Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386507	08/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
University Of Iowa Health Care	2943 Northgate Drive, Iowa City, 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 laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10: 00 am on 08/26/2022, the laboratory failed to take and document corrective action for three unacceptable PT scores from three out of five PT testing events (2021 events 1 and 2 and 2022 event 1) from 01/01/2021- 08/26/2022. The findings include: 1. For 2021 testing event 1, the laboratory received unacceptable PT test scores for the following: *2021 Core Chemistry 1st event: prostate-specific antigen (PSA) (specimen IA-03) 2. For 2021 testing event 2, the laboratory received unacceptable PT scores for the following: *2021 Core Chemistry 2nd event: PSA (specimen IA-05) 3. For 2022 testing event 1, the laboratory received unacceptable PT scores for the following: *2022 Core Chemistry 1st event: PSA (specimen IA-04) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.
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 the Laboratory Test List and Annual volume form and confirmed by personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 08/26/2022, the laboratory failed to verify the accuracy for performing urine sediment examinations twice annually for five out of five time periods from 01 /01/2020 - 08/26/2022. At the time of the survey, the laboratory did not enroll in proficiency testing for urine sediment examinations and did not verify the accuracy of the testing by another method from 01/01/2020 - 08/26/2022.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of Qualigen calibration and quality control (QC) records and confirmed by personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10:40 am on 08/26/2022, the laboratory failed to perform prostate-specific antigen (PSA) QC after a system calibration for 10 out of 10 calibrations performed from 01/01/2022 to 08/26/2022. The findings include: 1. The Qualigen Fastpack IP Operator's Manual stated that Qualigen recommends that users run controls whenever a calibration is performed. 2. The laboratory performed calibrations on the Qualigen Fastpack IP test system for PSA on the following dates: 01/07/2022, 01/20/2022, 02/22/2022, 03/08/2022, 04/08/2022, 05/12/2022, 05/25/2022, 06/23 /2022, 07/25/2022, and 08/12/2022. 3. At the time of the survey, personnel identifier #5 confirmed that the laboratory did not run QC after performing PSA calibrations on the dates listed above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable

	limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of Qualigen calibration verification records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10:40 am on 08/26/2022, the laboratory failed to perform calibration verification every six months for two out of three time periods from 02/02/2021- 08/26 /2022 for the Qualigen test system. The findings include: 1. The laboratory performed calibration verification for the Qualigen test system on 02/02/2021. 2. At the time of the survey, personnel identifier #5 confirmed that the laboratory did not have calibration verification records for the time period between 08/02/2021 and 02/02 /2022 or the time period between 02/02/2022 and 08/26/2022. This is a repeat deficiency cited on 06/28/2016.
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 identifier #5 (refer to the Laboratory Personnel Report) at approximately 9:45 am on 08/26/2022, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for three out of five testing personnel in 2020 (personnel identifiers #1-3) and five out of five testing personnel in 2021 (personnel identifiers #1-3, 5, and 8).