

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0387141	<b>(X3) Date Survey Completed</b>  07/26/2018
<b>Name of Provider or Supplier</b>  Monroe County Hospital	<b>Street Address, City, State</b>  6580 165th Street, Albia, 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>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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: Based on observations made during a tour of the laboratory and confirmed by laboratory personnel identifiers #2 and #3 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 07/26/2018, the laboratory failed to ensure that they did not use the 0.8% Affirmagen A1 and B cells reagents beyond their expiration date. The findings include: 1. Observations made during a tour of the laboratory revealed the 0.8% Affirmagen A1 and B cells (lot number 8A812) currently in use had expired 07/17/2018. 2. Review of the blood bank patient record book indicated that the laboratory performed one ABO group test on 07/23/2018 and one ABO group test on 07/24/2018.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:  
Based on review of personnel records and confirmed by laboratory personnel identifier #28 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 07/26/2018, the laboratory director failed to ensure that prior to testing patients' specimens, all testing personnel performing moderate complexity testing received the appropriate training for one out of 11 new testing personnel (laboratory personnel identifier #23) hired between October 2016 and May 2018. The findings include: 1. Personnel identifier #23 began patient testing in December 2016. 2. At the time of the survey, the laboratory did not have documented training for personnel identifier #23.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of personnel records and confirmed by laboratory personnel identifier #28 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 07/26/2018, the technical consultant failed to assess the competency of individuals performing moderate complexity testing at least semiannually during the first year the individual tests patient specimens for one out of 11 new testing personnel (personnel identifier #23) hired between October 2016 and May 2018. At the time of the survey, the laboratory did not have semiannual competency assessments for personnel identifier #23.