Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403228	06/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southdale Obgyn Consultants	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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in a Microbiology Individualized Quality Control Plan (IQCP) in 2 of 12 months reviewed . Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by Testing Personnel 14 (TP14) during a tour of the laboratory at 1:10 p.m. on 06/23/21. 2. A BD Affirm VPIII Microbial Identification System was observed as present and available for use during the tour. 3. BD Affirm VPIII Microbial Identification System QC performance was required monthly, with new lots, and new shipments as established in the BD Affirm VPIII Microbial Identification Test procedure found in the BD Affirm Assay Binder and every 30 days, with new lots, and new shipments as established in the laboratory's BD Affirm IQCP. 4. The laboratory exceeded the time interval for QC performance in 1 of 12 months in 2020 and failed to perform QC on 1 new lot in 1 of 12 months in 2020, potentially affecting 38 patient (Pt) test results. See below. Quality Control Log data Lot QC date 0008773 04/22/20 0077370 06/22/20 Patient Log data Lot Pt's tested post 05/22/20 0008773

	May 2020 - 7 pt's June 2020 - 9 pt's Lot Pt's tested prior to QC 0077370 06/08/20-06 /21/20 - 22 pt's 5. In an interview at 3:00 p.m. on 06/23/21, TP14 confirmed the above finding. .
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on review of personnel documents and interview with laboratory personnel, the laboratory failed to ensure staff performing moderate complexity testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for 2 testing personnel performing moderately complex Microbiology and Diagnostic Immunology testing. See D6065. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to obtain an equivalency evaluation of foreign education credentials for 2 of 10 testing personnel who were performing moderate complexity testing between November 2019 and June 2021. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology and General Immunology testing as confirmed by Testing Personnel 14 (TP14) during a tour of the laboratory at 1:10 p.m. on 06/23/21. A BD Affirm VPIII Microbial Identification System, ROM Plus test kits, and a Nikon microscope were observed as present and available for use during the tour. 2. Testing Personnel 16 (TP16) and Testing Personnel 22 (TP22) were listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as employees performing moderate complexity testing. 3. Education credentials found in personnel records indicated TP16 completed education in Ethiopia and TP22 completed education in Venezuela. 4. Employees with foreign education credentials must have the credentials evaluated for United States equivalency as indicated in the Laboratory Personnel Requirements and Responsibilities policy located in the General Laboratory Policy and Procedure

	Manual. 5. Equivalency evaluations of TP16's and TP22's foreign credentials were not found in personnel records. The laboratory was unable to provide the equivalency evaluations upon request. 6. In an interview at 2:30 p.m. on 06/23/21, TP14 confirmed the above finding.