

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0396494	<b>(X3) Date Survey Completed</b>  06/23/2021
<b>Name of Provider or Supplier</b>  Hirsch Clinic-Vmh	<b>Street Address, City, State</b>  407 S Main St Ste 400, Viroqua, WI	
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>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not perform two levels of quality control (QC) on the serum human chorionic gonadotropin (HCG) test on twenty-one of twenty-seven patient testing days and did not have evidence of an individualized quality control plan (IQCP). Findings include: 1. Review of "Patient results-Serum Pregnancy Test" log showed two levels of QC run on: a. January 5, 2021, Lot# HCG0042017 b. February 2, 2021, Lot# HCG0042017; February 2 and 4, 2021, Lot#0042098 c. March 2, 2021, Lot#0042098 d. April 14, 2021, Lot#0082128 e. May 13, 2021, Lot#0092129 2. Further review of the "Patient results-Serum Pregnancy Test" log showed patient or proficiency testing (PT) on: a. January 5, 25 and 28, 2021 b. February 2, 3, 4, 8, 9, 10, 11, 12, 16, 17, 18, 19, 25 and 27, 2021 c. March 2 and 29, 2021 d. April 14, 15, 27 and 29, 2021 e. May 13, 14, 17 and 18, 2021 3. Interview with the technical consultant on June 23, 2021 at 11:25 AM confirmed the laboratory did not perform two levels of QC on the serum HCG test on twenty-one of twenty-seven patient testing days and did not have evidence of an IQCP.</p>