

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384037	(X3) Date Survey Completed 06/21/2022
Name of Provider or Supplier Mercyone Buffalo Center Rural Family Medicine	Street Address, City, State 115 North Main Street, Buffalo Center, 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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the c-reactive protein (CRP) procedure, quality controls records, the laboratory specimen log, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 6/21/2022; the laboratory failed to perform two levels of CRP quality control materials each day of patient testing for one out of 12 days from 1/1/2022 - 3/4/2022. The findings include: 1. The CRP procedure stated that quality controls will be performed each day of patient testing. 2. On 1/12/2022, the laboratory performed CRP testing on one patient using reagent lot number KL18-5, expiration date 2022-02-05. 3. The laboratory did not perform two levels of CRP quality controls on 1/12/2022.</p>