Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0665215	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lucas County Health Center	1200 North Seventh Street, Chariton, 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 #1 (refer to Laboratory Personnel Report) at approximately 10:30 am on 6/8/2021, the laboratory failed to perform a self evaluation of ungraded PT scores for four out of six PT testing events from 1/1/2019 - 12/31/2020. The findings include: 1. For 2019 testing event 1, the laboratory received ungraded PT test scores for the following: *opiates, sample 1 2. For 2020 testing event 1, the laboratory received ungraded PT test scores for the following: *total creatine kinase, sample 1 *acetaminophen, sample 1 *unexpected antibody identification, sample 4 3. For 2020 testing event 2, the laboratory received ungraded PT test scores for the following: *albumin, samples 1 - 5 *unexpected antibody identification, sample 6 *compatibility testing, sample 6 4. For 2020 testing event 3, the laboratory received ungraded PT test scores for the following: *manual white blood cell identification, sample 11 5. At the time of the survey, the laboratory did not perform a self evaluation for the ungraded 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 proficiency testing records, the Laboratory Test List & Annual Volume list and confirmed by testing identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 6/08/21, the laboratory failed to verify the accuracy of the analyte, procalcitonin twice annually for three out of three time periods from 1/1/2020 - 6/8/2021. At the time of the survey, the laboratory did not enroll in proficiency testing for procalcitonin and they did not verify the accuracy of the testing by another method from 1/1/2020 - 6/8/2021.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Clostridium difficile Individualized Quality Control Plan (IQCP), quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 6/8/2021, the laboratory failed to perform QC for one out of one lot number of Clostridium difficile test kits in February 2021. The findings include: 1. The Clostridium difficile IQCP plan states that external QC will be performed with each new lot and/or shipment of test kits. 2. Patient identifier A had Clostridium difficile testing performed on 2/27/2021 using lot number 7120OSMO80 and expiration date 11/25/21 of test kit. 3. At the time of the survey, the laboratory did not have external QC records for lot number 7120OSMO80 of Clostridium difficile test kit.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of performance specification and calibration verification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:45 pm on 6/8/2021, the laboratory director failed to ensure that the performance specification and calibration verification procedures are adequate to determine accuracy, precision and reportable range on the Roche Cobas chemistry analyzer from 11/1/2019 - 6/8/2021. The findings include: 1. The laboratory verified the performance specifications for the new Roche Cobas chemistry analyzer in November of 2019. 2. The laboratory performed calibration verification

	procedures on the Roche Cobas chemistry analyzer on 4/14/2020 and 10/6/2020. 3. At the time of the survey, the laboratory director failed to ensure that the performance specification and calibration verification procedures are adequate. The records did not indicate they had been reviewed by the laboratory director or other laboratory staff.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10: 30 am on 6/8/2021, the laboratory director failed to ensure that an approved corrective action plan is followed when the laboratory received unacceptable PT scores for five out of six PT events from 1/1/2019 - 12/31/2020. The findings include: 1. For 2019 PT event 2, the laboratory received an unacceptable score of 50% for direct antiglobulin test (DAT). 2. For 2019 PT event 3, the laboratory received unacceptable scores of: *80% for low density lipoprotein cholesterol *80% for arterial blood gas pH, *80% for arterial blood gas pCO2, *80% for arterial blood gas pO2, and *80% for high density lipoprotein cholesterol. 3. For 2020 PT event 1, the laboratory received an unacceptable score of 60% for hemoglobin. 4. For 2020 PT event 2, the laboratory received unacceptable scores of: *80% for acetaminophen, and *50% for DAT. 5. For 2020 PT event 3, the laboratory received an unacceptable score of 40% for digoxin. 6. At the time of the survey, the laboratory director did not ensure the laboratory documented corrective action for the above unacceptable PT scores.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 observations made during the survey, review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 12:45 pm on 6/8/2021, the laboratory director failed to ensure that prior to testing patient specimens six out of seven personnel received documented training when the laboratory began performing patient testing on the new chemistry analyzer in November of 2019. The findings include: 1. The laboratory began performing patient testing using a new Roche Cobas chemistry analyzer in November 2019. 2. At the time of the survey, the laboratory did not have documentation of training on the new analyzer prior to performing patient testing for personnel identifiers #1 - #6.