

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0289651	(X3) Date Survey Completed 08/12/2024
Name of Provider or Supplier South Bay Hospital - Blood Gas Laboratory	Street Address, City, State 4016 Sun City Center Blvd, Sun City Center, FL	
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
D0000	An announced CLIA validation survey was conducted at South Shore Hospital on 08/06/2024 - 08/12/2024. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathology (CAP) proficiency testing records, review of laboratory policy, and interview, the laboratory failed to run proficiency testing in the same manner as patient specimens for 2 (1st testing event in 2022 and 2nd testing event in 2023) out of 7 (1st, 2nd, 3rd testing event in 2022 and 2023, and 1st testing event in 2024) testing events reviewed in Critical Care Blood Gas with Chemistry. Findings Included: Review of CAP proficiency testing for 1st testing event in 2022 (AQ-A 2022) revealed that 5 Testing people each ran 1 CAP specimen on Blood Gas Machine #45873 starting at 2:26 PM on 03/15/2022 (these 5 samples were the results submitted to CAP), and 5 different Testing people each ran 1 CAP specimen on Blood Gas Machine #45866 starting at 2:55 PM on 03/15/2022. The CAP proficiency testing was due 03/16/2022. Review of CAP proficiency testing for 2nd testing event in 2023 (AQ-B 2023) revealed that 5 Testing people each ran 1 CAP specimen on Blood Gas Machine #56000 starting at 12:37 PM on 07/05/2023</p>

(these 5 samples were the results submitted to CAP) and 5 different Testing people each ran 1 CAP specimen on Blood Gas Machine #55957 starting at 1:15 PM on 07/05/2023. The CAP proficiency testing was due 07/18/2023. Review of "ABG-CAP Proficiency Surveys and Testing" last reviewed 11/2022 showed "Second instrument CANNOT be used for any CAP samples until after the deadline for submission." Interview on 08/08/2024 at 11:00 AM with the Respiratory Manager confirmed that patient specimens are not ran on both Blood Gas instruments and confirmed the proficiency testing was not being run as patient samples.

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 College of American Pathology (CAP) proficiency testing (PT) and interview, the Laboratory Director failed to review PT results or have a delegate perform the review for 5 (1st, 2nd, and 3rd testing events in 2022 and 1st, and 2nd testing events in 2023) out of 6 Testing events (1st, 2nd, and 3rd testing events in 2022 and 2023) reviewed. Findings Included: Review of CAP PT results revealed that the Laboratory Director did not review the PT results for 1st, 2nd, and 3rd testing events in 2022 and 1st, and 2nd testing events in 2023 for Blood Gas. Interview on 08/06/2024 at 3:50 PM with the Respiratory Manager confirmed that there was no delegation signed by the Laboratory Director.