

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0704407	(X3) Date Survey Completed 09/18/2018
Name of Provider or Supplier Centra Danville Medical Center	Street Address, City, State 414 Park Avenue, Danville, VA	
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
D0000	An announced CLIA Recertification survey was conducted at Centra Danville Medical on September 18, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration records for the chemistry analyzer and interviews, the</p>

laboratory failed to perform the calibration verification twice a year for the Sodium (NA), Potassium (K+) and Chloride (CL) analytes for the sixteen (16) of the sixteen (16) months reviewed. Findings include: 1. Review of calibration records for the Vitros 350 chemistry analyzer from October 1, 2016 and up to the date of survey (a total of 16 months) revealed that the NA, K+, and CL analyte calibrations were a 2-point calibration. The inspector requested to review calibration verification documentation for the above-listed analytes. The documentation was not available for review. 2. An interview with the technical consultant and primary testing personnel at approximately 5:20 PM confirmed the findings.

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 a tour of the laboratory, review of policies and procedures, hematology records, and interviews, the laboratory failed to establish and follow a policy for the comparison of hematology Complete Blood Count (CBC) test results performed on the two (2) Abbott Cell Dyn Emerald instruments for sixteen (16) of the sixteen (16) months reviewed. Findings include: 1. Tour of the laboratory at approximately 10: 15 AM revealed that the laboratory has 2 Abbott Cell Dyn Emerald instruments. The instruments are identified as EM2 (Serial Number 031013) and EM6 (Serial Number 030614). 2. Review of the policies and procedures revealed no documentation of a policy or procedure to evaluate a comparison of CBC test results assayed on the 2 hematology analyzers. 3. Review of the hematology records, to include Quality Control and instrument maintenance, from October 1, 2016 and up to the date of survey revealed no documentation or evaluation of CBC result comparison records for the 2 hematology instruments listed above. 4. An interview with the technical consultant and primary testing personnel at approximately 5:20 PM confirmed the findings.