Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2063316	10/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Spiriplex, Inc	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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. 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 College of American Pathologists (CAP); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the Specialty Diagnostic Immunology. Findings include: 1. Review of the CASPER Report 155 on October 02, 2018 and communication with the PT vendor CAP on 10/03/17 at 2:45 PM, the initial unsuccessful PT performance was confirmed under the Subspecialty of General Immunology and analyte Allergen-Specific Immunoglobulin E (IGE) during event 1 and 2 of 2018. See D-2084.

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 communication with the PT vendor College of American Pathologists (CAP); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the Specialty Diagnostic Immunology. Findings include: 1. Review of the CASPER Report 155 on October 02, 2018, the initial unsuccessful PT performance was confirmed under the Subspecialty of General Immunology and analyte Allergen-Specific Immunoglobulin E (IGE) as described below: GENERAL IMMUNOLOGY EVENT -1, 2018 (0% Unsatisfactory) EVENT -2, 2018 (40% Unsatisfactory) EVENT -1, 2018 (IGE = 0% Unsatisfactory) EVENT -2, 2018 (IGE = 40% Unsatisfactory) 2. During a phone communication with the PT vendor CAP on October 03, 2018 at 2:45 PM, confirmed the PT failing scores.