Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0037201	04/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Caro Community Hospital	401 N Hooper St, Caro, MI	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the General Supervisor #1 (GS1), the laboratory failed to use 3 (red top Becton Dicken drawing tubes) of 3 specimen collection supplies before the expiration date found in the laboratory drawing station. Findings include: 1. During a tour of the laboratory on 04/11/2022 at 9:32 am, the surveyor observed 3 of 3 specimen collection supplies still in circulation in the laboratory drawing station past their expiration dates. 2. An interview on 04/11/2022 at 9:32 am, the GS1 confirmed the above supplies were still in circulation past their expiration dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by:

	. Based on observation, lack of documentation, and interview with General Supervisor #1 (GS1), the laboratory failed to establish a maintenance protocol for its centrifuges for 2 (April 2020 to April 2022) of 2 years reviewed. Findings include: 1. The surveyor observed the Clearpoint Diagnostic centrifuge located in the specimen collection area of the laboratory making loud noises while in operation on 4/11/22 at 9: 02 am. The centrifuge had a sticker on the side noting service was performed in April 2021 and due in July 2021. 2. The surveyor requested documentation of centrifuge maintenance on 4/11/22 at 9:33 am and it was not made available. 3. The surveyor requested the centrifuge maintenance policy on 4/11/22 at 2:26 pm and it was not made available. 4. An interview on 4/11/22 at 2:35 pm with GS1 confirmed documentation of maintenance for centrifuges and a policy for the performance of centrifuge maintenance was not available.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #1 (GS1), the laboratory failed to perform and document the visual inspection of red blood cells immediately before distribution in accordance with 21 CFR 606.160(b)(3)(ii) for 3 (Patients FLTB3935, FLT3615, and SFFY0365) of 4 patient transfusion records reviewed. Findings include: 1. A review of the laboratory's "Blood Bank" policy revealed a section titled, "Visual Inspection of Blood" stating, "Each unit of blood is inspected when initially circulated. All units in circulation are inspected daily. Each unit is inspected again when it is selected for crossmatching. Each unit is inspected when it is issued." 2. A review of patient transfusion records revealed a lack of documentation of visual inspections performed immediately before distribution for the following patients: a. Patient FLTB3935 receiving two units packed red blood cells on 1/27/22. b. Patient FLT3615 receiving two units of packed red blood cells on 8/4/21. c. Patient SFFY0365 receiving one unit of packed red blood cells on 5/27/20. 3. An interview on 4/11/22 at 11:00 am with GS1 confirmed documentation of the visual inspection of blood products immediately before distribution was not available.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with General Supervisor #1 (GS1), the laboratory director failed to monitor the preanalytic,

	analytic, and postanalytic systems in the established Individualized Quality Control Plan (IQCP) for 2 (April 2020 to April 2022) of 2 years reviewed. Findings include: 1. A record review of the laboratory's established IQCP revealed the lack of documentation to monitor, assess, review, and correct problems identified for the serum human chorionic gonadatropin (hCG) and the D-dimer testing for 2 (April 2020 to April 2022) of 2 years reviewed. 2. The established "IQCP Procedure" in step 3 "Quality Assessment (QA) states the following: "A. Quality Assessment puts into place the following: 1. Outlines the Quality Assessment (QA) practices for the laboratory 2. Monitor the Quality Control Plan (QCP) continuously for effectiveness 3. Revises policies, and procedures necessary to prevent recurrence of problems 4. Discusses reviewing QA with appropriate staff 5. Documents all QA activities" 3. An interview on 4/11/2022 at 11:49 am, GS1 confirmed the laboratory director did not monitor the quality assessment plan on a routine basis, monitor the effectiveness, revise policies and procedures, discuss with appropriate staff and document all QA activities.