

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384448	(X3) Date Survey Completed 08/17/2023
Name of Provider or Supplier Van Diest Medical Center	Street Address, City, State 2350 Hospital Drive, Webster City, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of Sysmex CA Series coagulation reagent verification records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at 11:47 am on 08/17/2023, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) for one out of one lot number of prothrombin time reagent (lot number 564631, expiration 09/22/2025). The findings include: 1. The laboratory began using prothrombin time reagent lot number 564631 (expiration 09/22/2025) on 05/25/2023. 2. At the time of the survey, the laboratory did not have documentation of a manual check of the INR calculation from the instrument for prothrombin reagent lot number 564631.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on lack of an Individualized Quality Control Plan (IQCP), review of quality control (QC) records, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at 1:12 pm on 08/17/2023, the laboratory failed to perform a positive and negative control each day of patient testing for the Clostridium difficile Quik Chek Complete test system. The findings include: 1. The laboratory performed a positive and negative control with each new lot and shipment of tests for the Clostridium difficile Quik Chek Complete test system. 2. Laboratory personnel identifier #5 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 the Clostridium difficile Quik Chek Complete 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 test volume forms and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at 1:21 pm on 08/17/2023, the laboratory failed to perform twice annual comparison testing for three out of three time periods from 01/01/2022 - 08/17/2023 for the following tests: Clostridium difficile, urine drug screen panel, and white blood cell (WBC) count. The findings include: 1. The laboratory performed Clostridium difficile testing using both the BioFire and Clostridium difficile Quik Chek Complete test systems. 2. The laboratory performed urine drug screen panel testing using two MedtoxScan Profile V test systems. 3. The laboratory performed WBC count testing using both the Sysmex xs-1000i and Hemocue WBC test systems. 4. At the time of the survey, the laboratory did not have documentation of comparison testing for Clostridium difficile, urine drug screen panel, and WBC count testing from 01/01/2022 - 08/17/2023.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the Chemistry Annual Test Volumes form, chemistry quality control (QC) records, the Dimension EXL operator's guide, and confirmed by laboratory personnel identifier #5 (refer to the laboratory personnel report) at 11:55 am on 08/17/2023, the laboratory failed to perform and document corrective action when the chemistry equipment failed to meet the laboratory's established operating parameters for 18 out of 28 days of patient testing reviewed from 02/01/2023- 02/28/2023. The findings include: 1. The laboratory performed c-reactive protein (CRP) testing on two Dimension EXL chemistry instruments (serial number DR270630 and DR270631). 2. Review of QC records revealed that for the following dates on the Dimension EXL with serial number DR270630, the system flagged CRP QC (level 1) results with the test report message "assay range": 02/01/23- 02/02/23, 02/13/23, 02/15/23, 02/23/23, 02/25/23, and 02/27/23. 3. Review of QC records revealed that for the following dates on the Dimension EXL with serial number DR270631, the system flagged CRP QC (level 1) results with the test report message "assay range": 02/01/23- 02/02/23, 02/04/23, 02/07/23- 02/10/23, 02/12/23- 02/13/23, 02/15/23- 02/19/23, and 02/21/23. 4. The Dimension EXL operator's guide stated that results flagged with the "assay range" test report message are above or below the assay range of the instrument. The results are non-reportable and must be addressed. 5. The laboratory reported a total of 184 CRP patient test results for the dates listed above. 6. At the time of the survey, personnel identifier #5 confirmed that additional action had not been taken for QC results flagged with assay range test report messages on the dates listed above.