

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0661823	(X3) Date Survey Completed 09/12/2019
Name of Provider or Supplier Grafton City Hospital	Street Address, City, State 1 Hospital Plaza, Grafton, WV	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with Technical Supervisor 1 (TS1), the laboratory failed to attain a score of at least 80 percent for the analyte Ammonia in the 1st Chemistry Miscellaneous 2019 testing event. Findings: 1. A review of PT records identified an unsatisfactory performance of 67 percent for the analyte Ammonia in the Chemistry Miscellaneous 2019 1st testing event. 2. An interview with TS1, on 9/11 /19 at approximately 10:00 AM, confirmed the findings.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on a review of laboratory Quality Control (QC) records, calibration records, and an interview with Technical Supervisor 1 (TS1), the laboratory failed to perform and document calibration verification for the Sodium, Potassium, and Chloride analytes in chemistry testing. Findings: 1. A review of QC and calibration records from 2018 and 2019 established that no calibration verification of Sodium, Potassium, and Chloride analytes had been performed and documented on the Vitros 350 chemistry analyzer. 2. A review of QC records identified the laboratory ran 2 levels of Quality Control materials once each day of testing on the Vitros 350 chemistry analyzer. 3. An interview with TS1, on 9/12/19 at approximately 10:25 AM, confirmed that the laboratory had not performed or documented calibration verification for the Sodium, Potassium, and Chloride analyte testing on the Vitros 350.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of Quality Control (QC) records, laboratory written policies and procedures, and an interview with Technical Supervisor 1 (TS1), the laboratory failed to perform and document an external negative and positive control for the MedTox urine drug screen test kit daily. Findings: 1. Review of the laboratory QC records identified MedTox external negative and positive controls were ran 1/6/19, 1/13/19, 1/20/19, 1/27/19, 2/3/19, 2/10/19, 2/17/19, 2/24/19, 3/3/19, 3/10/19, 3/17/19, 3/19/19, 3/24/19, 3/31/19, 4/7/19, 4/14/19, 4/21/19, 4/28/19, 5/5/19, 5/12/19, 5/19/19, 5/20/19, 5/26/19, 6/2/19, 6/9/19, 6/16/19, 6/23/19, 6/30/19, 7/5/19, 7/7/19, 7/14/19, 7/21/19, and 7/28/19. Patient MedTox urine drug testing was performed on a routine/daily basis, with approximately 300 MedTox urine drug screen tests on patients from 1/1/19 to 8/1/19. 2. The written policy/procedure for the MedTox urine drug screen test kit states "2 levels of external QC will be ran daily" and with any new lot or new shipment. 3. No IQCP could be located for the MedTox urine drug screen test. 4. An interview with TS1, on 9/12/19 at approximately 10:45 AM, confirmed that MedTox urine drug screen testing is performed on patients daily, that external negative and positive controls are ran on the MedTox urine drug screen test kit weekly and with each new lot/shipment, and that no IQCP for the MedTox urine drug screen could be located.