

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1039920	(X3) Date Survey Completed 08/07/2018
Name of Provider or Supplier Bond And Steele Clinic Pa D/B/A Bond Clinic Pa	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<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 observation and interview with the Laboratory Manager, the laboratory failed to document refrigerator (where Hematology Controls were stored) temperatures for one of one month in which the refrigerator had been in use. Findings Included: Observation during the tour of the laboratory on 08/07/2018 at 12:15 PM revealed hematology controls were being stored in a refrigerator. Refrigerator temperature logs were not available upon request by the surveyor. Interview on 08/07/2018 at 1:45 PM with the Laboratory Manager revealed the laboratory had just installed the refrigerator about a month ago. She stated, they had forgotten to put a thermometer in the refrigerator and instruct Testing Personnel #A to take daily temperatures.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have a Quality Assessment policy and procedure in place for two of two years reviewed (2016-2018). Findings included: Record review on 08/07/2018 of the policy and procedure manual signed by the laboratory director showed no policy or procedure was in place for Quality Assessment. Interview with the Laboratory Manager on 08/07/18 at 1:30 PM revealed they did not know they needed a Quality Assessment policy and procedure.