

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0386206	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Mercyone Elkader Medical Center	Street Address, City, State 901 Davidson Street Nw, Elkader, 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 failed to successfully participate in a proficiency testing program for the analyte, white blood cell differential, for two consecutive testing events: 2023 events 1 and 2 (refer to D2130).
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

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 (PT) reports and records, the laboratory fails to achieve satisfactory performance for the analyte, white blood cell differential, for two consecutive PT events for unsuccessful participation. The laboratory received unsatisfactory performance scores of 8% for 2023 testing event 1 and 64% for 2023 testing event 2.