Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0661823	(X3) Date Survey Completed 07/25/2022
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	An unannounced, off site, proficiency testing (PT) desk review was conducted for Grafton City Hospital on July 25, 2022, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations from American Proficiency Institute (API) were reviewed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficency testing (PT) evaluations and the CLIA 155D report for Grafton City Hospital, the laboratory failed

	to successfully participate in a program approved by CMS for the analyte #0325 PO2 Blood Gas for two of 3 consecutive PT events. Findings: 1. PO2 Blood Gas (#0325) 3rd Event 2021- 60% 2nd Event 2022- 0%
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CLIA 155D report and the failures summary report from the American Proficiency Institute (API) proficiency testing (PT) evaluations, the laboratory failed to achieve satisfactory performance for the analyte PO2 Blood Gas (#0325) in two of three consecutive PT events. Findings: 1. Review of 155D revealed the following unsatisfactory scores for PO2 Blood Gas (#0325): 3rd event 2021- 60% 2nd event 2022- 0% 2. Review of API failures summary report confirmed the unsuccesful performance and unsatisfactory analyte scores for PO2 Blood Gas (#0325).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, the laboratory director failed to assure compliance with the the regulation requiring successful participation in proficiency testing (PT) for the analyte PO2 Blood Gas (#0325) in two of three consecutive PT events. Findings: 1. Refer to D2000 2. Refer to D2096