

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0260979	<b>(X3) Date Survey Completed</b>  10/19/2022
<b>Name of Provider or Supplier</b>  Evans Memorial Hospital	<b>Street Address, City, State</b>  200 North River Street, Claxton, GA	
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>D0000</b>	Based on the onsite recertification survey conducted on 10/19/2022, this facility was found NOT in compliance with CLIA regulations found at 42 CFR 493.1250 Condition: Analytic Systems 493.1403 Condition: Laboratory Director
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Blood Bank (BB) Quality Control Records, BB Transfusion Record Log, and staff interview, it was revealed the laboratory failed to ensure quality lab services in analytic systems. The findings include: 1. The laboratory failed to ensure that reagents used for BB testing had not exceeded their expiration date prior to patient testing. (refer to D5417).</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Blood Bank (BB) Quality Control Records (QCR), and staff interview, the laboratory failed to ensure testing reagents did not exceed their expiration date prior to clinical use. The findings include: 1. A review of the of the BBCC (Blood Bank Check Cells) QCR data, from November 2020 to October 2022, revealed: a. 02/23/2022 BBCC used this day of testing was documented as expired on 02/21/2022 There was a two unit crossmatch performed on this day b. 03/30/2022, BBCC used this day of testing was documented as expired on 03/28/2022 There was a two unit crossmatch and Group and rH performed on this day c. 05/24/2022 BBCC used this day of testing was documented as expired on 5/23/2022. There was a one unit crossmatch performed on this day d. 06/23/2022 BBCC used this day of testing was documented as expired on 06/20/2022. There was a two unit crossmatch performed on this day. 2. An interview with the Laboratory Technical Supervisor, and the BB General Supervisor, on 10/19/2022, at approximately 2pm, in the Hospital Conference Room, confirmed the above findings.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:  
Based on review of the Blood Bank Quality Control Record (BBCR) and staff interview, it was revealed the testing personnel failed to recognize that the Blood Bank Check Cells (BBCC), used on four days of patient testing, expired prior to the date of clinical use. The findings include: 1. A review of the BBCR revealed that laboratory personnel are required to write the lot number and expiration date of the reagents in use for the Blood Bank (BB) testing on the day of testing. 2. The laboratory personnel failed to recognize that the BBCC, in use the day of testing, had expired. a. patient testing performed 02/23/2022, BBCC cells documented as expired on 02/21/2022 b. patient testing performed 03/30/2022, BBCC cells documented as expired on 03/28/2022 c. patient testing performed 05/24/2022, BBCC cells documented as expired on 05/23/2022. d. patient testing performed 06/23/2022, BBCC cells documented as expired on 06/20/2022. 2. Staff interview with the Laboratory Technical Supervisor, and the BB General Supervisor, on 10/19/2022, at approximately 2pm, in the Hospital Conference Room, confirmed the above aforementioned statements.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
A review of the Blood Bank Quality Control Record (BBCR), and staff interview, revealed the Laboratory Director (LD) failed to provide overall guidance and direction of the laboratory. The findings include: 1. The Laboratory Director failed to ensure the laboratory's BB quality control program was effective. ( refer to D6093).

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the Blood Bank Quality Control Records (BBQR), signed as reviewed by the Laboratory Director (LD), revealed the LD failed to provide overall management and direction on the use of expired Blood Bank Check Cells (BBCC) for the testing of Group and Type, rH, and Crossmatch units of blood. The findings include: 1. A review of the BB QCR the BBCC used for the following days revealed the LD reviewed and signed QC records indicating the use of expired BBCC for the following days of testing. a. LD signoff on the use of expired cells for patient testing on 02/23/2022, BBCC expired on 02/21/2022. b. LD signoff on the use of expired cells for patient testing on 03/30/2022, BBCC expired on 03/28/2022. c. LD signoff on the use of expired cells for patient testing on 05/24/2022, BBCC expired on 05/23/2022. d. LD signoff on the use of expired cells for patient testing on 06/23/2022, BBCC expired on 06/20/2022. 2. Interview with the Laboratory Technical Supervisor and the BB General Supervisor, on 10/19/2022, at approximately 2pm, in the hospital conference room, confirmed the above aforementioned statements.