

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0665215	<b>(X3) Date Survey Completed</b>  04/25/2023
<b>Name of Provider or Supplier</b>  Lucas County Health Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 04/25/2023, the laboratory failed to perform a self evaluation when the laboratory received 24 ungraded PT scores from five out of seven PT testing events from 01/01/2021- 04/25/2023. The findings include: 1. For 2021 testing event 2, the laboratory received ungraded PT test scores for the following: *Q2 Chemistry 2021: Acetaminophen (specimens 6-10) 2. For 2021 testing event 3, the laboratory received ungraded PT test scores for the following: *Q3 Chemistry 2021: Acetaminophen (specimens 11-15) and troponin T (specimen 15) 3. For 2022 testing event 1, the laboratory received ungraded PT test scores for the following: *Q1 Chemistry 2022: Troponin T (specimens 2, 4, and 5) *Q1 Non-Chemistry 2022: Direct antiglobulin test (specimen 2) 4. For 2022 testing event 2, the laboratory received ungraded PT test scores for the following: *Q2 Chemistry 2022: Acetaminophen (specimens 6-10) and troponin T (specimen 9) 5. For 2022 testing event 3, the laboratory received ungraded PT test scores for the following: *Q3 Chemistry 2022: Troponin T (specimens 13 and 14) *Q3 Non-Chemistry 2022: Compatibility testing (specimen 14) 6. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores listed above. This is a repeat deficiency cited on 06/08/2021.</p>

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of chemistry quality control (QC) records, the laboratory's Chemistry Quality Control policy, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:45 pm on 04/25/2023, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for two out of 30 days of patient testing in November 2022. The findings include: 1. The laboratory performs chemistry testing on the Roche Cobas 6000 instrument. 2. The laboratory's Chemistry Quality Control policy stated that the laboratory follows Westgard rules for quality control acceptability. If one control measurement exceeds the mean, plus or minus two standard deviations (1-2 SD), the control run can be accepted. Control runs are unacceptable if both controls of the same analyte exceed the mean, plus or minus 2 standard deviations. 3. Review of chemistry QC records revealed "1-2s" QC rule failure flags on both levels of control for the following dates and analytes: \* 11/08/2022- low-density lipoprotein (LDL) cholesterol (levels 1 and 3) \* 11/12/2022- LDL cholesterol (levels 1 and 3) 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the unacceptable control runs listed above.

**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) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 04/25/2023, the laboratory director failed to ensure that an approved corrective action plan is followed when the laboratory received six unacceptable PT scores from three out of seven PT testing events (2021 events 2 and 3 and 2022 event 1) from 01/01/2021- 04/25/2023. The findings include: 1. For 2021 testing event 2, the laboratory received unacceptable PT test scores for the following: \*Q2 Chemistry 2021- Glycohemoglobin (specimens 6 and 7) 2. For 2021 testing event 3, the laboratory received unacceptable PT scores for the following: \*Q3 Chemistry 2021- Alcohol, serum (specimens 12 and 14) 3. For 2022 testing event 1, the laboratory received unacceptable PT test scores for the following: \*Q1 Chemistry 2022- Albumin (specimen 3) \*Q1 Non-Chemistry 2022- Monocyte % (specimen 1) 4. At the

time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores listed above. This is a repeat deficiency cited on 06/08/2021.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:45 am on 04/25/2023, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for one out of five testing personnel (laboratory personnel identifier #1) in 2021 and 2022.