

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396915	(X3) Date Survey Completed 09/30/2020
Name of Provider or Supplier Spooner Health System	Street Address, City, State 1280 Chandler Dr, Spooner, WI	
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 the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) reports and American Proficiency Institute (API) PT records, the laboratory failed to successfully participate in PT for the Compatibility Testing subspecialty in the Immunohematology specialty for PT events 2020-1 and 2020-2. Findings include: 1. Review of PT records in the federal CASPER reporting system as of September 30, 2020 shows the laboratory had unsatisfactory performance for compatibility testing on events 2020-1 and 2020-2. A score of 100% is required for satisfactory performance for compatibility testing. Event 2020-1, score 80% Event 2020-2, score 80% 2. Surveyor review of the API PT</p>

evaluation reports confirmed the unsatisfactory scores for compatibility testing for two consecutive PT events which results in unsuccessful participation in PT for compatibility testing. See D 2181.

D2181

COMPATIBILITY TESTING
CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory 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 the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) reports and American Proficiency Institute(API) PT records, the laboratory failed to successfully participate in PT for the Compatibility Testing subspecialty in the Immunohematology specialty in events 2020-1 and 2020-2. Findings include: 1. Review of PT records in the federal CASPER reporting system on September 30, 2020 shows that the laboratory had unsatisfactory performance for compatibility testing on events 2020-1 and 2020-2. A score of 100% is required for satisfactory performance for compatibility testing. Event 2020-1, score 80% Event 2020-2, score 80% 2. Surveyor review of the API PT evaluation reports on September 30, 2020 confirmed the unsatisfactory scores for compatibility testing for two consecutive PT events which results in unsuccessful participation in PT for compatibility testing.