

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2138095	<b>(X3) Date Survey Completed</b>  04/23/2026
<b>Name of Provider or Supplier</b>  Buena Vista University Health Services	<b>Street Address, City, State</b>  610 W 4th Street, Storm Lake, IA	
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>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on observations made during the survey, review of test system manufacturer instructions, and confirmed by interview with the Clinic Nurse and Vice President of Student Success at 11:30 am on 04/23/2026, the laboratory failed to follow the manufacturer's storage requirements for four out of four test systems in use. The findings include: 1. Observations made during the survey revealed the laboratory had the following test systems in use: Consult Strep A dipsticks, Henry Schein Urispec 11-way urine dipsticks, Abbott BinaxNow Covid-19/ Flu A &amp; B kit test, and Pregmate Pregnancy test strips. 2. The manufacturer's instructions stated to store the Abbott BinaxNow Covid-19/Flu A &amp; B test kit at 36- 86 degrees Fahrenheit. 3. The manufacturer's instructions stated to store the Pregmate Pregnancy test strips and Henry Schein Urispec 11-way urine dipsticks at 39-86 degrees Fahrenheit. 4. The manufacturer's instructions stated to store the Consult Strep A dipsticks at room temperature or refrigerated (36- 46 degrees Fahrenheit or 2-8 degrees Celsius). 5. The laboratory stored all test systems at room temperature. 6. At the time of the survey, the Clinic Nurse and Vice President of Student Success confirmed the laboratory failed to document daily room temperatures in the room where the tests systems listed above are stored and used. B. Based on observations made during the survey, review of test system manufacturer instructions, and confirmed by interview with the Clinic Nurse and Vice President of Student Success at 11:30 am on 04/23/2026, the laboratory failed to follow the manufacturer's expiration date requirements for one out of four test systems in use. The findings include: 1. Observations made during the survey revealed the laboratory had one vial of Consult Strep A dipstick tests in use</p>

with lot number 844906 and expiration date 02/24/2026. 2. At the time of the survey, the Clinic Nurse and Vice President of Student Success confirmed the laboratory failed to follow expiration date requirements for the Consult Strep A dipsticks (lot 844906, expiration 02/24/2026) by using tests strips beyond the expiration date printed on the vial. C. Based on observations made during the survey, review of test system manufacturer instructions, review of quality control (QC) records, and confirmed by interview with the Clinic Nurse and Vice President of Student Success at 11:40 am on 04/23/2026, the laboratory failed to follow the manufacturer's QC requirements for two out of four test systems in use. The findings include: 1a. The Abbott BinaxNow Covid-19/Flu A & B kit manufacturer instructions stated materials required but not provided in the kit included an External Control (BinaxNow Covid-19/Flu A & B Control Swab Kit). 2a. Observations made during the survey revealed the laboratory had one Abbott BinaxNow Covid-19/Flu A & B test kit (Lot 01CCA049, expiration 08/16/2026) opened and in use. 3a. The laboratory documented QC for Abbott BinaxNow Covid-19/Flu A & B test kits on an electronic spreadsheet. The laboratory last documented QC for BinaxNow Covid-19/Flu A & B test kits on 09/16/2024. 4a. The QC spreadsheet did not include the lot number or expiration date of the kit QC' d on 09/16/2024. The laboratory also did not have documentation of when the Abbott BinaxNow Covid-19/Flu A & B test kit (Lot 01CCA049, expiration 08/16/2026) had been opened. 5a. At the time of the survey, the Clinic Nurse and Vice President of Student Success confirmed the laboratory failed to follow manufacturer QC requirements for the Abbott BinaxNow Covid-19/Flu A & B test system (Lot 01CCA049, expiration 08/16/2026). 1b. The Henry Schein Urispec 11-way urine dipstick manufacturer instructions stated to test at least one level of positive and negative control with a new bottle/new shipment/new lot of test strips and monthly. It also stated properly stored, the strips are stable until the date of expiration printed on the bottle. 2b. Observations made during the survey revealed the laboratory had one bottle of Urispec 11-way urine test strips (Lot 6524371, expiration 10/31/2026) opened and in use. 3b. The laboratory documented QC for the Urispec 11-way urine test strips on an electronic spreadsheet. The laboratory last documented QC for the Henry Schein Urispec 11-way urine dipsticks on 11/05/2024. 4b. The QC spreadsheet did not include the lot number or expiration date of the strips QC' d on 11/05/2024. The laboratory also did not have documentation of when the Henry Schein Urispec 11-way urine dipsticks (Lot 6524371, expiration 10/31/2026) had been opened. 5b. At the time of the survey, the Clinic Nurse and Vice President of Student Success confirmed the laboratory failed to follow manufacturer QC requirements for the Henry Schein Urispec 11-way urine dipsticks (Lot 6524371, expiration 10/31/2026). D. Based on observations made during the survey, review of test system manufacturer instructions, and confirmed by interview with the Clinic Nurse at 11:50 am on 04/23/2026, the laboratory failed to follow the manufacturer's instrument maintenance requirements for one out of four test systems in use. The findings include: 1. Observations made during the survey revealed the laboratory had in use a Henry Schein Urispec Plus instrument to perform urine dipstick testing. 2. The Henry Schein Urispec Plus manufacturer instructions stated to clean and disinfect the strip holder once daily. 3. At the time of the survey, the Clinic Nurse confirmed the laboratory failed to perform and document daily maintenance requirements for the Henry Schein Urispec Plus instrument.