

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0690398	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier San Antonio Regional Hospital	Street Address, City, State 999 San Bernardino Road, Upland, 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	An onsite validation survey was conducted on 05/13/2026. The laboratory was found to be NOT in compliance with the following condition level deficiency. D6063 - 42 C. F.R. 493.1421 Condition: Laboratories performing moderate complexity testing, testing personnel.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, lack of a Technical Consultant (TC) competency assessment procedure, and an interview with the TC #1, the laboratory failed to have a policy and procedure in place to assess the competency of two of two TC's. Findings: 1. A review of the laboratory personnel competency assessment policy, No: 7720.00702, revealed competency assessment for the TC role was not included in the policy. Further review of the policy, No: 7720.00702, revealed the laboratory failed to establish a competency assessment procedure for the TC role. 2. In an interview on 05/13/2026 at 11:15 AM, the TC confirmed the laboratory did not have a policy and procedure in place for the competency assessments of two of two TC's. II. Based on review of laboratory's policies and procedures, Testing Personnel (TP) competency records, and an interview with the TC #1, the laboratory failed to complete competency assessments for 2 of 97 TP. Findings: 1. A review of the laboratory personnel competency assessment policy, No: 7720.00702, revealed the following statements, "Respiratory Care employees are evaluated at an initial 90 day interval and annually thereafter. After ABG Lab orientation, RCPs are will receive their initial evaluation at a 6 month interval and annually thereafter." 2. A review of TP competency records revealed the laboratory failed to follow their competency</p>

assessment procedure of completing annual competency assessments for TP #25 and TP #38. 3. In an interview on 05/13/2026 at 11:15 AM, the TC #1 confirmed no competency assessments were completed for TP #25 and TP #38 in 2024 and 2025.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observations, review of testing system product specifications, review of room temperature log sheets, and an interview with the Technical Consultant (TC #1), the laboratory failed to define and monitor an acceptable room temperature and barometric pressure range based on the instrument manufacturers requirements for 6 of 6 blood gas analyzers. Findings: 1. In touring the following laboratory locations on 05/13/2026 at 9:40 AM, the following RAPIDPoint 500e Blood Gas analyzers were observed, used for patient sample testing: Intensive Care Unit-Blood Gas Lab Analyzer 1: SN 57693 Analyzer 2: SN 57696 Analyzer 3: SN 57675 Emergency Room # 2121 Analyzer 4: SN 63931 Analyzer 5: SN 68877 Neonatal Intensive Care Unit Analyzer 6: SN 57683 2. In review of the RAPIDPoint 500e Blood Gas System Product Specification, the following environmental requirements were stated: Temperature: 15C to 30C (59F to 86F) Barometric pressure: 523 to 800 mmHg 3. The following acceptable room temperature ranges were stated for each of the laboratory locations: Intensive Care Unit-Blood Gas Lab Room Temperature Range = 59F to 89.6 F Barometric Pressure Range = None Defined Emergency room #2121 Room Temperature Range = 59F to 89.6F Barometric Pressure Range = None Defined Neonatal Intensive Care Unit Room Temperature Range = 59F to 89.6F Barometric Pressure Range = None Defined 4. In an interview on 05/13/2026 at 2:38 PM, the TC #1 confirmed the laboratory did not define the correct acceptable room temperature range and did not define and monitor barometric pressure requirement based on the instrument manufacturer's requirements.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview with the

	<p>Technical Consultant #1 (TC #1), the Laboratory Director failed to define in writing the responsibilities and duties for two of two TC's. Findings: 1. Refer to D5209.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and an interview with the Technical Consultant #1 (TC #1), the laboratory failed to ensure 3 of 97 Testing Personnel were qualified to perform moderate complexity testing of patient samples and provide accurate results. Findings: 1. Refer to D6065</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Form CMS-209, review of personnel records, and an interview with the Technical Consultant #1 (TC #1), the laboratory failed to ensure 3 of 97 Testing Personnel (TP) had appropriate education and experience to be qualified to perform patient sample testing and provide accurate results. Findings: 1. From the Form CMS-209, 10 randomly selected TP records were reviewed for education and experience qualifications. The following three TP did not meet education and/or experience requirements: TP #42: No educational records provided, only Board of Registry Certificate. TP #65: No educational records and/or experience documentation provided. TP #90: High School Diploma provided with no experience documentation. 2. In an interview on 05/13/2026 at 2:45 PM, the TC #1 confirmed the findings stated above.</p>