Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0891326	(X3) Date Survey Completed 10/03/2019
Name of Provider or Supplier Women's Health Associates Llp	**Street Address, City, State** 3614 23rd Street, Lubbock, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon a review of proficiency testing records for program years 2018 and 2019 and staff interview, the laboratory failed to ensure that the attestation statements for Microbiology were signed by testing personnel and the laboratory director or designee in two of five events reviewed. Findings included: 1. Review of proficiency test records from the American Proficiency Institute (API) proficiency testing program revealed that Testing personnel and the Laboratory director or designee failed to physically sign attestation statements in two of five testing events between the first testing event of 2018 and the second testing event of 2019 (3 testing events per year). a. 2018 Microbiology 2nd Testing Event failed to have a physical signature of the testing personnel, only the Laboratory Director's signature. b. 2019 Microbiology 1st Testing event failed to have a physical signature of the testing personnel or the Laboratory Director. 2. Interview of the office manager conducted on October 3, 2019 at 9:42 AM confirmed the above findings.
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program

	within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Review of the laboratory's CMS 155 report, proficiency testing records from 2018 and 2019 and staff interview found the laboratory failed to participate in one of five Microbiology testing events reviewed. The findings included: 1. Review of the CMS report 155 (printed August 8, 2019) found that the proficiency testing agency reported a score of 0% for Bacteriology in the 2018 1st testing event. 2. A review of the laboratory's American Proficiency Institute's (API) bacteriology proficiency testing records from 2018 and 2019 found documentation on the 2018 Microbiology 1st event performance evaluation: "Samples were misplaced and run after the submission deadline. Positive (trivalent) and negative controls were run without interruption. After testing results were received, our results were compared to the correct results and were fond to be 100% correct." 3. Interview of the Office Manager conducted on Thursday, October 3, 2019 at 9:46 AM confirmed the laboratory failed to test and submit the results of the 2018 Microbiology 1st testing event prior to the submission date resulting in an overall score of 0% for the event.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Review of proficiency testing results and interview of facility personnel found that the laboratory director failed to ensure that attestation statements were signed by testing personnel and the laboratory director in two of five Microbiology testing events between the 1st testing event of 2018 and the 2nd testing event of 2019. (See D 2009)
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from 2018 and 2019 and staff interview the laboratory director failed to ensure proficiency test results were

	returned prior to the submission deadline in one of five Microbiology testing events. (refer to D2121).