

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0661823	(X3) Date Survey Completed 01/28/2026
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
D0000	A routine recertification survey was completed at Grafton City Hospital on January 29, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Noncompliance was found and the specific citations are explained below.
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;</p> <p>This STANDARD is not met as evidenced by: Based on review of Vitros 3400 XT quality control (QC) records for chemistry testing, lack of documented performance, patient test results from the Orchard laboratory information system (LIS), and interview with the laboratory manager and laboratory director (LD), the laboratory failed to document the performance of two levels of quality control (QC) for 15 of 33 days of patient testing for alcohol and 8 of 20 days of patient testing for ammonia during time period reviewed (February thru April 2025). Findings: 1. Review and comparison of Vitros 3400 XT QC data for alcohol testing with dates of patient testing from Orchard LIS (February thru April 2025) revealed the following: a. Alcohol patient testing on 33 days (2/10,2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 3/5, 3/6, 3/15, 3/18, 3/19, 3/21, 3/22, 3/28, 3/31, 4/1, 4/3, 4/8, 4/12, 4/13, 4/14, 4/15, 4/20, 4/22, 4/23, 4/30) b. No documented performance of alcohol QC for 15 of 33 days of patient testing (2/13, 2/14, 2/17, 2/18, 3/28, 4/3, 4/8, 4/12, 4/13, 4/14, 4/15, 4/20, 4/22, 4/23, 4/30) c. Alcohol results released for 17 patients without documented QC: 2/13: 840371 2/14: 840697 2/17: 841677 2/18: 842003 3/28: 848615 4/03: 849674 4/08: 850308 and 850446 4/12: 850962 4/13: 851079 4/14: 851224 4/15: 851333 4/20: 852025 4/22: 852251 and 852288 4/23: 852568 4/30: 853562 2. Review and comparison of Vitros 3400 XT QC</p>

data for ammonia testing with dates of patient testing from Orchard LIS (February thru April 2025) revealed the following: a. Ammonia patient testing on 20 days (3/5, 3/7, 3/11, 3/12, 3/15, 3/17, 3/18, 3/19, 3/20, 3/21, 3/24, 3/27, 4/5, 4/6, 4/10, 4/11, 4/12, 4/17, 4/28, 4/30) b. No documented performance of ammonia QC for 8 of 20 days of patient testing (4/5, 4/6, 4/10, 4/11, 4/12, 4/17, 4/28, 4/30) c. Ammonia results released for 8 patients without documented QC: 4/5: 850003 4/6: 850101 4/10: 850711 4/11: 850779 4/12: 850872 4/17: 851695 4/28: 853068 4/30: 853573 2. The laboratory manager confirmed the lack of documented performance of two levels of QC for alcohol and ammonia testing on the Vitros 3400 XT during an interview 1/29/26 at approximately 9:00 AM. 3. An exit interview, 1/29/26 at 12:30 PM, confirmed the findings with the LD.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of postanalytic quality assurance (QA) policies and procedures, documented Orchard laboratory information system (LIS) calculation checks, lack of documented performance, verification records for total iron binding capacity (TIBC), Orchard LIS patient reports for TIBC, and interview with the technical supervisor (TS1), the laboratory failed to document the performance of annual calculation checks for one of nine calculated values (TIBC) in chemistry from January 2025 thru date of survey, per laboratory established policy. Findings: 1. Review of postanalytic QA policies and procedures identified "Computer Calculation Checks for Chemistry Reporting" (effective 06/2023, LD review signed 6/2025) stating "In order to ensure correct values for chemistry reporting that is completed by computer calculations, the values will be checked annually." The policy listed the 9 calculated values as Albumin/Globulin, Anion Gap, Blood Urea Nitrogen/Creatinine, Globulin, Total Iron Binding Capacity (TIBC), LDL, Microalbumin/Creatinine Ratio, Urine Protein/ Creatinine Ratio, eGFR. 2. Review of the annual Orchard LIS computer calculation checks performed 3/10/2025 revealed 8 of 9 calculation checks completed. TS1 could not locate documentation for the annual TIBC calculation check in 2025. 3. Review of the verification records for TIBC identified calculation checks performed during implementation of the test with the laboratory director sign off as 6/18/2024. 4. Review of Orchard LIS patient reports (June and July 2025) identified the following 22 patients with TIBC calculated values released: 6/3: 858018T, 858234T, 858332T 6/9: 858385T 6/10: 859426T, 859468T, 859485T 6/14: 859934T 6/17: 860325T, 860545T 6/24: 861707T, 861732T 7/1: 862456T, 863034T 7/7: 863873T, 863352T, 863643T, 863628T 7/9: 864345T 7/23: 866186T 7/25: 866670T, 866533T 5. An interview with TS1, 1/29/26 at 10:14 AM, verified the lack of documented performance for the TIBC calculation check from date of implementation thru date of survey.