

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D0862073	(X3) Date Survey Completed 05/12/2021
Name of Provider or Supplier Guam Memorial Hospital Blood Gas Lab	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on technical consultant remote interview and proficiency testing record review on May 12, 2021, the laboratory failed to ensure that the laboratory director attested to the routine integration of the proficiency testing samples into the patient workload using the laboratory's routine methods. Findings included: a. For the following proficiency testing modules and events, attestation statements provided by the laboratory's proficiency testing provider were not signed by the laboratory director: AQ-C 2020 (Aqueous Blood Gas) and SO-C 2020 (Blood Oximetry). b. These attestation statements were provided by the proficiency testing provider so that the laboratory director could attest to the routine integration of the proficiency testing samples into the patient workload using the laboratory's routine methods.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-</p>

approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on technical consultant remote interview and proficiency testing record review on May 12, 2021, the laboratory failed to successfully participate in a proficiency testing program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. Findings included: The laboratory failed to achieve satisfactory performance for hematocrit in two of three consecutive proficiency testing events in the specialty of hematology constituting unsuccessful hematocrit proficiency testing performance. See D2130.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on technical consultant remote interview and proficiency testing record review on May 12, 2021, the laboratory failed to attain a score of at least 80% of acceptable responses for each hematology analyte in each proficiency testing event resulting in unsatisfactory performance for the analyte in the testing event. Findings included: a. The laboratory failed to attain a proficiency testing score of at least 80% as follows: 2021 Q1 Hemoglobin 20% Q1 = First Proficiency Testing Event b. Failure to attain a proficiency testing score of at least 80% events resulted in unsatisfactory proficiency testing performance for the analyte hemoglobin.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on technical consultant remote interview and proficiency testing record review on May 12, 2021, the laboratory failed to achieve satisfactory performance for the analyte hematocrit in two of three consecutive proficiency testing events resulting in initial unsuccessful hematocrit proficiency testing performance. Findings included: a. The laboratory failed to maintain successful hematocrit proficiency testing performance by failing to obtain a score of 80% in two of three consecutive hematocrit proficiency testing events as follows: 2020 Q2 2021 Q1 Hematocrit 0% 20% Q1 = First Proficiency Testing Event Q2 = Second Proficiency Testing Event b. Failure to achieve satisfactory performance for the same analyte in two of three

	<p>consecutive proficiency testing events resulted in initial unsuccessful proficiency testing performance for the analyte hematocrit.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>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 proficiency testing samples were tested as required under Subpart H of this part (see D6016).</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on technical consultant remote interview and proficiency testing record review on May 12, 2021, the laboratory director, moderate complexity testing, failed to ensure that proficiency testing samples were tested as required under Subpart H of this part. Findings included: a. The laboratory director failed to attest to the routine integration of the proficiency testing samples into the patient workload using the laboratory's routine methods. See D2009. b. The laboratory failed to attain a score of at least 80% of acceptable responses for the analyte hemoglobin in each proficiency testing event resulting in unsatisfactory performance for the analyte hemoglobin in the testing event. See D2121. b. For the analyte hematocrit, the laboratory repeatedly failed to achieve satisfactory proficiency testing scores in two of three consecutive proficiency testing events resulting in unsuccessful hematocrit proficiency testing performance. See D2016 and D2130.</p>