Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 51D0236290	**(X3) Date Survey Completed** 03/19/2021
Name of Provider or Supplier Webster Memorial Hospital, Inc	**Street Address, City, State** 125 Diana Drive, Webster Springs, 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 at Webster County Memorial Hospital on March 19, 2021, by the West Virginia Office of Laboratory Services. The laboratory proficiency testing evaluations with the 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 a review of CASPER 153D Unsuccessful PT Report, CASPER 155D Individual Laboratory Profile Report, and the Failures Summary report from the

	American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing (PT) for the analyte # 0325 pO2 for 2 of the last 3 testing events. Findings: 1. Review of CASPER 153D Unsuccessful PT Report identified an unsuccessful performance for the analyte # 0325. 2. Review of CASPER 155D Individual Laboratory Profile Report revealed the following unsatisfactory scores for analyte # 0325 pO2: 2nd event 2020- 40% 1st event 2021- 60% 3. Review of API Failures Summary Report confirmed the unsuccessful score of 40% for analyte # 0325 pO2 for the 2nd event 2020 and a score of 60% for pO2 for the 1st event 2021.
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 a review of the individual laboratory proficiency testing (PT) scores (CASPER Report 153D) and the American Proficiency Institute (API) laboratory evaluation scores, the laboratory received unsuccessful scores for the analyte # 0365 pO2 in 2 of 3 consecutive testing events resulting in an unsatisfactory performance. Findings: 1. Review of the individual laboratory PT report scores (CASPER report 155D) and comparative evaluation scores from API demonstrated the following unsatisfactory analyte performance for analyte # 0365 pO2 in 2 of 3 consecutive testing events: 2nd event 2020- 40% 1st event 2021- 60%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and the CASPER 155D Individual Laboratory Profile report for Webster County Memorial Hospital, the laboratory director failed to ensure successful participation in a program approved by CMS for the analyte # 0325 pO2 (2nd event 2020 and 1st event 2021). The findings include: 1. pO2 Event 2 (2020) - 40% Event 1 (2021)- 60%
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 review of the American Proficiency Institute (API) proficiency testing (PT) records and the CASPER 155D Individual Laboratory Profile report for Webster County Memorial Hospital, the laboratory director failed to assure compliance with the regulation requiring successful participation in PT testing (see D2016) for the analyte # 0325 pO2 (2nd event 2020 and 1st event 2021). The findings include: 1. pO2 Event 2 (2020) - 40% Event 1 (2021) - 60%