Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2018182	09/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Horn Physicians Clinic - Mapleton	520 Main Street, Mapleton, IA	

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 review of proficiency testing (PT) records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 9:00 am on 09/21/2018, the laboratory failed to enroll in an approved proficiency testing program for two out of two years (2017 and 2018) for the analytes: troponin and creatine kinase isoenzyme (CK-MB). The findings include: 1. The laboratory listed troponin and CK-MB as testing being performed on the Laboratory Test List and Annual Volume form. 2. At the time of the survey, the laboratory failed to enroll in PT testing in 2017 and 2018 for the analytes: troponin and CK-MB.
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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) and patient test records and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 9:30 am on 09/21/2018, the laboratory failed to perform two levels of QC each day of patient testing for the analytes troponin and creatine kinase isoenzyme (CK-MB) for one out of one day of patient testing (2/20/2018). The findings include: 1. Patient identifier A, had troponin and CK-MB testing performed on 2/20/2018 using the Cardiac Status test system (lot number 17TTK03080, expiration date 05/31/2018). 2. The laboratory performed positive and negative QC for the Cardiac Status test system (lot number 17TTK03080, expiration date 05/31/2018) on 11/17/2017. 3. The Cardiac Status Procedure stated, "Positive and negative external QC must be performed with each new shipment and or lot number of test kits, anytime the validity of the test results is questioned, and according to the established laboratory Quality Assurance Policy." 4. At the time of the survey, the laboratory did not have an IQCP for the Cardiac Status test system.