

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385956	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Shenandoah Medical Center	Street Address, City, State 300 Pershing Avenue, Shenandoah, 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	<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 #8 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 05/11/2023, the laboratory failed to perform a self evaluation when the laboratory received eight ungraded PT scores from three out of seven PT testing events from 01/01/2021- 05/11/2023. The findings include: 1. For 2021 testing event 3, the laboratory received ungraded PT test scores for the following: *Q3 Chemistry 2021: Urine chemistry total protein (specimen 11) and stool leukocytes (specimen 11) 2. For 2022 testing event 2, the laboratory received ungraded PT test scores for the following: *Q2 Chemistry 2022: Urine chemistry amylase (specimens 6 and 7); urine chemistry sodium (specimen 6); urine chemistry total protein (specimen 6); and urine chemistry urea nitrogen (specimen 6). 3. For 2022 testing event 3, the laboratory received ungraded PT test scores for the following: *Q3 Non-Chemistry 2022: Erythrocyte sedimentation rate, rapid (specimen 11) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores listed above.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

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 General Chemistry Testing policy, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 05/11/2023, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for four out of 30 days of patient testing in November 2022. The findings include: 1. The laboratory performs chemistry testing on the Vitros 7600 instrument. 2. The laboratory's General Chemistry Testing policy stated, "Two distinct levels of appropriate chemistry controls will be performed each day of use. Both levels of controls must be within 2 SD. If controls are outside the specified range, the problem must be investigated and resolved." 3. Review of chemistry QC records revealed results greater than 2 SD for the following dates and analytes: * 11/13/2022- chloride (level 3); sodium (level 3); and total protein (level 3) * 11/14/2022- albumin (level 1); chloride (level 3); and total protein (level 3) * 11-19/2022- total protein (level 3) * 11/27/2022- albumin (level 1) 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have documented corrective action for the unacceptable control runs listed above.

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 8:20 am on 05/11/2023, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for one out of six testing personnel (laboratory personnel identifier #1) in 2021 and 2022.