

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0577116	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Garden Grove Hospital Medical Center	Street Address, City, State 12601 Garden Grove Blvd, Garden Grove, CA	
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	A complaint survey was completed on February 7, 2025, the laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and Testing of Samples and 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing: laboratory director.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: I. Based the CMS Certification and Survey Enhanced Reporting System (CASPER) 0155D report, American Proficiency Institute (API) proficiency test (PT) records, and interview with the staff, the laboratory failed to ensure no interlaboratory communication of proficiency testing Blood Gas results occurred prior to the date by which the laboratory must report PT. Refer to D2011. II. Based on direct observation, a review of laboratory policy, CMS Certification and Survey Enhanced Reporting System (CASPER) 0155D report, American Proficiency Institute (API) proficiency test (PT) records, and interview with the staff, the laboratory failed to ensure proficiency testing samples for Blood Gas Analysis were not referred to another laboratory for analysis for two of two testing events reviewed from 2023. Refer to D2013.</p>

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based the surveyor's direct observation, the laboratory's proficiency testing policy, CMS Certification and Survey Enhanced Reporting System (CASPER) 0155D report, American Proficiency Institute (API) proficiency test (PT) records, and interview with the staff, the laboratory failed to ensure no interlaboratory communication of proficiency testing Blood Gas results occurred prior to the date by which the laboratory must report PT for one of two (2023-3) testing events from 2023. Findings included: 1. During the laboratory tour, on 2/7/2025 at approximately 3:30 p.m. the surveyor observed no instrumentation for Blood Gas Analysis in the laboratory (Laboratory A). 2. The laboratory policy (LAB-ADM 5200) stated: "Laboratory personnel do not engage in any interlaboratory communication pertaining to the results of the PT samples until after evaluation by the PT agency" and " Proficiency samples are not sent to another laboratory for analysis, nor the Clinical Laboratory accepts proficiency testing samples from another laboratory for analysis." 3. A review of the CASPER 155D report revealed the laboratory was enrolled, participated, and received a score of 100% on the 2023-3 testing events for the analytes Lactate Blood Gas, pCO₂ Blood Gas, pO₂ Blood Gas, pH Blood Gas, Carboxyhemoglobin Blood Oximetry, Hemoglobin Blood Oximetry, Methemoglobin Blood Oximetry, and Oxyhemoglobin Blood Oximetry. 4. A review of the laboratory's API- PT records revealed this laboratory submitted the following results to API that were performed on the Rapid Point 500 (Serial Number: 0500-37656): 2023 Chemistry-Core 3rd Event 100% acceptable results Analyte/Method, Sample, Reported Result Lactate (Blood Gas) BG-11, 3.8 Lactate (Blood Gas) BG-12, 2.0 Lactate (Blood Gas) BG-13, 6.8 Lactate (Blood Gas) BG-14, 9.5 Lactate (Blood Gas) BG-15, 7.3 pCO₂ (Blood Gas) BG-11, 71 pCO₂ (Blood Gas) BG-12, 21 pCO₂ (Blood Gas) BG-13, 35 pCO₂ (Blood Gas) BG-14, 27 pCO₂ (Blood Gas) BG-15, 68 pO₂ (Blood Gas) BG-11, 173 pO₂ (Blood Gas) BG-12, 127 pO₂ (Blood Gas) BG-13, 100 pO₂ (Blood Gas) BG-14, 80 pO₂ (Blood Gas) BG-15, 51 pH (Blood Gas) BG-11, 7.11 pH (Blood Gas) BG-12, 7.63 pH (Blood Gas) BG-13, 7.44 pH (Blood Gas) BG-14, 7.59 pH (Blood Gas) BG-15, 7.15 Carboxyhemoglobin (Blood Oximetry) BLX-11, 9.9 BLX 12, 0.8 BLX-13, 20.6 BLX-14, 16.1 BLX-15, 5.5 Hemoglobin (Blood Oximetry) BLX-11, 11.3 BLX 12, 18.1 BLX-13, 14.2 BLX-14, 12.7 BLX-15, 18.1 Methemoglobin (Blood Oximetry) BLX-11, 6.7 BLX 12, 0.7 BLX-13, 17.2 BLX-14, 12.1 BLX-15, 0.6 Oxyhemoglobin (Blood Oximetry) BLX-11, 83.2 BLX 12, 98.3 BLX-13, 61.7 BLX-14, 71.5 BLX-15, 93.6 5. Review of the CASPER 155D PT and API-PT reports revealed this laboratory and Laboratory B reported the same PT test results for the third 2023 event. 6. Review of the laboratory's submitted CMS-209 form and this laboratory's API signed attestation statement of API PT event 2023-3 revealed the testing personnel that signed the attestation statements were not listed on this laboratory's CMS-209. 7. In an interview on February 7, 2023, at approximately 3:30

