

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2056586	<b>(X3) Date Survey Completed</b>  04/29/2019
<b>Name of Provider or Supplier</b>  Muscatine Fire Department	<b>Street Address, City, State</b>  312 East Fifth Street Ste 2, Muscatine, 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>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 04/29/2019, the laboratory failed to retain signed PT attestation statements for three out of seven PT testing events in 2017- 2019 (2018 events 2 and 3 and 2019 event 1). At the time of the survey, the laboratory did not have signed PT attestation statements available for 2018 testing events 2 and 3 and 2019 testing event 1.</p>
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 04/29/2019, the laboratory failed to perform a self evaluation of ungraded PT scores for four out of seven PT testing events in 2017-2019 (2018 events 1, 2, 3 and 2019 event 1). The findings include: 1. For 2018 testing event 1, the laboratory received ungraded PT test scores for the following: *2018 Chemistry Core Survey- creatine</p>

kinase muscle/brain isoenzyme (CK-MB), specimen CM- 01 \*2018 Chemistry Core Survey- Myoglobin, specimens CM- 01, CM- 03, and CM- 04 \*2018 Chemistry Core Survey- Troponin I, specimen CM- 04 2. For 2018 testing event 2, the laboratory received ungraded PT test scores for the following: \*2018 Chemistry Core Survey- CK-MB, specimen CM- 10 \*2018 Chemistry Core Survey- Myoglobin, specimens CM- 06, CM- 07, CM- 08, and CM- 09 3. For 2018 testing event 3, the laboratory received ungraded PT test scores for the following: \*2018 Chemistry Core Survey- CK-MB, specimen CM- 12 \*2018 Chemistry Core Survey- Myoglobin, specimens CM- 11, CM- 13, CM- 14, and CM-15 4. For 2019 testing event 1, the laboratory received ungraded PT test scores for the following: \*2018 Chemistry Core Survey- Myoglobin, specimen CM- 02 \*2018 Chemistry Core Survey- Troponin I, specimen CM-05 5. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores. THIS IS A REPEAT DEFICIENCY.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of the Cardiac STATus control package insert, reagent refrigerator temperature records, and confirmed by personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 04/29/2019, the laboratory failed to perform and document corrective action when the reagent refrigerator temperature fell outside the acceptable range for 120 out of 212 days from 08/01/2018- 02/28/2019. The findings include: 1. The laboratory stored the Cardiac STATus controls in a refrigerator located in the storage area. 2. Review of the package insert indicated controls must be stored between 2 and 8 degrees Celsius (35.6- 46.4 degrees Fahrenheit). 3. The refrigerator temperature log listed the acceptable temperature range as 35.6- 46.4 degrees Fahrenheit. 4. The laboratory documented the refrigerator temperature as 47 degrees Fahrenheit on the following dates: 09/06/2018, 10/01/2018, 10/22/2018, and 12/16/2018. 5. The laboratory documented the refrigerator temperature as 48 degrees Fahrenheit on the following dates: August 2018: 08/01- 08/02, 08/08, 08/12, 08/14, 08/16- 08/20, 08/26; September 2018: 09/05, 09/07- 09/12, 09/14, 09/16, 09/20- 09/25, 09/27; October 2018: 10/06- 10/07, 10/11, 10/13, 10/16, 10/20- 10/21, 10/23- 10/24, 10/29- 10/31; November 2018: 11/05, 11/12, 11/14- 11/15, 11/23; December 2018: 12/04, 12/17- 12/18, 12/23- 12/29, 12/31; January 2019: 01/02- 01/03, 01/05, 01/10- 01/13, 01/15- 01/18, 01/21- 01/23, 01/26; February 2019: 02/03- 02/06, 02/12- 02/13, 02/15- 02/16, 02/19- 02/24, 02/27. 6. The laboratory documented the refrigerator temperature as 49 degrees Fahrenheit on the following date: 12/14/2018. 7. The laboratory documented the refrigerator temperature as 50 degrees Fahrenheit on the following dates: August 2018: 02/28; September 2018: 09/01, 09/13, 09/15, 09/17- 09/19, 09/26, 09/28- 09/29; October 2018: 10/02- 10/05, 10

/10, 10/12, 10/19, 10/27- 10/28; December 2018: 12/19- 12/22; January 2019: 01/01, 01/09, 01/19; February 2019: 02/14, 02/17- 02/18. 8. The laboratory documented the refrigerator temperature as 52 degrees Fahrenheit on the following date: 08/27/2018. 9. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform or document corrective action when the refrigerator temperatures fell outside the acceptable range on the previously listed dates.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by personnel identifier #14 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 04/29/2019, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for four out of nine new testing personnel (laboratory personnel identifiers #12, #13, #37, and #38). The findings include: 1. Since the last survey on 04/04/2017, the laboratory hired personnel identifiers #12, #13, #23- #26, and #36- #38. 2. Personnel identifier #14 stated that each of the newly hired personnel had been trained to perform Cardiac STATus testing. 3. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #12, #13, #37, and #38.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List and Annual Volume form, personnel records and confirmed by personnel identifiers #2 and #14 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/29/2019, the technical consultant failed to ensure that the 2018 competency evaluations documented the direct observation of routine patient testing for 28 out of 28 testing personnel (identifiers #2- #11, #14- #22, #27- #35). The findings include: 1. The Laboratory Test List and Annual Volume form indicated that the laboratory performed creatine kinase muscle /brain isoenzyme (CK-MB), myoglobin, and troponin testing. 2. The laboratory competency evaluations from 2018 included the names of all testing personnel who

