Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2145549	09/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Prevea Altoona Mob	3119 Woodman Drive, Altoona, WI	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and proficiency testing (PT) registration, and interview with the technical consultant, the laboratory had not enrolled in a PT program for serum pregnancy testing. Findings include: 1. Review of laboratory worksheets and test list showed the laboratory performed serum pregnancy testing. 2. Review of PT registration records for the laboratory showed the laboratory did not enroll in a PT program for serum pregnancy testing. 3. Interview with the technical consultant on September 6, 2018 at 11:15 AM confirmed the laboratory had not enrolled in a PT program for serum pregnancy testing as required in subpart I.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and worksheets, and interview with the technical consultant, the laboratory has not tested negative and positive control materials each day of patient serum hCG (Human chorionic gonadotropin) testing. Findings include: 1. Review of laboratory procedures showed the laboratory requires testing of two levels of quality control material each day of patient serum hCG testing. 2. Review of the Quidel QuickVue hCG worksheet for June 2018 showed controls were tested on June 1, 2018 and a patient sample was tested on June 6, 2018. The worksheet shows controls were not tested on June 6, 2018. 3. Interview with the technical consultant on September 6, 2018 at 11:15 AM confirmed the patient sample tested on June 6, 2018 was a serum sample and also confirmed controls were not tested that day. Further interview confirmed an Individualized Quality Control Plan had not been developed for serum hCG testing.