

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0382831	<b>(X3) Date Survey Completed</b>  07/26/2018
<b>Name of Provider or Supplier</b>  Greene County Medical Center	<b>Street Address, City, State</b>  1000 W Lincoln Way, Jefferson, IA	
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>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2017-2018 chemistry proficiency testing (PT) records and confirmed by the laboratory personal identifier #1 (refer to Laboratory Personal Report) at approximately 12:00 PM on 07/26/2018, the laboratory failed to take and document corrective action for two unsatisfactory PT scores from 2018 event-1 and three unacceptable PT scores from 2017 event-3, 2018 event-1 and 2018 event-2. The findings include: 1. For 2018 event-1, the laboratory received an unsatisfactory score of 60 percent (%) for alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT). 2. For 2017 event-3, the laboratory received an unacceptable score of 80% for blood urea nitrogen. 3. For 2018 event-1, the laboratory received an unacceptable score of 80% for calcium. 4. For 2018 event-2, the laboratory received an unacceptable score of 80% for NT-proB-type natriuretic peptide (BNP). 5. At the time of the survey, the laboratory did not take and document corrective action for the unsatisfactory and unacceptable proficiency testing results listed above.</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must</p>

be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

(A) Based on review of 2018 equipment maintenance records and procedure and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:40 AM on 07/26/2018, the laboratory failed to document centrifuge function checks, including revolutions per minute (RPM) and timer checks, for the Ortho ID-Micro Typing System (MTS) centrifuge installed and in use January 2018. The findings include: 1. According to the laboratory's procedure for centrifuge RPM and timer checks, centrifuge checks are to be performed twice a year by the Unity Point BioMed technician. 2. At the time of the survey, the laboratory did not have maintenance records documenting the RPM and timer checks for the new Ortho MTS centrifuge. 3. The laboratory personnel identifier #1 confirmed that the laboratory failed to check the new Ortho MTS centrifuge. (B) Based on review of 2018 blood bank maintenance log and records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:20 AM on 07/26/2018, the laboratory failed to perform and document Ortho ID-Micro Typing System (MTS) dispenser calibration checks each quarter for two out of two quarters in 2018. 1. According to the blood bank maintenance log, the laboratory is to calibrate the MTS dispenser quarterly. 2. At the time of the survey, the laboratory did not have quarterly calibration records for the MTS dispenser. 3. The laboratory personnel identifier #1 confirmed that the laboratory failed to calibrate the MTS dispenser quarterly.