Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2154004	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Joya Women's Healthcare, Corp	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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory documents for the BD Affirm testing system during survey 08/02/2022, the laboratory failed to enroll in an HHS approved Proficiency Testing (PT) program for 2021 and 2022. Findings include: 1. The BD AFFIRM instrument tests patient samples for three (3) microorganisms: Gardnerella vaginalis, Trichomonas vaginalis and Candida albicans. Candida albicans is a regulated analyte and thus requires PT testing according to CLIA. Upon request of PT records for review during survey 08/02/2022, no PT records could be produced. 2. During interview with the Laboratory Director (LD) and the lead Medical Assistant (MA) at approximately 1145 am, both confirmed they did not have enrollment in HHS PT for the BD AFFIRM test system for 2021 and 2022.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's documentation for the BD AFFIRM test system, the Laboratory Director (LD) failed to ensure the laboratory was enrolled in an HHS approved Profociency Testing (PT) for this test system. When asked for a Quality Assurance/Assessment (QA) plan for the Laboratory, the LD was unable to provide one nor any evidence of QA activity for 2021 or 2022. Findings include: 1. During interview with the LD at approximately 1145 am, the LD confirmed that the laboratory was not enrolled in a PT program for the analytes in the BD AFFIRM test system. One (1) of the three (3) analytes (Candida albicans) is a regulated analyte and requires PT testing by an HHS approved PT provider. 2. During interview with the LD at approximately 1200 pm, the LD confirmed that the lab had no written QA plan in place nor any evidence, written or digital, of QA activities. 3. See D6015 and D6021
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Director (LD) and lack of documentation, written or otherwise during survey 08/02/2022, the LD failed to ensure the laboratory was enrolled in an HHS approved Proficiency Testing (PT) program during 2021 and 2022. Findings include: 1. During interview with the LD at approximately 1145 am, the LD confirmed that the laboratory was not enrolled in a PT program for the analytes in the BD AFFIRM test system. One (1) of the three (3) analytes (Candida albicans) is a regulated analyte and requires PT testing by an HHS approved PT provider.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Director (LD) and the lead Medical Assistant (MA), the LD failed to ensure the laboratory had a written and active Quality Assurance/Assessment (QA) program in place. Findings include: 1. During interview with the LD and lead MA at approximately 1200 pm, the LD confirmed that the lab

	had no written QA plan in place nor any evidence, written or otherwise, of QA activities for 2021 or 2022.