Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384673	(X3) Date Survey Completed 10/03/2024
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
D0000	A proficiency testing desk review survey was completed on 10/2/2024, the laboratory was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R 493.803 Condition: Successful Participation D6076 - 42 C.F.R 493.1441 Condition: Laboratory Director, high complexity
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 the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute

	(API), the laboratory failed to successfully participate in two consecutive testing events in the subspecialty of compatibility testing. The laboratory had unsatisfactory scores for 2024 event 1 and 2024 event 2. 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 the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance (100% or greater) for two consecutive testing events in the subspecialty, compatibility testing. The findings include: 1. For 2024 event 1, the laboratory received an unsatisfactory performance score of 60% for the subspecialty, compatibility testing. 3. For 2024 event 2, the laboratory received an unsatisfactory performance score of 80% for the subspecialty, compatibility testing. 3. The CASPER 155 report and graded results from API confirm the findings listed above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from American Proficiency Institute (2024 event 1 and 2024 event 2), the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2181.