

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0233677	<b>(X3) Date Survey Completed</b> 03/25/2026
<b>Name of Provider or Supplier</b> Welch Community Hospital	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A routine recertification survey was conducted March 24 and 25, 2026, at Welch Community Hospital. The laboratory was assessed for compliance with 42 CFR Part 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by: Based on review of McKesson Consult Diagnostics Mononucleosis Cassette Test instructions for use (IFU), laboratory serology policies and procedures, quality control (QC) records for mononucleosis testing, patient results for mononucleosis testing, interview with testing personnel (TP1 and TP2), and exit interview with the general supervisor (GS), the laboratory failed to perform external QC on 22 of 26 days of patient testing, resulting in 27 patient results released from 1/1/26 thru date of survey, without the required daily external QC. Findings: 1. Review of of the McKesson Consult Diagnostics Mononucleosis Cassette Test IFU identified the test complexity as waived for whole blood specimens and moderate for serum or plasma specimens. The IFU stated Quality Control as "Good laboratory practice recommends the periodic use of external control materials to ensure proper kit performance" with no specified number of materials or frequency. 2. Review of the laboratory serology "Consult Diagnostics Mononucleosis Test Procedure" (reviewed 3/17/23) identified serum as the sample type used for patient mononucleosis testing. 3. Review of the laboratory serology "Quality Assessment Moderate Testing Kits" (reviewed 11/30/2023) revealed the external QC process as "positive and negative external controls will be run daily on the testing kits listed below" with mononucleosis test kits listed. 4. Review of external QC logs (1/1/26 thru date of survey) for mononucleosis kit testing identified documented external QC performed on 13 days: 1/1, 1/6, 1/13, 1/20, 1/27, 2/3, 2/10, 2/17, 2/24, 3/2, 3/9, 3/17, 3/24 5. Review of patient testing (1/1/26 thru date</p>

of survey) identified 26 days patient mononucleosis results were released: 1/1, 1/5, 1/10, 1/16, 1/17, 1/18, 1/19, 1/21, 1/24, 1/27, 1/28, 2/6, 2/7, 2/11, 2/13, 2/15, 2/18, 2/22, 2/24, 3/12, 3/13, 3/15, 3/17, 3/18, 3/21, 3/22 6. Comparison of the dates of patient testing with the dates of external QC identified 22 days of patient mononucleosis testing with no performance of external QC with the following 27 patients affected: 1/5 patient 1 1/10 patient 2 and patient 3 1/16 patient 4 1/17 patient 5 and patient 6 1/18 patient 7 1/19 patient 8 1/21 patient 9 and patient 10 1/24 patient 11 1/28 patient 12 2/6 patient 13 2/7 patient 14 2/11 patient 15 2/13 patient 16 2/15 patient 17 2/18 patient 18 2/22 patient 19 3/12 patient 20 3/13 patient 21 3/15 patient 22 3/18 patient 23 3/21 patient 24 3/22 patient 25. patient 26, patient 27 7. During an interview, 3/24/26 at 4:00 PM, TP1 and TP2 confirmed the specimen type for mononucleosis testing as serum and stated "QC is only ran on Tuesdays". 8. During an exit interview, 3/25/26 at 2:30 PM, the GS confirmed the lack of external QC for mononucleosis testing on 22 of 26 days of patient testing and the lack of an alternative Individualized Quality Control Plan (IQCP).