

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1039920	<b>(X3) Date Survey Completed</b>  01/03/2023
<b>Name of Provider or Supplier</b>  Bond And Steele Clinic Pa D/B/A Bond Clinic Pa	<b>Street Address, City, State</b>  325 1st St South, Ste 303, Winter Haven, FL	
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>	An announced CLIA recertification survey was conducted at Bond and Steele Clinic PA dba Bond Clinic PA on 01/03/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology analyzer's user manuals, lack of documentation, and interview with the Laboratory Manager, the laboratory failed to document the room temperature and humidity where the old and new hematology analyzers were located for two out of two years (2020 - 2022). Findings Included: Review of the hematology analyzer's user manual, which was in use from July 31, 2020 through December of 2021, revealed the "ambient" (room) temperature had to be 16 - 35 degrees Celsius or 61 - 95 degree Fahrenheit and the room humidity had to be less than 85%. Review of the new hematology analyzer's user manual (installed January 2022) revealed the "ambient" temperature had to be 15 - 35 degrees Celsius and the room humidity had to be 20 - 85%. Interview on 01/03/23 at 12:15 p.m. with the Laboratory Manager revealed she did not know the hematology analyzers had room temperature and humidity requirements. No documentation of room temperature and humidity from July 31, 2020 - January 3, 2023 could be provided.</p>

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation and interview with Testing Personnel #C, the laboratory failed to label the 3 levels of hematology controls (L1, L2, and L3 XN - L Check) with the date opened at time of survey. Findings Included: During a tour of the laboratory on 01/03/23 at 11:10 AM, 3 levels of hematology controls ( L1, L2, and L3) were observed in a cup in the refrigerator. The date opened or the expiration date after opening was not indicated on the controls. Record review of the XN Check instructions for use revealed that "... open vial stability of 7 days if stored at 2 - 8 degrees Celsius". On 01/03/23 at 11:15 AM, Testing Personnel #C stated she thought controls were opened before Christmas.