

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233677	(X3) Date Survey Completed 07/25/2025
Name of Provider or Supplier Welch Community Hospital	Street Address, City, State 454 Mcdowell Street, Welch, 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 offsite proficiency testing (PT) desk review was conducted for Welch Community Hospital on July 25, 2025, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. The identified unsuccessful participation is an initial occurrence and 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 CASPER 155D proficiency testing (PT) report and PT evaluations from the College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance for toxicology analyte #0610 acetaminophen in two</p>

consecutive testing events, resulting in an initial occurrence of unsuccessful participation in PT. Refer to D2109.

D2109

TOXICOLOGY

CFR(s): 493.845(a)

(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 CASPER 155D proficiency testing (PT) report and laboratory PT evaluations from the College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance for the toxicology analyte #0610 acetaminophen (serum) in two consecutive events of 2025, resulting in an initial occurrence of unsuccessful participation in PT. Findings: 1. Review of CASPER 155D PT report revealed the following unsatisfactory scores for analyte #0610 acetaminophen (serum): 60% 2025 event 1 60% 2025 event 2 2. Review of 2025 CAP General Chemistry/Therapeutic Drugs PT evaluation reports confirmed the unsatisfactory scores for toxicology analyte #0610 acetaminophen (serum) in two consecutive PT events.