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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 24D0400320 | (X3) Date Survey Completed 06/23/2021 |
| Name of Provider or Supplier Southdale Ob/Gyn Consultants | Street Address, City, State 305 E Nicollet Blvd #393, Burnsville, 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 |
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| D6063 | <p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>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. .</p> |
| D6065 | <p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p> |

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 13 (TP13) during a tour of the laboratory at 9:00 a.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 15 (TP15) and Testing Personnel 21 (TP21) 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 TP15 completed education in Ethiopia and TP21 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 TP15's and TP21'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 9:50 a.m. on 06/23/21, TP13 confirmed the above finding.