

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233527	(X3) Date Survey Completed 08/03/2021
Name of Provider or Supplier Wvu Med Princeton Community Hospital Bluefield	Street Address, City, State 500 Cherry St, Bluefield, 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 Princeton Community Hospital Bluefield on August 3, 2021, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations with the College of American Pathologists (CAP) were reviewed for compliance with Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. The unsuccessful PT performance deficiencies are explained below.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, Princeton Community</p>

	<p>Hospital Bluefield laboratory failed to (c) successfully perform in a program approved by CMS for the analyte #0825 Fibrinogen for 2 of 2 consecutive testing events in 2021. Findings: #0825 Fibrinogen 1st event 2021- 0% 2nd event 2021- 0%</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, Princeton Community Hospital Bluefield laboratory failed to successfully perform in a program approved by CMS for the analyte #0825 Fibrinogen for 2 of 2 consecutive testing events in 2021. Findings: #0825 Fibrinogen 1st event 2021- 0% 2nd event 2021- 0%</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, the Princeton Community Hospital Bluefield laboratory director failed to ensure successful participation in a program approved by CMS for the analyte #0825 Fibrinogen for 2 of 2 consecutive testing events in 2021. Findings: #0825 Fibrinogen 1st event 2021- 0% 2nd event 2021- 0%</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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 reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, the Princeton Community Hospital Bluefield laboratory director failed to ensure compliance with the regulation requiring successful participation in a program approved by CMS for</p>

the analyte #0825 Fibrinogen for 2 of 2 consecutive testing events in 2021. Findings:
#0825 Fibrinogen 1st event 2021- 0% 2nd event 2021- 0%