Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0038924	10/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Henry County Health Center Inc	407 South White Street, Mount Pleasant, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plans (IQCP) and quality control records for i-STAT analyzers, serial numbers (SN) 353208 and 393801, and confirmed by the laboratory personnel, identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:40 pm on 10/28/2020; the laboratory failed to follow its IQCP for the frequency of external liquid quality control (QC) testing for the i-STAT analyzers for 3 out of 3 months (January-March 2020). The findings include: 1. The laboratory used the i-STAT analyzers to perform arterial and venous blood gas testing. 2. The laboratory's i-STAT IQCP required the laboratory to perform external control testing with each new shipment, monthly, new user and any suspect cartridge lot. 3. Records revealed that the laboratory performed monthly QC on only analyzer SN 353208 for January and February 2020 and only analyzer SN 393801 for March 2020. 4. During January and February 2020, the laboratory used analyzer SN 393801 to test 34 patient specimens and failed to perform external liquid QC testing. 5. During March 2020, the laboratory used analyzer SN 353208 to test one patient specimen and failed to perform external liquid QC testing.
D5777	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of immunohematology testing records (ABO, Rh, antibody screen and compatibility testing) for February 2020 and interview with the laboratory personnel identifier #2 (Refer to the CMS-209 form, Laboratory Personnel Report) at 10:40 am on 10/28/2020, the laboratory failed to document the patient history check for 12 out of 12 patients who had testing performed for transfusion purposes. The findings include: 1. According to the laboratory personnel identifier #2, the testing personnel who performs the tests is to check the patient history in the laboratory information system and document the check. 2. Review of patient test records from February 2020 revealed that the laboratory failed to document the patient history check.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the histopathology patient test records and reports and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report, Form CMS-209) at approximately 2:50 pm on 10/28/2020; the laboratory failed to indicate on the test report the name and address of the laboratory performing frozen section testing for 7 out of 7 patients from January-October 2020. The findings include: 1. Records reveal that frozen sections were performed and read at the laboratory on the following patients and dates: patient identifier #1 01/20/2020; patient identifier #2 01 /30/2020; patient identifier #3 03/26/2020; patient identifier #4 05/28/2020; patient identifier #5 06/26/2020; patient identifier #6 09/03/2020 and patient identifier #7 10 /01/2020. 2. Review of the test reports for the patient identifiers #1-#7 revealed that the reports did not indicate the name and address of the laboratory location where the frozen sections testing was performed.