Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233778	(X3) Date Survey Completed 07/02/2021
Name of Provider or Supplier Pocahontas Memorial Hospital	**Street Address, City, State** 150 Duncan Road, Buckeye, 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 Pocahontas Memorial Hospital on July 2, 2021, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations with the American Association of Bioanalysts (AAB) 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 record review the laboratory failed to successfully participate in proficiency testing (PT) for the analyte #0895 Compatability Testing (Immunohematology) for 2

	of 2 American Association of Bioanalysts (AAB) PT events in 2021. Findings: 1. Review of PT evaluation reports from AAB for Q1 and Q2 of 2021 identified the folllowing unsatisfactory scores for analyte #0895 Compatability Testing (Immunohematology): Q1 event 2021 80% Q2 event 2021 60%
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for 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 record review the laboratory failed to successfully participate in proficiency testing (PT) for the analyte #0895 Compatability Testing (Hematology) for 2 of 2 American Association of Bioanalysts (AAB) PT events in 2021. Findings: 1. Review of PT evaluation reports from AAB for Q1 and Q2 of 2021 identified the following unsatisfactory scores for analyte #0895 Compatability Testing (Immunohematology): Q1 event 2021 80% Q2 event 2021 60%
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) evaluation scores for Pocahontas Memorial Hospital Laboratory, the laboratory director failed to ensure successful participation in a program approved by CMS for the analyte #0895 Compatability Testing for 2 of 2 PT events in 2021. Findings: 1. Review of PT evaluation reports from AAB for Q1 and Q2 of 2021 identified the following unsatisfactory scores for analyte #0895 Compatability Testing (Immunohematology): Q1 event 2021 80% Q2 event 2021 60%
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 Association of Bioanalysts (AAB) proficiency testing (PT) evaluation reports, the laboratory director failed to assure compliance with the regulation requiring successful participation in PT for the analyte #0895 Compatability Testing (Immunohematology) in 2 of 2 testing events of 2021. Findings: 1. Refer to D2016 2. Refer to D2181