

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384673	(X3) Date Survey Completed 06/04/2020
Name of Provider or Supplier Mercyone New Hampton Medical Center	Street Address, City, State 308 North Maple Avenue, New Hampton, IA	
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 review of proficiency records and reports, the laboratory fails to successfully participate in a proficiency testing program for the analyte, compatibility testing, for three consecutive testing events: 2019 event 2, 2019 event 3, and 2020 event 1 (refer to D2181).
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 review of proficiency testing reports and records, the laboratory fails to achieve satisfactory performance for the analyte, compatibility testing, for three consecutive proficiency testing events for unsuccessful participation. The laboratory received unsatisfactory performance scores of 60% for 2019 testing event 2, 80% for 2019 testing event 3 and zero for 2020 testing event 1.