

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 64D0724937	(X3) Date Survey Completed 04/04/2022
Name of Provider or Supplier Lbj Tropical Medical Center	Street Address, City, State 1234 Paul Turner Dr, Pago Pago, AS	
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
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-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.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site proficiency testing (PT) records review of the CMS-155 report, the laboratory's 2021 College of American Pathology (CAP) proficiency testing (PT) records and email received from the Laboratory Director on March 31, 2022 , it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte PO2 blood gas in two (2) out of three (3) Chemistry testing events resulting in unsuccessful PT performance. See D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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

This STANDARD is not met as evidenced by:

Based on an off-site proficiency testing (PT) records review of the CMS-155 report, the laboratory's 2021 College of American Pathology (CAP) proficiency testing (PT) records and email received from the Laboratory Director on March 31, 2022, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte PO2 blood gas in two (2) out of three (3) Chemistry testing events resulting in unsuccessful PT performance. Findings include:

1. Desk review of the CMS-155 report and the laboratory's 2021 CAP PT records revealed PO2 blood gas scores of less than eighty percent for the following Chemistry events: 2021 CAP Event 2 -score of 60% 2021 CAP Event 3- score of 60%
2. In an email received from the Laboratory Director on March 31, 2022 at 7:45 pm, it was confirmed that the laboratory was unsuccessful in the PT events listed above.