Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386318	07/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Regional Health Services Of Howard County	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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of Access II chemistry quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 07/07/2022, the laboratory failed to take and document corrective action when thyroid stimulating hormone (TSH) QC failed to meet the laboratory's established criteria for one out of 30 days of patient testing in April 2022. The findings include: 1. For level 3 TSH control lot number 85263 (expiration 11/30 /22), the laboratory established an acceptable range of 24.34- 32.06 uIU/mL. 2. On 04 /05/2022, the laboratory recorded a result of 32.35 uIU/mL for level 3 TSH QC. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have corrective action for the out of range QC on 04/05/2022.