

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2063316	<b>(X3) Date Survey Completed</b>  11/28/2022
<b>Name of Provider or Supplier</b>  Spiriplex, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with Chief Executive Officer (CEO), the laboratory failed to enroll in an approved proficiency testing (PT) program for high complexity Immunoglobulin E antibody testing from 2020 to the date of survey (11/28/2022). Finding Include: 1. Surveyor review of proficiency testing records failed to reveal documentation of the laboratory's enrollment in a Centers for Medicare &amp; Medicaid Services (CMS) approved PT program for testing Immunoglobulin E antibodies for three of three testing years (2020, 2021, and 2022). 2. Interview with CEO on 11/28/2022 at 12:30 p.m., revealed the laboratory did not participate in CMS approved PT due to the unavailability of dried blood stain samples required for testing.</p>
<b>D6141</b>	<p><b>GENERAL SUPERVISOR</b> CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p>

This CONDITION is not met as evidenced by:  
Based on review of laboratory records, Laboratory Personnel Report (CMS-209) and interview with Chief Executive Officer (CEO), the laboratory failed to ensure one of one general supervisors (GS) listed on the CMS-209 form met the qualification requirements for GS and provided day-to-day supervision of testing personnel and the reporting of high complexity immunology testing. (Refer to D6142 and D6143)

**D6142**

**GENERAL SUPERVISOR QUALIFICATIONS**  
CFR(s): 493.1461

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records, Laboratory Personnel Report (CMS-209), and interview with Chief Executive Officer (CEO), the laboratory failed to provide day-to-day supervision of testing personnel and the reporting of high complexity immunology testing. Findings Include: 1. Review of the laboratory qualifying records for the general supervisor (GS) listed on the CMS-209 revealed the laboratory failed to ensure the GS was qualified to perform day-to-day supervision of high complexity Immunoglobulin E Antibody testing and testing personnel for one of one testing year (2022). Refer to (D6143)

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**  
CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a

medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on review of laboratory records, Laboratory Personnel Report (CMS-209), lack of documentation, and interview with Chief Executive Officer (CEO), the laboratory failed to ensure one of one general supervisors (GS) was qualified for high complexity immunology testing. Findings Include: 1. Review of the master's degree and Bachelor of Science degree for one of one GS listed on CMS-209 (11/28/2022) revealed the GS failed to meet qualification requirements for supervising high complexity Immunoglobulin E Antibody testing. a. Master of Health Administration b. Bachelor of Science in Business 2. The laboratory failed to have college transcript records on file to confirm the required credit hours in biology and chemistry to qualify the GS. 3. On 11/28/2022 at 1:23 p.m., CEO confirmed the laboratory did not have college transcripts on file for the GS listed on the CMS-209 form.