

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0037201	<b>(X3) Date Survey Completed</b>  01/15/2020
<b>Name of Provider or Supplier</b>  Caro Community Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review and interview with General Supervisor (GS) 1 and GS2, the laboratory failed to retain the microbiology blood culture manufacturer's certificate of compliance for 2 (January 2018 to January 2020) of 2 years. Findings include: 1. Record review of the microbiology blood culture bottles revealed the laboratory did not retain the manufacturer's certificate of compliance with each new lot and/or shipment of blood culture bottles. 2. When queried on 01/15/2020 at approximately 1:55 pm, GS2 stated that central supply is unpacking and delivering the bottles to the lab and the certificate of compliance was not a part of the delivery. 3. During the interview on 01/15/2020 at 1:55 pm, GS1 and GS2 confirmed the certificate of compliance for the blood culture bottles was not retained for 2 of 2 years.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, record review, and interview with General Supervisor #1 (GS1) and General Supervisor #2 (GS2), the laboratory failed to label an aliquot of Bio-Rad Lyphochek Immunoassay Plus Control level 3 with the expiration date for one vial in use. Findings include: 1. An observation made by the surveyor on 1/15/2020 at 9:02 am revealed an aliquot in the laboratory's chemistry freezer labeled "Immunoassay + 3" with the date made being 12/30/2019, but no expiration date was indicated on the container. 2. A record review of the package insert for the Bio-Rad Lyphochek Immunoassay Plus Control revealed that, when reconstituted and frozen, the stability for all analytes is 20 days. 3. An interview on 1/15/2020 at 1:49 pm with GS1 and GS2 confirmed an expiration date was not present on the vial of quality control.

**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:

A. Based on manufacturer's package insert and interview with the General Supervisor (GS) 1 and GS2, the laboratory failed to calibrate the blood bank Antibody screening and identification, ABO blood grouping and Rh phenotyping, Compatibility testing, Reverse serum grouping and antigen typing MTS Dispensers (0.5 and 1.0) for 2 (January 2018 to January 2020) of 2 years in use. Findings include: 1. Manufacturer's package insert for the MT Dispenser (repetitive Dispenser of 0.5 or 1.0 ml) states under Calibration Check - "A calibration check should be done as part of a routine laboratory quality control schedule and after each repair." Further review of the insert revealed "Calibration of the MTS Dispenser is set by the manufacturer and cannot be adjusted by the user." Contact Ortho Clinical Diagnostics, Inc. for assistance. 2. When queried on 01/15/2020 at 1:38 pm, GS1 and GS2 were not able to provide the surveyor documentation of the calibrations for 2 of 2 years. 3. During the interview on 01/15/2020 at 1:38 pm, GS1 and GS2 confirmed the laboratory did not perform and document the MTS Dispenser calibrations for 2 years. B. Based on procedure manual review, record review, and interview with General Supervisor (GS) 1 and GS2, the laboratory failed to establish and implement thermometer calibrations for 2 (January 2018 to January 2020) of 2 years in use. Findings include: 1. Procedure manual review revealed the laboratory did not establish a policy for the function checks for the calibration of thermometers. 2. When queried on 01/15/2020 at 2:30 pm for the calibration records, GS2 was unable to produce the documentation for the surveyor. 3. During the interview on 01/15/2020 at 2:30 pm, GS1 and GS2 confirmed the laboratory failed to establish and implement a thermometer calibration function check.

**D5465**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(8)(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--  
Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview with General Supervisor #1 (GS1) and General Supervisor #2 (GS2), the laboratory failed to test quality control materials in the same manner as patients for Acetone testing for 2 (January 2018 to January 2020) of 2 years. Findings include: 1. An observation by the surveyor on 1/15/2020 at 9:02 am revealed a bottle of K-Check tablets, used in testing for Acetone, in the laboratory. 2. A record review of the laboratory's established "Acetone" policy revealed a section stating, "Acetest reagent tablets are primarily used to test for the presence of ketones in urine, serum, plasma." 3. A record review of the K-Check tablets package insert revealed a section titled "Quality Control for serum, plasma, or whole blood" stating, "Laboratories should follow the applicable government regulations and local guidelines for quality control. The control intervals should be adapted to each laboratory's requirements. The recommended serum controls can be purchased. At least a positive and negative control must be run each time a new bottle of K-Check is opened. A positive control for urine can also be prepared by diluting 50 microlitres of acetone fo 40 mL of distilled water. The preparation should be comparable to "small" on the color chart." 4. A record review of the K-Check tablets package insert revealed a section titled "Quality Control for Urine (CLIA waived)" stating, "Perform QC with each test run. Follow the instructions under the "Procedure" section of the product insert." 5. A record review of the laboratory's established "Acetone" policy revealed a section titled "Quality Control" stating, "Run each day of patient testing. Positive control- MAS Urinalysis Level 1, Negative control- MAS Urinalysis Level 3." 6. An interview on 1/15/2020 at 12:18 pm with GS1 and GS2 confirmed the laboratory was testing patient urine, serum, and plasma specimens, but only performing quality control with the urine matrix.

**D5477**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on document review and interview with General Supervisor (GS) 1 and GS2, the laboratory failed to check each batch of media for physical characteristics, sterility, ability to support growth, select and/or inhibit specific organisms or produce a biochemical change for each new lot of Remel MacConkey Agar, Chocolate, and Blood Agar with sheep blood for 2 (January 2018 to January 2020) of 2 years of bacteriology testing. Findings include: 1. Record review revealed a lack of documentation for the media quality control checks for each new lot and/or shipment of MacConkey agar, Chocolate, and Blood agar with sheep blood media for 2 of 2 years of review. 2. When queried on 01/15/2020 at 1:55 pm, GS2 stated that the media is quality controlled at the main hospital and then transported to the satellite lab. 3. During the interview on 01/15/2020 at 1:55 pm, GS1 and GS2 confirmed the quality

control is performed at the main hospital and that no verification of that testing is transported with the media to the satellite office and that the physical characteristics of the media were not documented when the media arrived at the satellite lab.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

. Based on record review and interview with General Supervisor #1 (GS1) and General Supervisor #2 (GS2), the laboratory director failed to establish a quality assessment procedure to monitor preanalytic, analytic, and postanalytic systems in the established Individualized Quality Control Plan for 2 (January 2018 to January 2020) of 2 years. Findings include: 1. A record review of the laboratory's established Individualized Quality Control Plan (IQCP) revealed a lack of quality assessment procedures to monitor, assess, review and correct problems identified in serum human chorionic gonadotropin (hCG) and D-dimer testing. 2. The surveyor requested the IQCP quality assessment plan on 1/15/2020 at 2:35 pm and it was not made available. 3. An interview on 1/15/2020 at 2:35 pm with GS1 and GS2 confirmed the laboratory director did not establish a quality assessment plan as part of the IQCP.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

. Based on record review and interview with General Supervisor #2 (GS2), the laboratory director failed to ensure proficiency testing reports were reviewed by testing personnel for 3 (third chemistry event of 2018, second microbiology event of 2019, and the third chemistry event of 2019) of 18 testing events reviewed. Findings include: 1. A record review of the American Proficiency Institute (API) proficiency testing records revealed a lack of testing personnel review for the following testing events: a. Third chemistry event of 2018 b. Second microbiology event of 2019 c. Third chemistry event of 2019 2. An interview on 1/15/2020 at 10:12 am with GS2 confirmed there was no documented review of proficiency testing by testing personnel performing the events listed above.