Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0915078	05/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Huron Medical Center Pc	1221 Pine Grove Ave, 2nd Floor, Port Huron, MI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to retain all daily Abbott Cell-Dyn 1800 background count records for two (May 2017 to May 2019) of two years reviewed. Findings include: 1. Record review revealed the daily background counts were not maintained for two years as follows: a. Patient testing on 08/23/18 b. Patient testing on 11/20/18 2. On May 30, 2019 at 11:00 AM, TC1 acknowledged the background counts had not been maintained for at least two years.
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 with Technical Consultant #1 (TC1), the laboratory failed to perform the hematology complete blood cell count (CBC) quality control each day of patient testing for two (#5 and #6) of nine patient charts audited. Findings include: 1. Review of the daily CBC quality control records revealed the laboratory did not run at least two different levels of controls on the day of patient testing as follows: a. 24 patients had CBC testing on 08/23/18 - no controls run b. 26 patients had CBC testing on 11/20/18 - no controls run 2. During the interview on May 30, 2019 at 11:00 am, TC1 acknowledged that at least two different levels of controls had not been performed and documented on the days of patient testing.