

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2063316	(X3) Date Survey Completed 09/17/2026
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to follow written policies and procedures to assess technical supervisor (TS) and general supervisor (GS) competency for one of one individual serving as the TS and GS. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed the same individual serving as both the TS and the GS for laboratory. 2. Review of laboratory policies and procedures revealed the procedure titled "Employee Training and Competency", which stated, under "6. Laboratory Supervisor-Laboratory Director will evaluate Lab Supervisor for competency as follows: "6.1 Is the Supervisor available to test personnel at all times testing is performed? Whether on site or by phone is acceptable. "6.2 Must provide regular on-going supervision of testing personnel. "6.3 Must monitor test analyses through adjustments and QC [Quality Control] to ensure acceptable levels of performance. "6.4 Reviewed QC prior to patient analysis and reviews patient results for release. "6.5 Fulfills responsibilities as delegated by the Laboratory Director. "6.6 Resolves any technical issues in laboratory. "6.7 Provides orientation and training to test staff personnel. "6.8 Annually, evaluates and documents the performance of all laboratory testing staff. "6.9 Performs Quality Assurance monitors on regular basis. "6.10 Report all findings and nonconformance to the Laboratory Director." 3. Review of laboratory records, including personnel files containing employee competencies, revealed a lack of competencies for one of one individual serving as the TS and GS. 4. Interview with the LD on 09/17/2026, at 1:31

pm, confirmed the laboratory failed to follow written policies and procedures to assess TS and GS competency for one of one individual serving as the TS and GS.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory system for 24 of 24 months reviewed. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Management Plan", which stated, under "6. Quality Indicators", "6.1 The Quality Management Committee will determine what areas need to be surveyed outside of those monitors scheduled throughout the year. Problems may be identified by regular review of the laboratory's data sources by establishing monitors, setting criteria, and measuring actual practice against criteria. Monitors may at times be removed and replaced with other monitors. "6.2 Personnel Training and Competency 6.2.1 Annual review in January "6.3 Proficiency Testing "6.4 Internal Quality Control [QC] 6.4.1 Review monthly QC reports with LD 6.4.2 Responsible person: Laboratory Manager 6.4.3 Internal QC (monitoring of test results by using controls within acceptable ranges) shall be reviewed weekly, monthly and at the periodic QA [Quality Assurance] meetings. The LO [Laboratory Owner] shall evaluate and decide any remedial action to be taken. 6.4.4 Data Source and Acceptance Criteria: a) Monthly Levy-Jennings charts, shifts and trends reviewed by LO with recommendations b) Remedial Action Reports, reviewed at the periodic QA meetings for unusual events, procedures updated accordingly. c) Acceptable threshold: 95% "6.5 Maintenance of Equipment Used to Perform Laboratory Tests 6.5.1 Responsible person: Laboratory Manager [LM] 6.5.2 Visual check of equipment is done daily by testing personnel. Preventative maintenance is performed daily and/ or per run, weekly, and monthly on all equipment according to manufacturer's specifications. a) Daily, weekly, and monthly preventative maintenance logs will be reviewed. b) Repair records, excessive calls to customer service resulting in repair by the field engineer must be investigated and resolved with the manufacturer. "6.6 Effectiveness of Policies and Procedures 6.6.1 Responsible person: Laboratory Director 6.6.2 All policy and procedure manuals shall be reviewed annually by the LO and updated as necessary by the LM to reflect current practice. New policies may be generated based on the review. "6.7 Data Entry Tracking 6.7.1 This task can be done several times per year especially during new hires and training periods. 6.7.2 Responsible person: Laboratory Manager 6.7.3 Randomly select 10 requisitions and check the entered information to make sure that all the information was entered properly. If errors are found, they will be discussed with the employee that entered the information and another random check will occur within 30 days. If at the second check errors are found, the issue will be brought to the LD's attention and LO with LM will decide if the data entry tasks are appropriate for the employee." 2. Review of laboratory records revealed a lack of documentation of quality assurance checks performing in the laboratory for the previous 24 months

reviewed. 3. Interview with the LD on 09/17/2026, at 1:33 pm, confirmed the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory system for 24 of 24 months reviewed.