Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0862073	05/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Guam Memorial Hospital Blood Gas Lab	850 Gov Carlos G Camacho Rd, Tamuning, GU	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to have a procedure manual that included the step-by-step performance of the procedure to operate the laboratory's Siemens Rapid Point 500 instruments (see D5403); ensure that test results of blood gas and hematology quality control materials met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient test results (see D5481); document the laboratory's system that twice a year evaluates and defines the relationship between test results using different instruments (see D5775); and establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283 (see D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on testing personnel interview and written policies and procedures record review on May 1, 2023 at 1:25 pm, the laboratory failed to have a procedure manual that included the step-by-step performance of the procedure to operate the laboratory's Siemens Rapid Point 500 instruments. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. The laboratory's written protocol for the Siemens Rapid Point 500 instruments failed to include the step-by-step performance of the procedure to operate the instruments. c. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on testing personnel interview and quality control record review on May 1, 2023 at 2:00 pm, the laboratory failed to ensure that test results of blood gas and hematology quality control materials met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient test results. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. The laboratory tested three levels of blood gas and hematology quality control materials each day of patient testing and relied on the instruments' software to monitor whether quality control material test results met the laboratory's and the manufacturer's test system criteria for acceptability. To do so, with each new lot of quality control materials, the manufacturer provided the laboratory with the appropriate quality control material test result ranges which were to be uploaded/updated by the laboratory in the instruments' software. c. Upon review, the laboratory failed to upload /update the instruments' software with any quality control material test results ranges so that the instruments' software could monitor whether quality control test material results met the laboratory's and the manufacturer's test system criteria for acceptability. At the time of this onsite survey, it could not be determined when the

	laboratory began performing quality control material testing without monitoring quality control material test results for acceptability. d. Consequently, the laboratory performed and reported patient blood gas and hematology tests results even though the laboratory had no assurance quality control material test results met the laboratory's and the manufacturer's test system criteria for acceptability. e. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
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 testing personnel interview and laboratory written policies and procedures record review on May 1, 2023 at 2:50 pm, the laboratory, which performs patient blood gas and hematology tests using one of two instruments, failed to document the laboratory's system that twice a year evaluates and defines the relationship between test results using the different instruments. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. Although the laboratory maintained a written protocol titled "Comparison of Blood Gas Results," that detailed the laboratory's semi-annual protocol for comparing test results performed on the two instruments, including the criteria used to determine that test results compared, the laboratory maintained no documentation to indicate that this protocol had been followed. c. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on testing personnel interview and analytic systems record review on May 1, 2023 at 3:00 pm, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. The laboratory failed to have an established written policy and procedure for an ongoing mechanism to monitor, assess, and when indicated, correct the following problems

	identified in the laboratory's analytic systems: i. The laboratory failed to have a procedure manual that included the step-by-step performance of the procedure to operate the laboratory's Siemens Rapid Point 500 instruments. See D5403. ii. The laboratory failed to ensure that test results of blood gas and hematology quality control materials met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient test results. See D5481. iii. The laboratory, which performs patient blood gas and hematology tests using one of two instruments, failed to document the laboratory's system that twice a year evaluates and defines the relationship between test results using the different instruments. See D5775. c. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director was not met. The laboratory director, moderate complexity testing, failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory (see D6019); quality control programs were established and maintained to assure the quality of laboratory blood gas and hematology services provided (see D6020); a quality assessment program was established and maintained to assure the quality of laboratory blood gas and hematology services provided (see D6021); written policies and procedures were established for monitoring individuals who conducted analytical phases of testing to assure that they are competent and maintained their competency to perform test procedures and, whenever necessary, identify needs for remedial training or continuing education to improve skills (see D6030); and, an approved procedure manual was available to all personnel responsible for any aspect of the testing process (see D6031).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on testing personnel interview and proficiency testing written policies and procedures record review on May 1, 2023 at 1:20 pm, the laboratory director, moderate complexity testing, failed to ensure that an approved corrective action plan

	is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. Although the laboratory was enrolled in and performing proficiency testing for the patient tests it performed, in the event proficiency testing results were found to be unacceptable or unsatisfactory, the laboratory maintained no written policies and procedures detailing the laboratory's protocol to investigate and to conduct appropriate corrective actions for the proficiency testing failures. c. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on testing personnel interview and quality control record review on May 1, 2023 at 2:00 pm, the laboratory director, moderate complexity testing, failed to ensure that quality control programs were established and maintained to assure the quality of laboratory blood gas and hematology services provided. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. The laboratory failed to ensure that test results of blood gas and hematology quality control materials met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient test results. See D5481. c. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on testing personnel interview and analytic systems record review on May 1, 2023 at 3:00 pm, the laboratory director, moderate complexity testing, failed to ensure that a quality assessment program was established and maintained to assure the quality of laboratory blood gas and hematology services provided. Findings included: a. The laboratory failed to establish written policies and procedures for an ongoing

	mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. See D5791. b. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on testing personnel interview and analytic systems record review on May 1, 2023 at 3:00 pm, the laboratory director, moderate complexity testing, failed to ensure that written policies and procedures were established for monitoring individuals who conducted analytical phases of testing to assure that they are competent and maintained their competency to perform test procedures and, whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. According to laboratory personnel, the laboratory performed and documented competency evaluations pursuant to the CLIA regulation at 42 CFR 493.1413(b)(9) to ensure that laboratory personnel were performing and reporting patient blood gas and hematology tests accurately and reliably. c. However, based on the Condition: Analytic Systems not being met (see D5400), the competency evaluations performed failed to ensure that individuals who conducted analytical phases of patient blood gas and hematology testing are competent and maintained their competency to perform test procedures and, whenever necessary, identify needs for remedial training or continuing education to improve skills. d. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on testing personnel interview and written policies and procedures record review on May 1, 2023 at 2:00 pm, the laboratory director, moderate complexity testing, failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings included: a. It was the practice of the laboratory to perform patient blood gas and hematology tests using one of two Siemens Rapid Point 500 instruments. b. The laboratory maintained no documentation to indicate that any of the laboratory's written policies and procedures had been approved by the laboratory director. e. According to survey records submitted by the laboratory, the laboratory performed approximately 13,446 patient blood gas tests and 8,964 patient hematology tests annually.