Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2056586	(X3) Date Survey Completed 08/25/2021
Name of Provider or Supplier Muscatine Fire Department	**Street Address, City, State** 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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by testing personnel #4 and #23 (refer to the Laboratory Personnel Report) at approximately 10: 00 am on 8/25/2021, the laboratory failed to document corrective action for unacceptable PT scores received on one out of five PT events (2020 - event 3) from 1 /1/2020 - 8/25/2021. The findings include: 1. For 2020 PT event 3, the laboratory received an unacceptable score of 60% for the analytes, troponin and creatine kinase isoenzymes (CK-MB). 2. At the time of the survey, the laboratory did not have documentation of corrective action for the unacceptable PT scores.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel #4 and #23 (refer to the Laboratory Personnel Report) at approximately 10:

	00 am on 8/25/2021, the laboratory failed to retain all proficiency testing records for four out of five PT events from 1/1/2020 - 8/25/2021. The findings include: 1. For 2020 event 1, the laboratory did not retain the PT results. 2. For 2020 event 3, the laboratory did not retain the forms submitted to the PT company, the attestation statement and the PT results. 3. For 2021 event 1, the laboratory did not retain the forms submitted to the PT company, the attestation statement and the PT results. 4. For 2021 event 2, the laboratory did not retain the forms submitted to the PT company, the attestation statement and the PT results. This is a repeat deficiency from the survey on 4/29/2019.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, the Laboratory Test List & Annual Volume form, and confirmed by laboratory personnel identifier #4 and #23 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 8/25/2021, the laboratory failed to verify the accuracy for the analyte, myoglobin for three out of three time periods from 1/1/2020 - 8/25/2021. The findings include: 1. The Laboratory Test List & Annual Volume form indicated the laboratory performed myoglobin, troponin and creatine kinase isoenzymes (CK-MB) testing. 2. The laboratory enrolled in proficiency testing for troponin and CK-MB. 3. At the time of the survey, the laboratory did not submit results to the proficiency testing company for myoglobin and they did not verify the accuracy by another method. This is a repeat deficiency from the survey on 10/28/2013.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel #4 and #23 (refer to the Laboratory Personnel Report) at approximately 10: 00 am on 8/25/2021, the laboratory director failed to ensure that PT reports are reviewed and corrective action documented by the appropriate staff and for four out of five events from 1/1/2020 - 8/25/2021. The findings include: 1. The laboratory did not have PT results available for four PT events. Refer to D3037. 2. The laboratory did not document corrective action for unacceptable PT scores. Refer to D2094.
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 laboratory personnel identifiers #4 and #23 (refer to Laboratory Personnel Report) at approximately 10:15 am on 08/25/2021, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for 12 out of 33 testing personnel (laboratory personnel identifiers #14, #16, #18, #19, #20, #23, #26, #27, #28, #29, #30 and #31) in 2020. At the time of the survey, the laboratory did not have 2020 competency assessments records for the listed testing personnel. This is a repeat deficiency from the survey on 4/29/2019.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifiers #4 and #23 at approximately 10:15 am on 08/25/2021, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform moderate complexity as specified in standard D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifiers #4 and #23 (refer to the Laboratory Personnel Report) at approximately 10:15 am on 08/25/2021, the laboratory failed to have documentation to qualify six out of 33 testing personnel who perform moderate complexity testing. The findings include: 1. Since the last survey performed on 4/29/2019, the laboratory

	employed six new testing personnel: identifiers #4, #15, #22, #24, #32, and #33. 2. At the time of the survey, the laboratory did not have diplomas and/or transcripts to qualify the above listed testing personnel.