Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0861377	09/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Punxsutawney Hosp Blood Gas Lab	81 Hillcrest Drive, Punxsutawney, PA	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of records, lack of documentation and interview with the technical consultant (TC) #2, the laboratory failed to monitor room temperatures where the arterial blood gas (ABG) test reagents were stored from 09/15/2019 to the day of survey. Findings Include: 1. The Area Hospital - ABG laboratory manual procedure, B. Storage and Stability states, "1. ABL 90 solution packs: store at room temperature (2-25 degrees celsius)". "3. Qualicheck 5+ external QC levels 1, 2, 3 and calibration verification kit: store at room temperature (2-25 degrees celsius)". 2. On the day of survey, 09/15/2021, review of records revealed, the laboratory did not monitor room temperatures where the Radiometer ABL90 Flex ABG reagents were stored from 09 /15/2019 to 09/15/2021. 3. The TC #2 confirmed the findings about on 09/15/2021 around 10:00 am.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: Based on review of the laboratory records, lack of documentation and interview with technical consultant (TC) #2, the laboratory failed to establish a complete procedure, demonstrate and document verification of performance specifications for precision, reportable range of test results and verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population performed on the Radiometer ABL90 Flex, before reporting patient results in 2019. Findings Include: 1. On the days of survey, 09/15/2021, the laboratory provided a copy of an EP evaluator alternative method comparison performed for the Radiometer ABL90 Flex analyzer, that was not signed by the current laboratory director. 2. The laboratory could not provide verification of performance specifications for precision, reportable range of test results and verification that the manufacturer's reference intervals are appropriate for the laboratory's patient population performed on the Radiometer ABL90 Flex before reporting patient results in 2019. 3. TC# 2 confirmed the findings above on 09/15 /2021 around 10:20 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the technical consultant (TC) #2, the laboratory director failed to ensure 2 of 3 PT events received, identified problems that require corrective actions in 2020. Findings include: 1. On the day of survey, 09/15/2021, review of the 2020 CAP PT records revealed, the laboratory did not perform or document corrective actions for 2 of 3 events in 2020: CAP Routine Chemistry Event 1 - score 80% for PO2 Blood Gas. CAP Routine Chemistry Event 2 - score 80% for PO2 Blood Gas. 2. The TC #2 confirmed the findings above on 09/15/2021 around 09: 30 am.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel

	have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of testing personnel records, lack of documentation and interview with the technical consultant (TC) #2 the laboratory director failed to ensure that prior to testing patients specimens, 3 of 9 testing personnel (TP) received the appropriate training for performing blood gases testing on the Radiometer ABL90 Flex in 2020. Findings include: 1. On the day of survey, 09/15/2021, the laboratory could not provide training records for 3 of 9 TP (TP #7, #8 and #9) performing blood gases testing on the Radiometer ABL90 Flex starting December of 2020. 2. TP#1 confirmed the finding above on 05/27/2021 around 9:30 am.