

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2023923	(X3) Date Survey Completed 08/03/2020
Name of Provider or Supplier F C Lab Lemont	Street Address, City, State 807 State St, Lemont, IL	
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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records and communication with the PT vendor American Association of Bioanalysts (AAB); this laboratory failed to successfully participate in the testing of Bacteriology PT samples. Findings include: 1. Review of the CASPER Report 155 on August 03, 2020 and communication with the PT provider at 09:53 AM confirmed the initial unsuccessful PT performance under the subspecialty of Bacteriology for PT event 1 and 2, of 2020. See D-2028.</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 surveyor review of CASPER Report 155, Proficiency Testing (PT) records and communication with the PT vendor American Association of Bioanalysts (AAB); this laboratory failed to successfully participate in the testing of Bacteriology PT samples. Findings include: 1. Review of the CASPER Report 155 on August 03, 2020 revealed that the initial unsuccessful PT performance occurred under the subspecialty of Bacteriology for PT event 1 and 2, of 2020 as listed below: BACTERIOLOGY EVENT - 1, 2020 = 0% Unsatisfactory EVENT - 2, 2020 = 0% Unsatisfactory 2. During a phone communication with the PT vendor AAB on August 03, 2020 at 09:53 AM, the Bacteriology PT failing scores for events 1 and 2, of 2020 were confirmed.