Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	10/05/2020
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
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 the CLIA database CASPER Reports 155D and 153D and the proficiency testing (PT) records from the American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in proficiency testing for each analyte on their CLIA test menu. Findings: 1. Review of the CLIA database, via CASPER Report 153D for failed proficiency testing results, identified a PT failure of the laboratory for the analyte #0565 (T3 Uptake). 2. Review of the individual laboratory PT scores,via CASPER Report 155D, identified the following unsatisfactory scores for analyte #0565 (T3 Uptake): a. 0% for T3 Uptake 3rd event 2019 b. 0% for T3 Uptake 1st event 2020 3. Comparative evaluation scores from

	AAB identified no analyte #0565 (T3 Uptake) enrolled or tested for the facility for the 3rd event 2019 and the 1st event 2020.
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 CLIA database CASPER Reports 155D and 153D and the proficiency testing (PT) records from the American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in proficiency testing for each analyte on their CLIA test menu. Findings: 1. Review of the CLIA database, via CASPER Report 153D for failed proficiency testing results, identified a PT failure of the laboratory for the analyte #0565 (T3 Uptake). 2. Review of the individual laboratory PT scores,via CASPER Report 155D, identified the following unsatisfactory scores for analyte #0565 (T3 Uptake): a. 0% for T3 Uptake 3rd event 2019 b. 0% for T3 Uptake 1st event 2020 3. Comparative evaluation scores from AAB identified no analyte #0565 (T3 Uptake) enrolled or tested for the facility for the 3rd event 2019 and the 1st event 2020.
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 a review of the CLIA database CASPER Reports 155D and 153D and the proficiency testing (PT) records from the American Association of Bioanalysts (AAB), the laboratory director failed to provide overall management and direction in accordance with CLIA regulations. Findings: 1. Review of the CLIA database, via CASPER Report 153D for failed proficiency testing results, identified a PT failure of the laboratory for the analyte #0565 (T3 Uptake). 2. Review of the individual laboratory PT scores,via CASPER Report 155D, identified the following unsatisfactory scores for analyte #0565 (T3 Uptake): a. 0% for T3 Uptake 3rd event 2019 b. 0% for T3 Uptake 1st event 2020 3. Comparative evaluation scores from AAB identified no analyte #0565 (T3 Uptake) enrolled for the facility for the 3rd event 2019 and the 1st event 2020.
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 a review of the CLIA database CASPER Reports 155D and 153D and the proficiency testing (PT) records from the American Association of Bioanalysts (AAB), the laboratory director failed to ensure satisfactory performance from the laboratory in proficiency testing (PT). Findings: 1. Review of the CLIA database, via CASPER Report 153D for failed proficiency testing results, identified a PT failure of the laboratory for the analyte #0565 (T3 Uptake). 2. Review of the individual laboratory PT scores,via CASPER Report 155D, identified the following unsatisfactory scores for analyte #0565 (T3 Uptake): a. 0% for T3 Uptake 3rd event 2019 b. 0% for T3 Uptake 1st event 2020 3. Comparative evaluation scores from AAB identified no analyte #0565 (T3 Uptake) enrolled for the facility for the 3rd event 2019 and the 1st event 2020.