Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0685754	07/27/2021
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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Laboratory Director (LD) and the Technical Consultant (TC), the laboratory failed to report SARS-CoV-2 test results every day of patient testing for 43 (10/29/2020 to 7/27/2021) of 43 days of testing. Findings include: 1. SARS-CoV-2 "Laboratory test turnaround" log was reviewed from 10/29/2020 to 7/27/2021. 2. Lack of documentation of SARS-CoV-2 test result reporting to a "healthcare provider and relevant public health authorities" from 10/29/2020 to 7/27/2021. 3. Lack of documentation of test reporting revealed for 49 SARS-CoV-2 Total Antibody assay (CV2T) patient test results were not reported as required. 4. The LD and TC confirmed the findings on 7/27/2021 at 2: 21 pm that CV2T patient test results are not reported to a relevant public health authority, only being reported to the in-house Infection Control Manager.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the General Supervisor (GS), the laboratory failed to use 3 (hematology, microbiology, and histopathology) of 3 specimen collection supplies before the expiration date. Findings include: 1. During a tour of the laboratory on 7/27/2021 at 9:05 am, the surveyor observed 3 of 3 specimen collection supplies still in circulation in the laboratory past their expiration dates as follows: a. hematology - Beckton Dickinson dipotassium ethylenediaminetetraacetic acid (K2 EDTA) tubes - expiration date of 5/31/2021 (5 tubes) b. microbiology - Cary Blair with indicator - expiration date of 5/17/2021 (1 container) c. histopathology - Histopak 10% Neutral Buffered Formalin - expiration date of 6/2021 (45 containers) 2. Review of the "Laboratory Reagents and Supplies" policy/procedure states under section IX "Reagent and Item Use and Disposal" under step 2 "Expiration Dates" detail ii "If an item is past the expiration date is should be properly disposed of immediately." 3. An interview on 7/27/2021 at 9:13 am, the GS confirmed the above supplies were still in circulation past their expiration dates. ***Repeat Deficiency from 12/13/2016 survey ***
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to comply with 21 CFR 606.100(b)(12) and did not establish criteria for determining whether returned blood is suitable for reissue for 2 (July 2019 to July 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's policy binder "Blood Bank" revealed the absence of criteria for determining whether returned blood is suitable for reissue. 2. An interview on 7/27/21 at 11:31 am with the GS confirmed the laboratory did not have criteria for determining whether returned blood is suitable for reissue.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the General Supervisor (GS), the

	laboratory failed to perform comparison testing between the troponin test using the Quidel Triage analyzer and the troponin test using the Siemens Dimension analyzer at least twice a year to evaluate the relationship between the test results for 2 (July 2019 to July 2021) of 2 years. Findings include: 1. A review of the laboratory's chemistry analytic system records revealed a lack of documentation showing the comparison testing between the two troponin test methods using the Quidel Triage analyzer and the Siemens Dimension analyzer at least twice a year to evaluate the relationship between the test results. 2. An interview on 7/27/21 at 2:15 pm with the GS confirmed the laboratory did not have documentation of comparison testing for the two methods used in troponin testing.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Office Staff, the laboratory failed to ensure ABO typing results were transferred to the final report for 2 (Patient 20059804 and Patient 20063706) of 4 blood bank patient test records reviewed. Findings include: 1. A review of blood bank patient test records revealed the following patients had ABO type and screen testing performed: a. Patient 20059804 performed on 8/5/20 b. Patient 20063706 performed on 1/4/21 2. A review of the test reports for the patients listed above revealed a lack of results of the ABO types on the test reports. 3. An interview on 7/27/21 at 1:27 pm with Office Staff confirmed the patients listed above did not have the ABO type test results on the test reports. B. Based on record review and interview with Office Staff, the laboratory failed to ensure blood unit compatibility test results were transferred to the final report for 3 (Patients 20059804, 20063706, and 20066131) of 4 blood bank patient test records reviewed. Findings include: 1. A review of blood bank patient testing log revealed the following patients had compatibility testing performed: a. Patient 20059804 on 8/5/20, 2 units were crossmatched b. Patient 20063706 on 1/4/21, 3 units were crossmatched c. Patient 20066131 on 4/22/21, 2 units were crossmatched 2. A review of the test reports for the patients listed above revealed a lack of results of the compatibility testing. 3. An interview on 7/27/21 at 1:27 pm with Office Staff confirmed the test reports did not include the results of compatibility testing for the patients listed.