| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 65D0862073 | 07/17/2025 |
| **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 |
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| **D0000** | A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a recertification survey on 7/17/2025. The following condition level and standard level deficiencies were cited: |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on direct observation, manufacturer's instructions, temperature records, and interview with the Technical Consultant, the laboratory failed to define room temperature ranges consistent with the manufacturer's instructions for 4 of 4 reagents. Findings Included: 1. In direct observation on 7/17/2025 at 10:38 AM, the following reagents and supplies were found: a. One box Siemens Rapid Complete Level 1, Lot #361124, Manufacturer storage temperature requirement 18 C to 25 C. b. One box Siemens Rapid Complete Level 2, Lot #362224, Manufacturer storage temperature requirement 18 C to 25 C. c. One box Siemens Rapid Complete Level 3, Lot #363224, Manufacturer storage temperature requirement 18 C to 25 C. d. 1 Tube Siemens Multicap blood collection capillary tubes, Ref# 04549544, Manufacturer storage temperature requirement 4 to 25 C. 2. Review of temperature records showed an acceptable room temperature range of 2 to 25 degrees C. The following dates between October 2024 to July 2025 (Random review), the room temperature fell outside of the |

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| | manufacturer's minimum temperature requirement of 18 C (64.4 F): a. October, 2024 i. 64 degrees F - 10/18, 10/21, 10/22, 10/24, 10/25, 10/26, 10/27, 10/28 ii. 63 degrees F - 10/23 b. November, 2024 i. 64 degrees F - 11/18, 11/19, 11/20, 11/21, 11/22, 11 /23, 11/25, 11/27, 11/28, 11/29 ii. 63 degrees F - 11/24, 11/26, 11/30 c. July, 2025 i. 64 degrees F - 7/14, 7/15 3. During an interview on 7/17/2025 at 11:48 AM, the Technical Consultant confirmed that the temperature range was not in accordance with manufacturer instructions, and routinely dropped below the minimum acceptable threshold of the reagents stored. II. Based on direct observation, manufacturer's instructions, and interview with the Technical Consultant, the laboratory failed to define, monitor and document the room humidity level where 2 of 2 Siemens Rapid Point 500 analyzers were in use. Findings Included: 1. During a tour of the laboratory on 7/17/2025 at 10:38 AM, two Siemens Rapid Point 500 analyzers (#42502 and #42504) were observed in use, with no room humidity monitoring or documentation. 2. Review of the operator's manual for the Siemens Rapid Point 500 analyzer revealed a humidity requirement of 5 to 85% non-condensing. 3. During an interview on 7/17 /2025 at 11:48 AM, the Technical Consultant confirmed that the laboratory did not define, monitor or record humidity. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, instrument comparison records, and interview with the Technical Consultant, the laboratory failed to evaluate and define the relationship of blood gas testing performed at least twice a year, for 2 of 2 Siemens Rapid Point 500 analyzers. Findings Included: 1. During a tour of the laboratory on 7/17/2025 at 10:38 AM, two Siemens Rapid Point 500 analyzers (#42502 and #42504) were observed in use for blood gas testing 2. Review of the laboratory's twice annual instrument comparison records revealed linearity studies, but no comparison records to evaluate and define the relationship of blood gas testing for the two Siemens Rapid Point 500 analyzers in use. 3. During an interview on 7/17/2025 at 1:30 PM, the Technical Consultant confirmed the findings of no twice annual comparison records between the two analyzers. |
| **D6045** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(7)<br><br>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records, and confirmed in interview by the Technical Consultant (TC), the TC failed to identify the need for training for 1 of 1 testing person (TP-2). Refer to D6066 |
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| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the Centers for Medicare and Medicaid (CMS) 209 Form, personnel records, and interview with staff, the laboratory failed to ensure individuals performing testing met the required qualifications. The laboratory failed to ensure 2 of 21 testing personnel met requirements to perform moderate complexity testing. Refer to D6065 |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS) 209 Form, personnel records, and confirmed in an interview with the Technical Supervisor (TS), the laboratory failed to meet testing personnel (TP) qualifications for 2 of 21 individuals performing moderate complexity testing. Findings Included: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report (CLIA), provided by the laboratory on 7/17/2025, identified TP-16 and TP-17 performing moderate complexity testing. 2. Review of the laboratory's TP educational credential records revealed Bachelor of Science degrees in Respiratory Therapy from the Philippines, but no foreign degree equivalency to U.S. standards to meet requirements of performing moderate complexity testing. 3. In an interview on 7 /17/2025 at 1:34 PM, the TS confirmed that TP-16 and TP-17 did not have record of foreign degree equivalency, in order to qualify for moderate complexity testing. |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, |

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| | including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Centers for Medicare and Medicaid (CMS) 209 Form, laboratory policies and procedures, personnel records and interview with the Technical Consultant, it was revealed the laboratory failed to have documentation of training for 1 of 21 testing personnel (TP) performing moderate complexity testing. Findings Included: 1. Review of the CMS-209 Form included 21 testing personnel listed to perform moderate complexity testing using the Siemens Rapid Point 500 blood gas analyzers. 2. Review of the laboratory's policy titled, 'Guam Memorial Hospital Authority Respiratory Care Manual' stated the following: "D. Personnel Competency - Testing personnel must complete ten (10) arterial blood samples in the first (6) months of employment then Annual Personnel Competency Program which includes all aspects of the ABG Quality Assurance Program, successful completion of a proficiency examination, and direct observation of at least four arterial puncture and analysis procedure for the annual competencies." 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency for TP-2 (Date of Hire 5/12/2025), according to the CMS-209 Form. 4. During an interview on 7/17/2025 at 10:10AM in the laboratory, the Technical Consultant confirmed the lack of competency documentation. |