Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0685754	06/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pontiac General Hospital	461 W Huron, Pontiac, 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: . A. Based on record review and interview with the General Supervisor (GS), the laboratory failed to retain the ABL 800 blood gas analyzer original instrument data for 1 (July 2017 event) of 4 calibration verification testing events. Findings include: 1. A review of calibration verification data from the ABL 800 blood gas analyzer revealed a lack of original instrument data from the July 2017 calibration verification. The documentation was not available when requested by the surveyor on 6/18/19 at 9:30 am. 2. An interview on 6/18/19 at 9:30 am with the GS revealed the calibration verification data from the July 2017 testing event were not available. B. Based on record review and interview with the General Supervisor (GS), the laboratory failed to retain ABL 800 blood gas analyzer, Beckman Coulter AcT 5 Diff hematology analyzer, and "Beckman Coulter Access" chemistry analyzer maintenance logs for 7 (June - December 2017) of 24 months reviewed. Findings include: 1. A review of the ABL 800 blood gas analyzer, Beckman Coulter AcT Diff hematology analyzer, and "Beckman Coulter Access" chemistry analyzer maintenance logs revealed a lack of documentation of instrument maintenance for June-December 2017. The documentation was not available when requested by the surveyor on 6/18/19 at 11:18 am. 2. An interview on 6/18/19 at 11:18 am with the GS confirmed maintenance logs for the ABL 800, Beckman Coulter AcT Diff, and the "Beckman Coulter Access" instruments were not retained. ***Repeat Deficiency from 12/13/16 survey***
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform Beckman Coulter AcT 5 Diff hematology analyzer monthly maintenance as required by the manufacturer for 3 (June, July, and September 2018) of 24 months reviewed. Findings include: 1. A record review of the "Beckman Coulter AcT-5 Diff Series Analyzer" maintenance logs revealed a lack of documentation of monthly maintenance performed in June, July, and September 2018 as required by the manufacturer. Monthly maintenance includes the following: a. "Check lower rinse block and clean if necessary" b. "Check baths, perform extended clean" 2. An interview on 6/18/19 at 11:35 am with the GS confirmed monthly maintenance had not been performed and documented for the Beckman Coulter AcT 5 Diff analyzer for June, July, and September 2018.
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 Triage Cardiac Panel Quick Reference sheet, record review, and interview with the General Supervisor (GS), the laboratory failed to perform quality control as required for the chemistry Troponin testing for 7 (December 2018 to June 2019) of 7 months reviewed. Findings include: 1. The Triage Cardiac Panel Quick Reference sheet under the header "QC Panel" states to "run daily (every 24 hours)" and "External Controls (2) - run on every new lot, every new shipment, and every 30 days thereafter." 2. Quality Control record review revealed for 7 months the laboratory ran external controls monthly which does not meet the CLIA minimum requirement of "at least each day patient specimens are assayed or examined' or perform and develop an Individualized Quality Assurance Plan (IQCP). 3. During the phone interview on June 24, 2019 at approximately 3:15 pm, the GS confirmed controls were not performed and documented each day of patient testing and and IQCP plan had not been established. 4. The laboratory ran approximately 2206 Troponin testing from December 2018 to June 18, 2019.