovations ROM Plus test kits were observed as present and available for use during the tour. 3. A ROM Plus patient test report from August 2022 was requested on date of survey. 4. Patient LT received ROM Plus testing on 08/16/22 as indicated in the ROM + Patient Log found in the ROM Plus manual. 5. A ROM Plus result from 08/16/22 was not found in patient LT's EMR on date of survey. 6. In an interview at 1:25 p.m. on 05/04/23, TP1 confirmed the above finding. .