

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0648144	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier Van Buren County Hospital	Street Address, City, State 304 Franklin Street, Keosauqua, 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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, corrective action reports and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 10:16 am on 8/22/2023, the laboratory failed to take effective corrective action when the laboratory received unacceptable direct bilirubin PT scores for three out of five PT events from 1/1/2022 - 8/22/2023. The findings include: 1. For 2022 PT event 2, the laboratory received an unacceptable PT score of 40% for the analyte, direct bilirubin. The laboratory's corrective action stated, "Re-education for sample processing prior to analysis. Employee no longer works at VBCH. Both levels of QC (quality control) were acceptable. Repeats of CH06, CH08, and CH10 all were within acceptable survey ranges post graded survey results." 2. For 2022 PT event 3, the laboratory received an unacceptable PT score of 20% for the analyte, direct bilirubin. The laboratory had a check list that stated they reviewed specimen handling, clerical errors, quality control, calibration, instrumentation, and reagents. 3. For 2023 PT event 2, the laboratory received an unacceptable PT score of 60% for the analyte, direct bilirubin. The laboratory's corrective action stated, "Repeat of CH07, CH09, and CH10 post survey results were all within acceptable range. Calibration was up to date and acceptable. Quality control was within acceptable range as well. Will review pre-analytical possibilities of error such as leaving out at room temp for appropriate</p>

time, mixing well, etc. Next survey will be monitored closely." 4. The above corrective action steps have not been effective in ensuring the laboratory receives acceptable PT scores for the analyte, direct bilirubin.

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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at 12:58 pm and 1:30 pm on 8/22/2023, the laboratory failed to perform two levels of QC each day of patient testing for the serum human chorionic gonadotropin (hCG) test kit and Afinion test system. The findings include: 1. The laboratory performed QC using the hCG test kit and Afinion test system with each new lot and or shipment of test cartridges and monthly. 2. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for either the serum hCG test kit or the Afinion test system.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory annual test volume list and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 12:27 pm on 8/22/2023, the laboratory failed to perform and document comparison testing for the analyte troponin for three out of three time periods from 1/1/2022 - 8/23/2023. The finding include: 1. The laboratory performed troponin testing using the Vitros 350 chemistry analyzer. 2. As a backup method, the laboratory performed troponin testing on the Triage test system. 3. At the time of the survey, the laboratory had not performed troponin comparison testing between both analyzers.