Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0386318	(X3) Date Survey Completed 06/27/2018
Name of Provider or Supplier Regional Health Services Of Howard County	**Street Address, City, State** 235 8th Avenue West, Cresco, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient testing and quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 06/27/2018, the laboratory failed to perform and document a negative and positive control at least each day of patient testing for rheumatoid factor testing for 16 days of patient testing from 09/08/2017- 05/25/2018. The findings include: 1. The laboratory's rheumatoid factor procedure stated that two levels of quality control are to be performed each day of patient testing. 2. Review of the laboratory's patient testing and QC records indicated that the laboratory performed rheumatoid factor patient testing but did not document QC performance on the following dates: 09/08/2017 (1 patient test), 09/12/2017 (1 patient test), 09/19/2017 (1 patient test), 10/05/2017 (1 patient test), 10/12/2017 (1 patient test), 10/20/2017 (1 patient test), 11/30/2017 (1 patient test), 02/01/2018 (1 patient test), 02/13/2018 (1 patient test), 03/01/2018 (1 patient test), 03/12/2018 (1 patient test), 03/27/2018 (1 patient test), 04/09/2018(2 patient tests), 04/20/2018 (1 patient test), 04/23/2018 (1 patient test), and 05/25/2018 (1 patient test). 2. At the time of the survey, the laboratory did not have QC documentation for the previously listed dates of patient testing.