

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0147460	(X3) Date Survey Completed 03/22/2019
Name of Provider or Supplier Associates In Ob-Gyn Care Pc	Street Address, City, State 2044 Ocean Avenue, Suite A4, Brooklyn, NY	
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 a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT data reports and PT records from the American Proficiency Institute (API) PT program, the laboratory failed to participate and perform successfully in a PT program, for the Subspecialty Bacteriology/Gardnerella vaginalis. The following scores were assigned: 2018 first event= 60% 2018 second event = 60% 2018 third event = 100% 2019 first event = 0% [failure to participate] This is considered repeatedly unsuccessful PT performance. Refer to D2028.</p>
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 a PT desk review of the CMS PT data reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, for the Subspecialty Bacteriology/*Gardnerella vaginalis*. The following scores were assigned: 2018 first event = 60% 2018 second event = 60% 2018 third event = 100% 2019 first event = 0% [failure to participate] This is considered repeatedly unsuccessful PT performance.

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 a PT desk review of the CMS PT data reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program for the Subspecialty Mycology/*Candida*. The following scores were assigned: 2019 first event = 0% [failure to participate] This is considered unsatisfactory PT performance.

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 a PT desk review of the CMS PT data reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT

program for the Subspecialty Parasitology/Trichomonas The following scores were assigned: 2019 first event = 0% [failure to participate] This is considered unsatisfactory PT performance.

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 PT desk review of the PT CMS data reports and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program for the Subspecialties Bacteriology/Gardnerella vaginalis, Mycology/Candida and Parasitology/Trichomonas. Refer to D6016.

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:
Based on PT desk review of the PT CMS data reports and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program for the Subspecialties Bacteriology/Gardnerella vaginalis, Mycology/Candida and Parasitology/Trichomonas. The following scores were assigned: 2018 first event= 60% 2018 second event = 60% 2018 third event = 100% 2019 first event = 0% [failure to participate] This is considered repeatedly unsuccessful PT performance. Mycology/Candida and Parasitology/Trichomonas. 2019 first event = 0% [failure to participate] This is considered unsatisfactory PT performance.