

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2154004	(X3) Date Survey Completed 12/27/2018
Name of Provider or Supplier Joya Women's Healthcare, Corp	Street Address, City, State 2332 Nw Irving Street, Portland, OR	
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 upon review of the Individualized Quality Control Plan (IQCP) for the Affirm testing assays, the laboratory failed to have one (1) of the three (3) required parts of an IQCP. Findings include: 1. Upon review of records and interview with the Lab Lead and Laboratory Director (LD) on 12/27/2018 at approximately 12:00 p.m., the laboratory failed to develop the Quality Assessment (QA) part of the IQCP. 2. The LD confirmed that this part of the IQCP has not been developed or approved by her.</p>