Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0494937	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Care For Women	350 Kingwood Medical Drive, Suite #350, Kingwood, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records from 2017 to 2019 and confirmed in interview, the laboratory failed to test all proficiency samples in the same manner as it tests patient specimens. Findings were: 1. A review of 6 American Proficiency Institute (API) proficiency testing (PT) events from 2017 to 2019 revealed 6 of 6 events were tested by the same testing person (TP# 1). The facility listed 4 testing persons involved in testing patient specimens. By not involving all testing personnel who normally test patient specimens in the testing of proficiency testing samples, the facility failed to treat proficiency samples in the same manner as patient samples. 2. An interview with the laboratory director on 06/12/19 at 1040 hours in the laboratory confirmed the above findings. She acknowledged that the PT should be rotated.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	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. This STANDARD is not met as evidenced by: Based on review of the laboratory test records, quality control records, and confirmed in interview, the laboratory failed to document a complete INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) for the Bd Affirm. (quality assessment plan) Findings were: 1. Review of the laboratory IQCP for BD Affirm revealed no documentation of 1 of 3 components: the quality assessment plan. 2. An interview with the laboratory director on 6/12/19 at 1030 hours confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory's accuracy assessments, and confirmed in interview, the laboratory failed to verify, at least twice annually, the accuracy of 1 test for 2018. (BD Affirm) Findings were: 1. Review of the laboratory policy Care for Women/Instrument/Method correlation revealed "correlations must be performed semi-annually for analytes that are tested." 2. Review of the Instrument Validation and Correlation for 2018 revealed no documentation the laboratory performed accuracy assessment for the BD Affirm test. 3. An interview with the laboratory director on 6/12/19 at 1035 hours in the laboratory confirmed the above findings. key: BD Affirm - microbial identification system for the detection of vaginitis
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on review of the laboratory records, review of laboratory procedures, and confirmed in interview, the laboratory failed to establish quality assessment policies to monitor, assess, and correct problems in analytic systems. Refer to D5445, D5775
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 review of the laboratory records, review of laboratory procedures, and confirmed in interview, the laboratory director failed to ensure the laboratory established quality assessment policies to monitor, assess, and correct problems in analytic systems. Refer to D5445, D5775