Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0949242	09/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Community Hospital Of Huntington Park	2623 E Slauson Ave, Huntington Park, 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 validation survey was conducted on September 8, 2025. The facility was found to be not incompliance with the following CLIA condition for the specialties /subspecialties surveyed: 493.1421 Testing Personnel (moderate complexity)
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing records (2024 and 2025), and interview with the Cardiopulmonary Director, the laboratory failed to test chemistry blood gas proficiency samples in the same manner as it tests patient specimens for 2 of 5 testing events in 2025 (1st and 2nd events). Findings included: 1. The laboratory policy titled "Proficiency Testing" stated, " ...Purpose: To ensure that proficiency sample testing is performed in the same manner as patient sample testing ...Policy ...Proficiency samples will be tested the same number of times as routine patient samples. ABG samples and proficiency samples are to be analyzed only ONCE, if they need to be run more than once, you must document the reason the sample was run more than once ..." 2. Review of CAP proficiency testing (PT) records from 2024 and 2025 revealed the following: a. The laboratory tested the "AQ-A 2025 Critical Care Blood Gas w/Chemistry" PT samples on 02/22/2025 the following times with the following results: Sample ID AQ-1: pH -

	7.46; pCO2 - 20; pO2 - 115; Tested at 11:16:01 Sample ID AQ-2: pH - 7.62; pCO2 - 20; pO2 - 141; Tested at 11:18:36 Sample ID AQ-3: pH - 7.32; pCO2 - 35; pO2 - 85; Tested at 11:21:23 Sample ID AQ-4: pH - 7.12; pCO2 - 58; pO2 - 109; Tested at 12: 33:24 Sample ID AQ-5: pH - 7.15; pCO2 - 64; pO2 - 53; Tested at 12:38:25 All testing was performed on the GEM Premier 5000 Blood Gas Analyzer, Serial Number 23054683. Further review of the PT records revealed the samples were tested again on 02/22/2025 at the following times with the following results: Sample ID AQ-1: pH - 7.47; pCO2 - 20; pO2 - 116; Tested at 12:43:51 Sample ID AQ-2: pH - 7.63; pCO2 - 19; pO2 - 144; Tested at 12:52:25 Sample ID AQ-3: pH - 7.31; pCO2 - 35; pO2 - 79; Tested at 12:58:51 Sample ID AQ-4: pH - 7.11; pCO2 - 58; pO2 - 116; Tested at 13: 05:17 Sample ID AQ-5: pH - 7.14; pCO2 - 66; pO2 - 63; Tested at 13:10:18 All testing was performed on the GEM Premier 5000 Blood Gas Analyzer, Serial Number 23054682. Review of the laboratory's CAP "Critical Care Blood Gas Survey Result Form" revealed the laboratory reported results from the GEM Premier 5000, serial number 23054682 b. The laboratory tested the "AQ-B 2025 Critical Care Blood Gas w /Chemistry" PT samples on 06/18/2025 the following times with the following results: Sample ID AQ-6: pH - 7.13; pCO2 - 47; pO2 - 145; Tested at 08:29:38 Sample ID AQ-7: pH - 7.53; pCO2 - 18; pO2 - 71; Tested at 08:32:25 Sample ID AQ-8: pH - 7.08; pCO2 - 57; pO2 - 100; Tested at 08:35:57 Sample ID AQ-9: pH - 7.46; pCO2 - 20; pO2 - 88; Tested at 08:39:49 Sample ID AQ-10: pH - 7.53; pCO2 - 19; pO2 - 119; Tested at 08:42:14 All testing was performed on the GEM Premier 5000 Blood Gas Analyzer, Serial Number 23054682. Further review of the PT records revealed the samples were tested again on 06/18/2025 at the following times with the following results: Sample ID AQ-6: pH - 7.13; pCO2 - 48; pO2 - 135; Tested at 08:49:55 Sample ID AQ-7: pH - 7.53; pCO2 - 18; pO2 - 75; Tested at 08:57:00 Sample ID AQ-8: pH - 7.07; pCO2 - 61; pO2 - 100; Tested at 09:00:19 Sample ID AQ-9: pH - 7.47; pCO2 - 20; pO2 - 92; Tested at 09:02:48 Sample ID AQ-10: pH - 7.54; pCO2 - 19; pO2 - 113; Tested at 09:05:24 All testing was performed on the GEM Premier 5000 Blood Gas Analyzer, Serial Number 23054683. Review of the laboratory's CAP "Critical Care Blood Gas Survey Result Form" revealed the laboratory reported results from the GEM Premier 5000, serial number 23054682 3. In an interview of September 8, 2025 at 10:05 am, the Cardiopulmonary Director was asked why the PT samples were tested twice. The director stated she did not know why the testing persons had tested the samples on each blood gas instrument. The director confirmed that proficiency testing was not performed that same way as patient testing. Word Key: ABG-Arterial Blood Gas
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 observation, review of the GEM Premier 5000 Blood Gas Analyzer operator's manual, laboratory environmental records, and interview with the

	Cardiopulmonary Director, the laboratory failed to ensure their relative humidity range in accordance with the GEM Premier 5000 manufacturer's specifications for two of three months (June-July 2025). Findings included: 1. During a tour of the blood gas testing area on 09/08/2025 at 12:09 pm, two GEM Premier 5000 Blood Gas Analyzers (Serial Numbers 23054682 and 23054683) were observed in use. 2. The operator's manual for the GEM Premier 5000 Blood Gas Analyzer (P/N 00024029449) stated, " ...The instrument has been designed to operate correctly ... with a relative humidity of 15% to 85% (non-condensing)." 3. Review of the laboratory's environmental records for June through August 2025 revealed the laboratory had an acceptable relative humidity range of 5% to 90%. The laboratory's acceptable humidity range exceeded the manufacturer's specifications. 4. In an interview on 09/08/2025 at 10:30 am, the Cardiopulmonary Director confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory personnel records, and interview with the Cardiopulmonary Director, the laboratory failed to have documentation that 14 of 14 testing persons met the educational qualifications required to perform moderate complexity testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (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 This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, laboratory personnel records, and confirmed in interview with the Cardiopulmonary Director, the laboratory failed to have documentation that 14 of 14 testing persons met the educational qualifications required to perform moderate complexity testing. Findings included: 1.The submitted CMS-209 form included Testing Person-1 through Testing Person-14 listed to

	perform moderate complexity testing. Testing person-1 through Testing person-14 performed testing on the GEM Premier 5000 Blood Gas Analyzer. 2. During a meeting on 09/08/2025 at 1:00 pm with the Cardiopulmonary Director, the Human Resources Director, and the Senior Business Partner, the laboratory was asked to provide education documentation for the testing persons. No documentation was provided. The laboratory failed to have documentation to ensure testing persons were qualified to perform moderate complexity testing. 3. During an interview on 09/08 /2025 at 1:30 pm, the Cardiopulmonary Director confirmed the findings.