

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2063316	(X3) Date Survey Completed 07/02/2019
Name of Provider or Supplier Spiriplex, Inc	Street Address, City, State 100 Tri State International, Ste 100, Lincolnshire, 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 phone communication with the PT vendor College of American Pathologist (CAP); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the specialty of Diagnostic Immunology. Findings include: 1. Review of PT CASPER Report 155 on July 01, 2019 at 8:01 AM revealed that the unsatisfactory PT performance was a 3rd Subsequent PT failure that occurred during calendar years 2018 and 2019. See D2084.</p>
D2084	GENERAL IMMUNOLOGY

CFR(s): 493.837(f)

Failure to achieve satisfactory performance for the same analyte or test in 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 phone communication with the PT vendor College of American Pathologist (CAP); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the subspecialty of General Immunology and Immunoglobulin (IgE). Findings include: 1. Review of PT CASPER Report 155 on July 01, 2019 at 8:01 AM, revealed that the unsatisfactory PT performance was the 3rd-Subsequent PT failure that occurred during calendar years 2018 and 2019 as listed below. (1st-Subsequent PT failure) DIAGNOSTIC IMMUNOLOGY General Immunology EVENT-1, 2018 = 0% EVENT-2, 2018 = 40% Immunoglobulin E (IgE) EVENT-1, 2018 = 0% EVENT-2, 2018 = 40% (2nd-Subsequent PT failure) DIAGNOSTIC IMMUNOLOGY General Immunology EVENT-1, 2018 = 0% EVENT-2, 2018 = 40% EVENT-3, 2018 = 40% Immunoglobulin E (IgE) EVENT-1, 2018 = 0% EVENT-2, 2018 = 40% EVENT-3, 2018 = 40% (3rd-Subsequent PT failure) DIAGNOSTIC IMMUNOLOGY General Immunology EVENT-1, 2018 = 0% EVENT-2, 2018 = 40% EVENT-3, 2018 = 40% EVENT-1, 2019 = 0% Immunoglobulin E (IgE) EVENT-1, 2018 = 0% EVENT-2, 2018 = 40% EVENT-3, 2018 = 40% EVENT-1, 2019 = 0% 2. During PT Desk review on July 01, 2019 and phone communication with the PT vendor CAP at 1:50 PM, the 3rd-Subsequent PT failing scores were confirmed.