Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0235758	12/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wood Health Care Clinic P C	1307 Lafayette Avenue, Moundsville, 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 review of the American Proficiency Institute (API) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile for Wood Health Care Clinic, the laboratory failed to successfully participate in a program approved by CMS for the Chemistry analyte of Sodium (NA) for the (2nd Event 2018, and 3rd Event 2018). The findings include: 1. Routine Chemistry - Sodium (NA) Event 2 (2018) - 0 % Event 3 (2018) - 20%
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile for Wood Health Care Clinic, the laboratory failed to receive satisfactory scores for the Routine Chemistry analyte of Sodium (NA) for the (2nd Event 2018, and 3rd Event 2018). The findings include: 1. The NA analyte received a score of 0% for the 2nd Routine Chemistry API proficiency testing of 2018. 2. The NA analyte received a score of 20% for the 3rd Routine Chemistry API proficiency testing event of 2018.
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) records and the CLIA 155 Individual Laboratory Profile, the laboratory director failed to ensure successful participation in a program approved by Centers for Medicare and Medicaid Services (CMS) for the analyte of sodium (NA) (2nd event 2018 and 3rd Event 2018). The findings include: 1. Refer to details outlined in standard D2087. 2. Refer to details outlined in standard D6004.
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) records and the CLIA 155 Individual Laboratory Profile, the laboratory director failed to ensure compliance with the regulation requiring successful participation in PT testing (D2016) for the analyte of Sodium (NA) (2nd event 2018 and 3rd Event 2018). The findings include: 1. The Sodium (NA) analyte received a score of 0% for the 2nd Routine Chemistry API proficiency testing of 2018. 2. The Sodium (NA) analyte received a score of 20% for the 3rd Routine Chemistry API proficiency testing event of 2018.