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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D2077152 | (X3) Date Survey Completed 05/15/2018 |
| Name of Provider or Supplier Mercyone Ankeny Briarwood Family Medicine Clinic | Street Address, City, State 120 Nw 36th Street, Ankeny, IA | |
| 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 |
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| D6029 | <p>LABORATORY DIRECTOR RESPONSIBILITIES 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> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 05/15/2018, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for three out of three new testing personnel (personnel identifiers #6, #7, and #8) hired in 2016. The findings include: 1. The laboratory hired personnel identifier #6 in April 2016. 2. The laboratory hired personnel identifier #7 in May 2016. 3. The laboratory hired personnel identifier #8 in August 2016. 4. At the time of the survey, laboratory personnel identifier #2 confirmed that the laboratory did not have training records available for personnel identifiers #6, #7, and #8.</p> |
| D6055 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test</p> |

methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of testing personnel records, the Alere Triage performance specification records, and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 2:15 pm on 05/15/2018, the technical consultant failed to document training for the Alere Triage (D-dimer) test system prior to reporting patient test results for four out of five testing personnel (laboratory personnel identifiers #3, #4, #5, and #7). The findings include: 1. The laboratory began using the Alere Triage test system in May 2016. 2. At the time of the survey, the laboratory did not have training records for testing personnel identifiers #3, #4, #5, and #7.