Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0891326	(X3) Date Survey Completed 08/11/2020
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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Testing (API). The facility was found to be out of compliance with the conditions of the CLIA program. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation in a proficiency testing program D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CMS Casper 153 & 155 proficiency testing reports and the

	American Proficiency Institute proficiency testing records for the 1st and 2nd testing events in 2020, the laboratory failed to successfully participate in proficiency testing for Bacteriology, Mycology, and Parasitology (See D2028, D2046, and D2055).
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: Based on desk review of proficiency testing records, the laboratory failed to participate in two consecutive testing events resulting in a test score of 0% in Bacteriology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in Bacteriology for the 1st and 2nd events of 2020. Review of the American Proficiency Institute Performance Summary for the 2020 Microbiology 1st and 2nd Events, respectively, show scores of 0% for Gardnerella vaginalis under the subspecialty of Bacteriology in the specialty of Microbiology and a Failure to Participate under the notes.
D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, the laboratory failed two consecutive testing events resulting in unsuccessful performance with a test score of 0% in Bacteriology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in Bacteriology for the 1st and 2nd events of 2020. Review of the American Proficiency Institute Performance Summary for the 2020 Microbiology 1st and 2nd Events, respectively, show scores of 0% for Gardnerella vaginalis under the subspecialty of Bacteriology in the specialty of Microbiology.
D2039	MYCOLOGY CFR(s): 493.827(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: Based on desk review of proficiency testing records, the laboratory failed to participate in two consecutive testing events resulting in a test score of 0% in Mycology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in Bacteriology for the 1st and 2nd events of 2020. Review of the American Proficiency Institute Performance Summary for the 2020 Microbiology 1st and 2nd Events, respectively, show scores of 0% for Candida sp. under the subspecialty of Mycology in the specialty of Microbiology and a Failure to Participate under the notes.
D2046	MYCOLOGY CFR(s): 493.827(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, the laboratory failed two consecutive testing events resulting in unsuccessful performance with a test score of 0% in Mycology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in Bacteriology for the 1st and 2nd events of 2020. Review of the American Proficiency Institute Performance Summary for the 2020 Microbiology 1st and 2nd Events, respectively, show scores of 0% for Candida sp. under the subspecialty of Mycology in the specialty of Microbiology.
D2048	PARASITOLOGY CFR(s): 493.829(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: Based on desk review of proficiency testing records, the laboratory failed to participate in two consecutive testing events resulting in a test score of 0% in Parasitology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in Bacteriology for the 1st and 2nd events of 2020. Review of the American Proficiency Institute Performance Summary for the 2020 Microbiology 1st and 2nd Events, respectively, show scores of 0% for Trichomonas vaginalis under the subspecialty of Parasitology in the specialty of Microbiology and a Failure to Participate under the notes.
D2055	PARASITOLOGY CFR(s): 493.829(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, the laboratory failed two consecutive testing events resulting in unsuccessful performance with a test score of 0% in Parasitology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in Bacteriology for the 1st and 2nd events of 2020. Review of the American Proficiency Institute Performance Summary for the 2020 Microbiology 1st and 2nd Events, respectively, show scores of 0% for Trichomonas vaginalis under the subspecialty of Parasitology in the specialty of Microbiology.
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 CMS Casper 153 & 155 proficiency testing reports and the American Proficiency Institute proficiency testing records for the 1st and 2nd testing events in 2020, the Laboratory Director failed to provide direction and management for the laboratory testing performed (see D6017).
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 CMS Casper 153 & 155 proficiency testing reports and the American Proficiency Institute proficiency testing records for the 1st and 2nd testing events in 2020, the Laboratory Director failed to ensure the laboratory participated in proficiency testing for Bacteriology, Mycology, and Parasitology (See D2028, D2046, and D2055).