

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236863	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier Braxton County Memorial Hospital	Street Address, City, State 100 Hoylman Drive, Gassaway, 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 Braxton County Memorial Hospital on April 2, 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	<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 record review, the laboratory failed to successfully participate in proficiency testing (PT) for the analyte #0895 Compatibility Testing (immunohematology) for</p>

two consecutive American Proficiency Institute (API) testing events in 2022 and 2023. Findings: 1. Review of CASPER 155D Individual Laboratory Profile Report identified the following consecutive, unsatisfactory scores for analyte #0895 Compatibility Testing (immunohematology): 80% event 3 2022 80% event 1 2023 2. Review of PT evaluation reports from API for the 3rd event of 2022 and the 1st event of 2023 confirmed the unsuccessful participation for analyte #0895 Compatibility Testing (Immunohematology).

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 and interview, the laboratory failed to perform successfully in proficiency testing (PT) for the analyte #0895 Compatibility Testing (Immunohematology) for two consecutive American Proficiency Institute (API) testing events in 2022 and 2023. Findings: 1. Review of CASPER 155D Individual Laboratory Profile Report identified the following unsatisfactory scores for analyte #0895 Compatibility Testing (Immunohematology): 80% event 3 2022 80% event 1 2023 2. Review of PT evaluation reports from API for the 3rd event of 2022 and the 1st event of 2023 confirmed the two consecutive unsatisfactory performance scores for analyte #0895 Compatibility Testing (Immunohematology). 3. An interview with the clinical laboratory director, on 5/2/23 at approximately 1:40 PM, confirmed the cumulative unsuccessful performance for analyte #0845 Compatibility Testing (Immunohematology).