

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0919777	(X3) Date Survey Completed 05/27/2020
Name of Provider or Supplier Women's Clinic Of Forrest City	Street Address, City, State 902 Holiday Drive, Suite 102, Forrest City, AR	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: . Based on review of 2019 and 2020 CMS Casper Reports 155D, 153D and American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to participate in proficiency testing for the test of Gardnerella Vaginalis as evidenced by: Failure to participate or failure to achieve satisfactory performance for test of Gardnerella Vaginalis in two consecutive proficiency testing events is unsuccessful performance, as cited at D 2028.</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p>

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 review of 2019 and 2020 CMS Casper Reports 0155D and 0153D and API proficiency testing results, it was determined the laboratory failed to participate in proficiency testing for the test of Gardnerella Vaginalis resulting in a score of 0 which is unsuccessful participation. As evidenced by: A. The laboratory failed to participate in the third API proficiency testing event of 2019 resulting in a score of 0% for the test Gardnerella Vaginalis. B. The laboratory failed to participate in the first API proficiency testing event of 2020 resulting in a score of 0% for the test Gardnerella Vaginalis.

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 a review of the 2019 and 2020 proficiency testing results, it was determined the Laboratory Director failed to ensure that corrective actions are followed when proficiency testing results are unacceptable, and failed to provide overall management and directions as cited at: D 6019: Failure to ensure corrective action is followed when proficiency testing events are unacceptable.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on review of 2019 and 2020 proficiency testing results, it was determined the Laboratory Director failed to ensure that correction actions followed for the unsatisfactory performance for the test Gardnerella Vaginalis as cited at D 2028.