Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0685754	01/21/2025
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation and interview with the owner, the laboratory failed to establish safety procedures to ensure protections against chemical and biohazardous materials for one observation of staff with a beverage in the laboratory. Findings include: 1. The surveyor observed a staff member walking through the laboratory between the urinalysis, chemistry, and hematology testing areas with an open beverage on 1/21/25 at 8:54 am. 2. A review of the laboratory's safety policies revealed a lack of policy about eating or drinking in laboratory spaces. 3. An interview with the owner of the laboratory at 8:54 am confirmed that the beverage was present, and beverages were not permitted in testing spaces.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the technical consultant, the laboratory failed to use approved test procedures for two (Vitros XT 7600 and Tosoh G8 chemistry analyzers) of three chemistry instruments used in the laboratory. Findings include: 1. The surveyor observed the Vitros XT 7600 and Tosoh G8

	chemistry analyzers in the laboratory on 1/21/25 at 8:58 am. 2. A review of the laboratory's procedure manuals revealed a lack of laboratory director approval for the use of the Vitros XT 7600 and Tosoh G8 chemistry analyzers. 3. An interview on 1/21 /25 with the technical consultant confirmed the laboratory director had not approved the test procedures for the Vitros XT 7600 and Tosoh G8 chemistry analyzers prior to use.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the technical consultant, the laboratory failed to label its control materials with the expiration dates for seven control materials observed. Findings include: 1. The surveyor observed three XN Check control vials used for the Sysmex XN-1000 hematology analyzer with the open date of "12/23" written on the vials on 1/21/25 at 8:58 am. 2. A review of the "XN CHECK" manufacturer's instructions revealed a section stating, "Open vials and vials which have been samples by cap piercing will retain stability for 7 days if stored at 2-8 degrees C after being recapped." 3. An interview on 1/21/25 at 9:41 am with the technical consultant confirmed the controls did not include the expiration date to reflect the open stability. 4. The surveyor observed four opened MAS DOA TOTAL urine toxicology controls in the refrigerator with no expiration date to reflect its stability once opened. 5. A review of the MAS DOA TOTAL manufacturer's instructions revealed a section stating, "24 month shelf life from date of manufacture at 2 to 8C; 30 day open vial stability for all analytes at 2 to 8C." 6. An interview on 1 /21/25 at 10:38 am with the technical consultant confirmed the MAS DOA TOTAL controls had been opened and did not include an expiration date. B. Based on observation and interview with the technical consultant, the laboratory failed to label two of four reagents observed onboard the Sysmex XN-1000 hematology analyzer. Findings include: 1. The surveyor observed four total reagents attached to the Sysmex XN-1000 hematology analyzer with two of them that had been removed from the original packaging, which would have included the name of the reagent, contents, lot numbers, and expiration dates on 1/21/25 at 8:58 am. 2. An interview on 1/21/25 at 10: 01 am with the technical consultant confirmed the two reagents lacked the name of the reagent, contents, lot numbers, and expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: . A. Based on observation, record review, and interview with the technical consultant,

	the laboratory failed to ensure control materials for its Sysmex XN-1000 did not exceed expiration dates for three controls in use. Findings include: 1. The surveyor observed three XN Check control vials used for the Sysmex XN-1000 hematology analyzer with the open date of "12/23" written on the vials on 1/21/25 at 8:58 am. 2. A review of the "XN CHECK" manufacturer's instructions revealed a section stating, "Open vials and vials which have been samples by cap piercing will retain stability for 7 days if stored at 2-8 degrees C after being recapped." 3. A review of the control records on the Sysmex XN-1000 revealed the previous four runs with this set of controls were performed on 1/7/25, 1/8/25, 1/10/25, and 1/17/25, after the controls had exceeded the seven day stability. 4. An interview on 1/21/25 at 9:41 am with the technical consultant confirmed the controls were no longer stable. B. Based on observation and interview with the technical consultant, the laboratory failed to ensure reagents used in performing partial thromboplastin time (PTT) testing did not exceed expiration dates for one box of reagent observed. Findings include: 1. The surveyor observed one box of PTT reagent with five bottles inside on 1/21/25 at 11:18 am with the lot number 263077 and the expiration date of 11/30/24. 2. A review of patients tested for PTT revealed the last patient performed was on 12/10/24. 3. An interview on 1/21/25 at 11:19 am with the technical consultant confirmed the reagent had exceeded its expiration date. C. Based on observation and interview with the technical consultant, the laboratory failed to ensure reagents used for its Sysmex XN-1000 did not exceed expiration dates for 2 of 5 bottles Hematology Buffer. Findings include: 1. The surveyor observed two bottles of Volu-Sol Hematology Buffer with an expiration date of 10/31/24 on 1/21/2025 at 9:45 am within the Flammable Storage Cabinet. 2. An interview on 1/21/2025 at 10:00 am with the technical consultant confirmed that the reagent had exceeded its expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the technical consultant, the laboratory failed to verify its reference intervals prior to using the Vitros XT 7600 chemistry analyzer for patient testing for 11 (February 2024 to January 2025) of 11 months since the laboratory started patient testing with the Vitros XT 7600. Findings include: 1. A review of the verification of performance specifications revealed a lack of documentation verifying reference intervals for analytes tested using the Vitros XT 7600 chemistry analyzer. 2. An interview on 1/21/25 at 3:48 pm with the technical consultant confirmed documentation of the verification of reference intervals for the Vitros XT 7600 was not present. B. Based on record review and interview with the technical consultant, the laboratory failed to establish verification of performance for its Sysmex XN 1000 analyzer for 11 (February 2024 to January 2025) of 11 months since the laboratory started patient testing with the Sysmex XN 1000. Findings include: 1. A review verification of performance revealed a lack of documentation for establishing verification of performance for the Sysmex XN 1000. 2. An interview on

	1/21/2025 at 3:39 pm with the technical consultant confirmed that documentation was not present, and testing started on 2/09/2024.