

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383535	(X3) Date Survey Completed 04/11/2018
Name of Provider or Supplier West Des Moines Ob/Gyn Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5445	<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 review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:40 am on 04/11/2018, the laboratory failed to perform a positive and negative control with each new lot of BD Affirm VPIII test cartridges for one out of three lot numbers (lot 7110743, expiration 03/08/2018) used between August and November 2017. The findings include: 1. Review of 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. The laboratory used the following lot numbers of BD Affirm VPIII test cartridges between August and November 2017: 7100551 (expiration 03/01/2018), 7110743 (expiration: 03/08/2018), and 709465 (expiration 06/22/2018). 3. Review of quality control records revealed that the laboratory performed QC when beginning a new lot for the following lot numbers: 7100551 and 709465. 4. The laboratory's log indicated that the laboratory began using lot 7110743 on 08/22/2017, but did not perform QC</p>

until 09/13/2017. 5. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not perform QC when it began using lot 7110743 of BD Affirm VPIII test cartridges.