

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2010489	<b>(X3) Date Survey Completed</b> 12/03/2025
<b>Name of Provider or Supplier</b> Bono Family Medical Clinic And Therapy Services	<b>Street Address, City, State</b> 9146 Hwy 63 N, Bono, AR	
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>	The complaint survey of the waived laboratory was conducted on 12/3/2025. The complaint was substantiated and a deficiency was cited. The laboratory failed to meet the following Condition: 493.1771 - Inspection Requirements
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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: Through a review of manufacturer's instructions, a review of patient test logs, observations made during a tour of the laboratory, and through interviews with staff, the laboratory failed to follow manufacturer's instructions for expiration dates, and testing for the BD Veritor COVID tests, Henry Schein Strep A Dipstick, Henry Schein H Pylori test, the Influenza test in use, and the ACCU-CHEK Inform II Glucose Test System. Survey findings follow: A. During a tour of the laboratory, at 10:35 a.m. on 12/3/2025, one of one test cartridge (the only test cartridge in the cabinet) of BD Veritor COVID test was observed available for use, stored in the laboratory cabinet. The cartridge (lot #2002051) had an expiration date, on the package, of 10/20/2022. B. In an interview, at 10:40 on 12/3/2025, the testing person stated that the laboratory was no longer performing COVID testing but a review of the COVID patient log listed a patient (#167) performed on the morning of the complaint survey (12/3/2025), a patient (#166) tested on 12/2/2025, and three patients (#163, #164, and #165) tested on 12/1/2025 C. During the tour of the laboratory, at 10:35 on 12/3/2025, an open box of Henry Schein Strep A Dipstick (lot STA0102019) was observed in the laboratory cabinet with an expiration date of 9/30/2022. D. A review of the patient test log for H. pylori revealed the lot number documented on the log was 8437-5 with an expiration date of 3/31/2025. Patient #20 on the log was tested on 5/29</p>

/2025 (2 months after the kit expiration date). E. A review of the patient test log for COVID testing revealed the lot number and expiration were not documented for tests from 4/29/2025 through the date of the survey. 142 patients (Patients #26 through #167 from the surveyor Patient Identifier List) were listed on six pages of patient COVID test logs during this time period. F. In a review of the patient test log for Strep it was determined the log did not include lot number or expiration of the Strep test in use from 4/23/2025 through 10/2/2025. 49 patients (Patients #1 through #49 from the surveyor Patient Identifier List) were listed on two pages of patient Strep test logs during these dates. G. A review of the "Flu" patient test log revealed the lot number and expiration were not documented for patient tests from 4/23/2025 through 9/29/2025. 75 patients were listed on three pages of Influenza patient test logs during this time. H. Through a review of the Glucose patient test log the surveyor determined the test strip lot (6710902) expiration (6/30/25) were listed at the top of the log. Two patients (Patients #6 and #7) were documented on this log on 11/4/2025. Patient #6 and Patient #7 were tested 4 months after the expiration of the test strips in use. I. The surveyor requested the manufacturer's instructions for the ACCU-CHEK Inform II glucose test system that the laboratory used for patient finger stick glucose testing. The testing person stated (11:14 a.m. on 12/3/2025) that she has never seen the instructions for using the ACCU-CHEK. The surveyor asked the testing person how long she had been performing testing. She stated that she has been performing patient testing for two months. During the interview (11:14 a.m. on 12/3/2025) the testing person was asked how she knew how to perform testing on the ACCU-CHEK without reading the Operator's Manual. She stated, "It's just natural". The surveyor located the operator's manual in a laboratory drawer at 11:20 a.m. on 12/3/2025. J. The Operator's Manual stated, "Only trained healthcare professionals may operate the ACCU-CHEK Inform II system. Operators must also have received comprehensive instruction in the operation, quality control, and care of the ACCU-CHEK Inform II system. K. In an interview at 12:15 on 12/3/2025, the clinic office manager stated there were no training records on site. She further stated the training of the laboratory testing person did not include maintenance and quality control. L. The test log for Glucose included two patients tested in the last two months. Patient #6 and #7 from the test log included testing person initials that match the one testing person present at the time of the complaint survey.

**D8100**

**INSPECTION REQUIREMENTS**  
CFR(s): 493.1771

(a) Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. (b) All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:  
Based on a review of test documentation, observations made during a tour of the laboratory, and interviews with laboratory staff, the laboratory failed to have records available for review. D8103 - The laboratory failed to have documentation of lot numbers, and expiration dates of test supplies available for surveyor review

**D8103**

**BASIC INSPECTION REQUIREMENTS**  
CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on a review of test documentation, observations made during a tour of the laboratory, and interviews with laboratory staff, the laboratory failed to have documentation of lot numbers, and expiration dates of test supplies available for surveyor review. Survey findings include: A. Patient test logs for the Strep test in use from 4/23/2025 through 10/2/2025 did not have documentation of lot number or expiration date of the kits. Forty-nine patients were listed on two pages of the Strep test logs during these dates. B. During a tour of the laboratory at 10:35 on 12/3/2025, an open box of Henry Schein Strep A Dipsticks (lot #STA0102019 Expiration 9/30/2022). This lot number and expiration were not documented on any test logs in the laboratory at the time of the survey. C. Patient test logs for the Influenza test in use from 4/23/2025 through 9/29/2025 did not have documentation of lot number or expiration date of the kits. Seventy-five patients were listed on three pages of Influenza test logs during these dates. D. Patient test logs for the COVID tests performed from 4/29/25 through 12/3/2025 did not have documentation of lot number or expiration date of the kits used. The test log for 3/31/2025 through 4/28/2025 included a lot number (2012448) but did not include an expiration date of the kit. One hundred, sixty-seven patients were listed on from 3/31/2025 through 12/3/2025. E. In an interview, at 10:40 on 12/3/2025, the testing person stated that the laboratory was no longer performing COVID testing but a review of the COVID patient log listed a patient (#167) performed on the morning of the complaint survey (12/3/2025), a patient (#166) tested on 12/2/2025, and three patients (#163, #164, and #165) tested on 12/1/2025. F. During a tour of the laboratory, at 10:35 on 12/3/2025, the surveyor observed one unopened BD Veritor COVID test cartridge in the laboratory cabinet (lot #2002051 Expiration 10/20/2022). This lot and expiration were not documented on any COVID test log. G. During an interview, at 11:15 on 12/3/2025, the only testing person in the laboratory stated that no other records of lot numbers and expirations were available.