Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383790	06/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
East University Clinic & Urgent Care	2508 East University Ave, Des Moines, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1: 20 pm on 06/29/2021, the laboratory failed to perform a self evaluation of ungraded PT scores for two out of seven PT testing events from 01/01/2019- 06/29/2021 (2019 event 1 and 2020 event 3). The findings include: 1. For 2019 testing event 1, the laboratory received ungraded PT test scores for the following: *2019 Hematology and Coagulation 1st event- urine sediment (specimen US-01) *2019 Hematology and Coagulation 1st event- vaginal wet prep potassium hydroxide (specimen VKP-01) 2. For 2020 testing event 3, the laboratory received ungraded PT test scores for the following: *2020 Hematology and Coagulation 3rd event- urine sediment (specimen US-06) 3. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1: 20 pm on 06/29/2021, the laboratory failed to take and document corrective action for three unacceptable PT scores from three out of seven PT testing events (2019 events 2 and 3 and 2021 event 1) from 01/01/2019- 06/29/2021. The findings include: 1. For 2019 testing event 2, the laboratory received unacceptable PT test scores for the following: *2019 Core Chemistry 2nd event- high-density lipoprotein (HDL) cholesterol (specimen CH-09) 2. For 2019 testing event 3, the laboratory received unacceptable PT scores for the following: *2019 Core Chemistry 3rd event- HDL cholesterol (specimen CH-11) 3. For 2021 testing event 1, the laboratory received unacceptable PT test scores for the following: *2021 Hematology and Coagulation 1st event- basophil % (specimen DXH-03) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.
D6055	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 whenever test 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, performance specification records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:40 pm on 06/29/2021, the technical consultant failed to document training for the Beckman Coulter DXH 520 hematology analyzer prior to reporting patient test results for three out of three testing personnel (laboratory personnel identifiers #2- #4). The findings include: 1. The laboratory began using the Beckman Coulter DXH 520 hematology analyzer in August 2019. 2. At the time of the survey, the laboratory did not have training records for testing personnel identifiers #2- #4.