

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0383535	<b>(X3) Date Survey Completed</b>  05/20/2022
<b>Name of Provider or Supplier</b>  West Des Moines Ob/Gyn Associates	<b>Street Address, City, State</b>  4949 Westown Parkway, Suite 140, West Des Moines, IA	
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><b>CONTROL PROCEDURES</b> 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 review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient test logs, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 05/20/2022, the laboratory failed to perform a positive and negative control with each new lot of BD Affirm VPIII test cartridges for three out of seven lot numbers reviewed from 01/01/2021- 02/28/2022. The findings include: 1. The laboratory's IQCP indicated that the laboratory intended to perform QC with each new lot and shipment of BD Affirm VPIII test cartridges. 2. Review of patient test logs and quality control records revealed that the laboratory did not perform QC for the following lot numbers of BD Affirm VPIII test cartridges: *0259017 (expiration 07/15/2021): 24 patient tests performed *1132730 (expiration 03/15/2022): 48 patient tests performed *1321439 (expiration 10/12/2022): 24 patient tests performed 3. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not perform QC for the BD Affirm VPIII test cartridges lot numbers listed above. THIS IS A REPEAT DEFICIENCY.</p>