

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1030563	(X3) Date Survey Completed 09/27/2021
Name of Provider or Supplier Women's Health Group, The	Street Address, City, State 300 Exempla Cir, Suite 470, Lafayette, CO	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on onsite survey, records review of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for bacteriology for two of three events (2020 Event 3 and 2021 Event 2), resulting in unsuccessful proficiency testing performance. See D2021."</p>
D2021	<p>BACTERIOLOGY CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a</p>

score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing scores and interview, the laboratory failed to participate in two testing events resulting in a score of 0 percent for bacteriology in two of three events in 2020 and 2021, resulting in unsuccessful performance. The findings include: 1. Review of the CMS-153 Unsuccessful Proficiency Testing Report included The Women's Health Group with unsatisfactory proficiency testing scores for bacteriology. 2. Review of the CMS-155 report, the American Academy of Family Physicians (AAFP) bacteriology score for event three of 2020 was 0% and event two of 2021 was 0%. 3. During an onsite recertification survey on September 27, 2021 at approximately 9:00 am, the lead medical assistant and testing personnel #4 from the current CMS-209 form stated that the proficiency testing kits were never received at the laboratory and were not tested, nor were results submitted.