Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	16D0386318	09/23/2020

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Cepheid GeneXpert operator's manual, maintenance records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory failed to perform an annual calibration of the Cepheid GeneXpert analyzer for two out of three time periods (2/14/2018 - 7/29/2020). The findings include: 1. The Cepheid GeneXpert operator's manual indicated it is necessary to calibrate the analyzer annually. 2. The laboratory calibrated the analyzer upon installation on 2/14/2018. 3. Laboratory personnel identifier #1 confirmed that laboratory had not calibrated the analyzer since the installation.