Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384720	10/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Community Memorial Hospital	909 West First Street, Sumner, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observations made during the survey, review of Vidas 30 calibration records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 10/14/2020, the laboratory failed to retain the thyroid stimulating hormone (TSH) Vidas 30 calibration records for a minimum of two years for 19 out of 21 months (1/1/2019 - 9/30/2020). The findings include: 1. The laboratory retained the Vidas 30 calibrations in the analyzer, and had TSH calibrations from 8/12/20, 8/28/20, 9/14/20 and 9/30/20. 2. The laboratory did not realize the Vidas only stored the last four calibrations. 3. At the time of the survey, the laboratory did not have any calibrations prior to 8/12/20.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the General Laboratory Procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 00 am on 10/14/20, the laboratory failed to have the following procedures: preparation and staining of manual blood smears; criteria for performing manual differentials and for pathology review of abnormal blood smears; and performing potassium hydroxide, wet mount, and urine sediment examinations.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on lack of thermal probe records, review of the i-STAT operator's guide and verification of performance specification records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 10/14/20, the laboratory failed to perform the thermal probe function check on the i-STAT test system every six months for two out of two time periods (9/1/2019 - 10/1 /2020). The findings include: 1. In September 2019, the laboratory started performing troponin testing on patients using the i-STAT test system. 2. The i-STAT operator's manual stated that the thermal probe check must be performed every six months. 3. At the time of the survey, the laboratory did not have thermal probe check records for the i-STAT test system.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on lack of training records, review of i-STAT verification of performance specification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 10/14/20, the laboratory director failed to ensure that prior to testing patients' samples using the i-STAT test system all personnel receive the appropriate training for three out of three testing personnel (identifiers #1 - #3). The findings include: 1. In September 2019, the laboratory started performing troponin testing on patients using the i-STAT test system. 2. At the time of the survey, the laboratory did not have training records for personnel identifiers #1 - #3 for the i-STAT test system.