

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0872283	(X3) Date Survey Completed 12/23/2021
Name of Provider or Supplier Drs Ahern And Galban	Street Address, City, State 77 Danbury Rd, Ridgefield, CT	
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	A proficiency testing desk review of the Drs. Ahern and Galban Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 record review of the CASPER Proficiency Testing (PT) data report 0155D and graded results from American Proficiency Institute (API) the laboratory failed to successfully participate for the regulated analyte 0005 Bacteriology. The laboratory received unsatisfactory scores for the 2nd and 3rd events of 2021. Refer to D2021 and D2028.</p>

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 record review, interview with the American Proficiency Institute (API) proficiency program and staff interview, the laboratory failed to participate in an approved PT program for Bacteriology. Findings include: 1. Record review on 12/20/2021 of the CASPER 0155D report revealed scores of 0% for the regulated analyte 0005 Bacteriology for 2021 Events 2 and 3. 2. Record review on 12/22/2021 of a letter received by email from the laboratory on 12/21/2021 at 8:42 PM confirmed the laboratory failed to participate in the above referenced PT events. 3. Record review of American Proficiency Institute (API) PT records received from the laboratory via email on 12/23/2021 at 9:25 AM revealed: a. API PT Performance Evaluation for 2021 Microbiology Event 1 listed a "next shipment reminder" of 6/14/2021 for Microbiology 2021 Event 2. b. API PT Performance Evaluation for 2021 Microbiology Event 2 listed a "next shipment reminder" of 9/20/2021 for Microbiology 2021 Event 3. c. API PT Performance Summary for 2021 Microbiology 2nd event listed a score of 0% for the regulated analyte Bacteriology with the remark, "failure to participate." d. API PT Performance Summary for 2021 Microbiology 3rd Event listed a score of 0% for the regulated analyte Bacteriology for 2021 Events 2 and 3 with the remarks, "unsuccessful" and "failure to participate." 4. Telephone Interview with API representative on 12/23/2021 at 2:21 PM revealed: a. 2021 Event 2 Throat Culture was delivered on 6/17/2021 at 1:05 PM and signed for by the laboratory director (LD). b. 2021 Event 3 Throat Culture was delivered on 9/23/2021 at 10:18 AM and signed for by the LD. 5. Staff interview via telephone with Physician #1 (P1) on 12/21/2021 at 1:33 PM: a. P1 stated it was P1's understanding that Event 2 was backordered by the PT program and Event 3 was not received. b. Confirmed the laboratory failed to participate in PT for 2021 Events 2 and 3 for the regulated analyte 005 Bacteriology.

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 proficiency testing (PT) record review and staff interview, the laboratory failed to successfully achieve satisfactory performance for two consecutive testing events for 2021 for the subspecialty of bacteriology. Findings include: 1. Record

review on 12/20/2021 of the Center for Medicare & Medicaid Services CASPER 0155D report revealed scores of 0% for the regulated analyte 0005 Bacteriology for 2021 Events 2 and 3. 2. Record review of American Proficiency Institute (API) PT records received from the laboratory via email on 12/23/2021 at 9:25 AM revealed: a. API PT Performance Summary for 2021 Microbiology 2nd event listed a score of 0% for the regulated analyte Bacteriology with the remark, "failure to participate." b. API PT Performance Summary for 2021 Microbiology 3rd Event listed a score of 0% for the regulated analyte Bacteriology for 2021 Events 2 and 3 with the remarks, "unsuccessful" and "failure to participate." 3. Staff interview via telephone with Physician #1 (P1) on 12/21/2021 at 1:33 PM: a. P1 stated it was P1's understanding that Event 2 was backordered by the PT program and Event 3 was not received. b. Confirmed the laboratory failed to participate in PT for 2021 Events 2 and 3 for the regulated analyte 0005 Bacteriology.