Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0293247	08/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bond & Steele Clinic Pa D/B/A Bond Clinic Pa	199 Ave B Nw, 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
D0000	An announced CLIA recertification survey was conducted at Bond & Steele Clinic PA DBA Bond Clinic PA on 08/18/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to have a completed IQCP (Individualized Quality Control Plan) to allow QC (Quality Control) to be ran weekly on the Beckman Coulter Microscan per the manufacturer's instructions instead of daily since 11/01/2019. Findings Included: Review of QC on the Beckman Coulter Microscan revealed that QC was ran weekly since being validated on 11/01/2019. Review of the procedure provided by Beckman Coulter (2015 Beckman Coulter, Inc.) stated "You can either develop an IQCP or perform daily QC as described in current CLIA regulations. It will no longer be acceptable for your laboratory to follow CLSI AST guidelines alone for converting from daily to weekly testing of QC strains." "The IQCP consists of three parts: a Risk Assessment, a Quality Control Plan, and a Quality

	Assurance Plan." Interview on 08/18/2021 at 5:18 PM the Laboratory General Supervisor and Microbiology Technical Supervisor confirmed that there was no IQCP for the Microscan.