	<p>attended an educational meeting regarding CK-MB, myoglobin, and troponin testing. 3. The competency evaluations did not document the direct observation of routine patient testing. THIS IS A REPEAT DEFICIENCY.</p>
<p><b>D6048</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(ii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, personnel records and confirmed by personnel identifiers #2 and #14 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/29/2019, the technical consultant failed to ensure that the 2018 competency evaluations documented monitoring the recording and reporting of test results for 28 out of 28 testing personnel (identifiers #2- #11, #14- #22, #27- #35). The findings include: 1. The Laboratory Test List and Annual Volume form indicated that the laboratory performed creatine kinase muscle /brain isoenzyme (CK-MB), myoglobin, and troponin testing. 2. The laboratory competency evaluations from 2018 included the names of all testing personnel who attended an educational meeting regarding CK-MB, myoglobin, and troponin testing. 3. The competency evaluations did not document monitoring the recording and reporting of test results. THIS IS A REPEAT DEFICIENCY.</p>
<p><b>D6049</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, personnel records and confirmed by personnel identifiers #2 and #14 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/29/2019, the technical consultant failed to ensure that the 2018 competency evaluations documented the review of patient test logs, quality control results, and proficiency testing results for 28 out of 28 testing personnel (identifiers #2- #11, #14- #22, #27- #35). The findings include: 1. The Laboratory Test List and Annual Volume form indicated that the laboratory performed creatine kinase muscle/brain isoenzyme (CK-MB), myoglobin, and troponin testing. 2. The laboratory competency evaluations from 2018 included the names of all testing personnel who attended an educational meeting regarding CK-MB, myoglobin, and troponin testing. 3. The competency evaluations did not document the review of patient test logs, quality control results, and proficiency testing results. THIS IS A REPEAT DEFICIENCY.</p>
<p><b>D6051</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed</p>

specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List and Annual Volume form, personnel records and confirmed by personnel identifiers #2 and #14 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/29/2019, the technical consultant failed to ensure that the 2018 competency evaluations documented the review of test performance through testing previously analyzed specimens or external proficiency testing results for 28 out of 28 testing personnel (identifiers #2- #11, #14- #22, #27- #35). The findings include: 1. The Laboratory Test List and Annual Volume form indicated that the laboratory performed creatine kinase muscle/brain isoenzyme (CK-MB), myoglobin, and troponin testing. 2. The laboratory competency evaluations from 2018 included the names of all testing personnel who attended an educational meeting regarding CK-MB, myoglobin, and troponin testing. 3. The competency evaluations did not document the review of test performance through testing previously analyzed specimens or external proficiency testing. THIS IS A REPEAT DEFICIENCY.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List and Annual Volume form, personnel records and confirmed by personnel identifiers #2 and #14 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/29/2019, the technical consultant failed to ensure that the 2018 competency evaluations documented the assessment of problem solving skills for 28 out of 28 testing personnel (identifiers #2- #11, #14- #22, #27- #35). The findings include: 1. The Laboratory Test List and Annual Volume form indicated that the laboratory performed creatine kinase muscle/brain isoenzyme (CK-MB), myoglobin, and troponin testing. 2. The laboratory competency evaluations from 2018 included the names of all testing personnel who attended an educational meeting regarding CK-MB, myoglobin, and troponin testing. 3. The competency evaluations did not document the assessment of problem solving skills. THIS IS A REPEAT DEFICIENCY.

**D6054**

**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 annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by personnel identifier #14 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 04/29/2019, the technical consultant failed to evaluate and document the competency of individuals performing moderate complexity testing at least annually for 19 out of 28 testing

personnel (personnel identifiers #2, #3, #5- #11, #14- #18, #20, #22, #27, #29, and #33) in 2018. The findings include: 1. Personnel identifier #14 stated that testing personnel are split into three shifts: Red, Blue, and Green. Each shift attends an educational meeting regarding the Cardiac STATus test system (creatine kinase muscle/brain isoenzyme [CK-MB], myoglobin, and troponin testing) and present testing personnel are listed on the competency evaluation form. 2. The 2018 Red shift educational meeting competency evaluation form included the following testing personnel: personnel identifiers #4, #19, #21, #28, #30- #32, and #34- #35. 3. At the time of the survey, personnel identifier #14 confirmed that the laboratory did not have the 2018 Blue and Green shift educational meeting competency evaluation forms, which included the following testing personnel: personnel identifiers #2, #3, #5- #11, #14- #18, #20, #22, #27, #29, and #33.