

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D2116885	<b>(X3) Date Survey Completed</b> 08/07/2019
<b>Name of Provider or Supplier</b> Avera Medical Group - Family Health Center	<b>Street Address, City, State</b> 2100 South Marion Road, Sioux Falls, SD	
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>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/7/19. The Avera Medical Group Family Health Center laboratory was found not in compliance with the following requirement: D5775.
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the current laboratory test menu, quality assessment (QA) activities, annual test volume form, and interview with the laboratory supervisor, the laboratory failed to establish and monitor criteria for acceptable differences between one analyte (human chorionic gonadotropin [hCG]) performed by two different methods (qualitative versus quantitative). Those test methods had not been evaluated twice a year in 2018 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's test menu revealed serum qualitative and serum quantitative hCG had been available test methods in 2018. Review of the annual test volume form revealed the laboratory had reported 366 patient serum qualitative hCG and 552 patient serum quantitative hCG test reports in 2018. Review of the laboratory's QA records revealed no comparison of qualitative versus quantitative hCG test methods had been completed in 2018. Other records reviewed did not include that comparison. Interview on 8/7/19 at 12:10 p.m. with the laboratory supervisor revealed: *The laboratory performed qualitative hCG testing with a serum test kit. *The laboratory performed quantitative hCG testing on the Beckman Access 2</p>

analyzer. \*He was not aware twice a year comparison testing was required for the two hCG test methods.