

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0577147	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Chino Valley Medical Center	Street Address, City, State 5451 Walnut, Chino, 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 enroll proficiency testing samples for Blood Gas Analysis for one of three events in 2023. Findings Include: 1. Review of the CASPER 155D PT revealed no scores for blood gas analysis for API 2023 second event. 2. Review of the API-PT reports revealed the laboratory did not enroll in a PT program for the second event of 2023 for Blood Gas Analysis. The laboratory failed to provide documentation of enrollment or proficiency testing for the second event in 2023 for Blood Gas Analysis with API or any other HHS approved proficiency testing agency. 3. In an interview on February 7, 2025, at approximately 2:30 p.m. the laboratory manager confirmed that the laboratory was not enrolled for the second</p>

event for Blood Gas Analysis for 2023. II. 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. III. 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 notify CMS of the receipt of Blood Gas proficiency samples from another laboratory. Refer to D2013.

D2011

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(3)

(b)(3) The laboratory must report PT results for microbiology organism identification to the highest level that it reports results on patient specimens.

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 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. Review of the Garden Grove Hospital & Medical Center Blood Gas Laboratory Proficiency Testing Departmental Policy # BG24 stated, "Referral of proficiency testing specimens to another laboratory is prohibited and there are not to be any interlaboratory communication until after the deadline for submission of data to the proficiency testing provider". 2. Review of the API 2023 order confirmation indicated this laboratory's technical supervisor (customer number 34256), as listed on the CMS-209, placed an order for Blood Gas Plus and Blood Oximetry on August 18, 2022, for the first and third PT events for 2023. 3. A review of the laboratory's Rapid Point 500 (Serial Number: 0500-37657), obtained by Testing Personnel 8485 for the API-PT 2023-3rd event revealed a successful score of 100% with the following 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 4. Review of the API Attestation Statement for 3rd event of 2023, Centers for Medicare and Medicaid Services Form (CMS) 209 "Laboratory Personnel Report" revealed the testing personnel for Blood Gas Analysis for the API - PT 3rd event in 2023 were testing personnel for this laboratory. 5. Further review of the CASPER 155D report and API-PT reports revealed the laboratory and Laboratory A reported the same results for the 3rd event of 2023. 6. In an interview on February 7, 2025, at approximately 4:00 p.m. with technical supervisor as listed on the CMS 209,

confirmed the laboratory received PT samples for the 3rd event 2023 directly from API for processing, testing, and reporting. 7. In an interview on February 7, 2025, at approximately 4:00 p.m., technical supervisor confirmed that the PT results for the 3rd event 2023 were reported to API by the laboratory and submitted to laboratory A.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

(b)(5) 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 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 failed to notify CMS of the receipt of Blood Gas proficiency samples from another laboratory for one of two (2023-2) testing events from 2023. The findings included: 1. Review of the Garden Grove Hospital & Medical Center Blood Gas Laboratory Proficiency Testing Departmental Policy # BG24 stated, "Referral of proficiency testing specimens to another laboratory is prohibited and there are not to be any interlaboratory communication until after the deadline for submission of data to the proficiency testing provider". 2. Review of the API 2023 order confirmation indicated that this laboratory's technical supervisor (customer number 34256), as listed on the CMS-209, placed an order for Blood Gas Plus and Blood Oximetry on August 18, 2022, for the first and third PT events for 2023. 3. A Review of the CASPER 155D and API proficiency testing report for 2023 revealed the laboratory was not enrolled for the 2nd API event of 2023 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. The laboratory received API second event of 2023 PT samples from laboratory A, tested the samples, and submitted the results to laboratory A to be reported to API. 4. A review of the laboratory's Rapid Point 500 (Serial Number: 0500-37656), obtained by Testing Personnel 8485 for the 2nd event revealed: 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. Review of the API Attestation Statement for 2nd event of 2023, Centers for Medicare and Medicaid Services Form (CMS) 209 "Laboratory Personnel Report" revealed the testing personnel for Blood Gas Analysis for the API - PT 2nd event in 2023 were testing personnel for this laboratory. 6. Further review of the CASPER 155D report and API-PT reports revealed the laboratory and Laboratory A reported the same results for the 2nd event of 2023. 7. In an interview on February 7, 2025, at approximately 12:30 p.m., the technical supervisor as listed on the CMS-209, confirmed that PT samples for Blood Gas and Blood Oximetry for 2023 2nd event were received from Laboratory A. The laboratory received the samples and tested them. 8. An interview with the technical supervisor on February 7, 2025, at approximately 3:30 p.m., confirmed the laboratory did not report the 2nd-2023 PT event results to API, but submitted the results to laboratory A that 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)

(e)(4)(i) 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.