p.m., the general supervisor stated the laboratory had no knowledge or record of receiving a of Blood Gas Analysis PT samples from API for the 2023-3rd event. 8. In further interview on February 7, 2025, at approximately 3:30 pm, the general supervisor as listed on the CMS-209, confirmed that laboratory B submitted Blood Gas analysis PT reports for third event of 2023 to this laboratory's (GS) to be reported to API.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on direct observation, a review of laboratory policy, CASPER 0155D report, API PT records, and interview with the staff, the laboratory failed to ensure proficiency testing samples for Blood Gas Analysis were not referred to another laboratory for analysis for one of two (2023-2) testing events reviewed from 2023. Findings included: 1. During the laboratory tour, on 2/7/2025 at approximately 3:30 p. m. the surveyor observed no instrumentation for Blood Gas Analysis in the laboratory. 2. A review of the laboratory policy (LAB-ADM 5200) stated: "Laboratory personnel do not engage in any interlaboratory communication pertaining to the results of the PT samples until after evaluation by the PT agency" and " Proficiency samples are not sent to another laboratory for analysis, nor the Clinical Laboratory accepts proficiency testing samples from another laboratory for analysis." 3. A Review of the CASPER 155D report revealed the laboratory was enrolled, participated, and received a score of 100% on the 2023-2 testing event for the analytes Lactate Blood Gas, pCO2 Blood Gas, pO2 Blood Gas, pH Blood Gas, Carboxyhemoglobin Blood Oximetry, Hemoglobin Blood Oximetry, Methemoglobin Blood Oximetry, and Oxyhemoglobin Blood Oximetry. 4. A review of the laboratory's API- PT records revealed this laboratory submitted the following results to API that were performed on the Rapid Point 500 (Serial Number: 0500-37656): 2023 Chemistry -Core-2nd Event 100% acceptable results: Analyte/Method, Sample, Reported Result Lactate (Blood Gas) BG-06, 6.9 Lactate (Blood Gas) BG-07, 9.4 Lactate (Blood Gas) BG-08, 4.6 Lactate (Blood Gas) BG-09, 2.6 Lactate (Blood Gas) BG-10, 7.1 pCO2 (Blood Gas) BG-06, 37 pCO2 (Blood Gas) BG-07, 33 pCO2 (Blood Gas) BG-08, 45 pCO2 (Blood Gas) BG-09, 79 pCO2 (Blood Gas) BG-10, 68 pO2 (Blood Gas) BG-06, 98 pO2 (Blood Gas) BG-07, 226 pO2 (Blood Gas) BG-08, 187 pO2 (Blood Gas) BG-09, 39 pO2 (Blood Gas) BG-10, 50 pH (Blood Gas) BG-06, 7.44 pH (Blood Gas) BG-07, 7.49 pH

(Blood Gas) BG-08, 7.34 pH (Blood Gas) BG-09, 7.03 pH (Blood Gas) BG-10, 7.15 Carboxyhemoglobin (Blood Oximetry) BLX-06, 20.7 BLX 07, 32 BLX-08, 26.1 BLX-09, 16.8 BLX-10, 0.8 Hemoglobin (Blood Oximetry) BLX-06, 14.4 BLX 07, 16.7 BLX-08, 15.6 BLX-09, 13.0 BLX-10, 18.5 Methemoglobin (Blood Oximetry) BLX-06, 17.4 BLX 07, 28.0 BLX-08, 21.6 BLX-09, 12.1 BLX-10, 0.7 Oxyhemoglobin (Blood Oximetry) BLX-06, 61.7 BLX 07, 39.7 BLX-08, 52.0 BLX-09, 70.9 BLX-10, 98.3 5. In interview on February 7, 2025 at approximately 2:30 p.m. the laboratory's general supervisor stated the laboratory received PT samples for Blood Gas Analysis Lactate Blood Gas, pCO2 Blood Gas, pO2 Blood Gas, pH Blood Gas, Carboxyhemoglobin Blood Oximetry, Hemoglobin Blood Oximetry, Methemoglobin Blood Oximetry, and Oxyhemoglobin Blood Oximetry from API for the 2nd event of 2023 and delivered the PT samples to laboratory B to be processed and tested. 6. Review of the laboratory's submitted CMS-209 form and this laboratory's API signed attestation statement of API PT events 2023-2 revealed the testing personnel that signed the attestation statements were not listed on this laboratory's CMS-209. 7. Further review of the CASPER 155D PT and API-PT reports revealed this laboratory and Laboratory B reported the same PT test results for the second 2023 event. 8. In an interview on February 7, 2025, at approximately 3:30 pm, the general supervisor as listed on the CMS 209, confirmed that laboratory B submitted Blood Gas analysis PT reports for the second event of 2023 to this laboratory to be reported to API.

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 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.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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;

This STANDARD is not met as evidenced by:
Based on a review of laboratory policy, the CMS CASPER 0155D report, API PT records, Rapid Point 500 blood gas analyzer test records, the CMS-209 form, and staff interview, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H of this part. Refer to D2011 and D2013.