Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	04/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pocahontas Memorial Hospital	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 April 26, 2023, by the West Virginia Office of Laboratory Services. The laboratory PT 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 of CASPER 153D Unsuccessful PT report, CASPER 155D Individual Laboratory Profile Report, and evaluation reports from the American

	Proficiency Institute (API), the laboratory failed to successfully participate in PT for the analyte #0045 Virology in 2 consecutive testing events. Findings: 1. Review of CASPER 153D Unsuccessful PT Report identified an unsuccessful perfromance for analyte #0045 Virology. 2. Review of CASPER 155D Individual Laboratory Profile Report identified the following unsatisfactory scores for analyte #0045 Virology: a. 0% event 3 2022 b. 0% event 1 2023 3. Review of API evaluation reports confirmed the 0% for analyte #0045 Virology in the 3rd event of 2022 and the 1st event of 2023.
D2057	VIROLOGY CFR(s): 493.831(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the laboratory failed to participate in 2 consecutive PT events resulting in a unsuccessful score of 0% for the analyte #0045 Virology. Findings: 1. API 3rd Event 2022 Virology 0% SARS-CoV-2 Antigen 2. API 1st Event 2023 Virology 0% SARS-CoV-2 Antigen 3. A phone call with the laboratory manager, 4/27/23 at approximately 8:15 AM, confirmed the failure to participate in the 2 consecutive events for Virology SARS-CoV-2 Antigen.
D2061	VIROLOGY CFR(s): 493.831(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interview, the laboratory failed to submit the PT results for the analyte #0045 Virology (SARS-CoV-2 antigen) within the timeframe for the 3rd Event of 2022 and the 1st Event of 2023. Findings: 1. Review of American Proficiency Institute (API) evaluations identified the following unsatisfactory scores: a. Virology (SARS-CoV-2) 0% for 2022 3rd event Failure to Participate b. Virology (SARS-CoV-2) 0% for 2023 3rd event Failure to Participate 2. A phone interview with the laboratory manager, 4/27/23 at approximately 8:15 AM, confirmed the failure to participate in the PT events.