

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233677	(X3) Date Survey Completed 07/29/2025
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 29, 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 the second occurrence involving three of ten laboratory testing personnel 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, laboratory PT evaluations from the College of American Pathologists (CAP), signed CAP PT</p>

	<p>attestation records, and the laboratory personnel roster (CMS-209 from 7/30/25), the laboratory failed to achieve satisfactory performance for analyte #0415 glucose in three of three consecutive testing events in 2024 and 2025, and has sustained a subsequent occurrence of unsuccessful participation in PT involving three of 10 testing personnel. Refer to D2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, PT evaluations from College of American Pathologists (CAP), current personnel roster (CMS-209), and signed CAP attestation records, the laboratory failed to achieve satisfactory performance for the analyte #0415 glucose in three of three consecutive testing events and has sustained a second occurrence of unsuccessful participation in PT involving three of 10 testing personnel. Findings: 1. Review of CASPER 155D PT report revealed the following unsatisfactory scores for analyte #0415 glucose: 60% 2024 event 3 40% 2025 event 1 60% 2025 event 2 2. Review of CAP PT evaluation reports confirmed the unsatisfactory scores and second unsuccessful performance for analyte #0415 glucose in three of three consecutive testing events. 3. Review of laboratory personnel roster (CMS-209), from 7/30/2025, identified TP1, TP2, and TP3 as current testing personnel. 4. Review of signed CAP attestation records identified three of 10 testing personnel (TP) responsible for the testing events. 60% 2024 event 3 (performed by TP1, TP2, TP3) 40% 2025 event 1 (performed by TP1) 60% 2025 event 2 (performed by TP1)</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 CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from the College of American Pathologists (CAP), signed CAP PT attestation records, and the current personnel roster (CMS-209), the laboratory director failed to ensure deficient practices leading to the initial unsuccessful participation in PT for analyte #0415 glucose were corrected, resulting in a subsequent occurrence of unsuccessful participation in three of three consecutive testing events, involving three of 10 testing personnel in 2024 and 2025. Refer to D6019.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing</p>

results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:

Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from the College of American Pathologists (CAP), current personnel roster (CMS-209), and signed CAP PT attestation records, the laboratory director failed to ensure deficient practices leading to the initial unsuccessful participation in PT for analyte #0415 glucose were corrected, resulting in a subsequent occurrence of unsuccessful participation in three of three consecutive testing events in 2024 and 2025 involving three of 10 laboratory testing personnel. Findings: 1. Review of CASPER 155D report revealed the following unsatisfactory scores for analyte #0415 glucose: 60% 2024 event 3 40% 2025 event 1 60% 2025 event 2 2. Review of CAP PT evaluation reports confirmed the unsatisfactory scores and second unsuccessful participation for analyte #0415 glucose in three of three consecutive testing events. 3. Review of laboratory personnel roster (CMS-209, 7/30/2025) identified TP1, TP2, and TP3 as current testing personnel. 4. Review of signed CAP PT attestation records identified three of 10 testing personnel (TP) responsible for the testing events. 60% 2024 event 3 (performed by TP1, TP2, TP3) 40% 2025 event 1 (performed by TP1) 60% 2025 event 2 (performed by TP1) 5. The unsatisfactory performance scores for analyte #0415 glucose in 2025 event 2 is a repeated occurrence of unsuccessful participation in three of three consecutive testing events involving three of 10 testing personnel.