Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0548135	09/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Community And Mission 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 09/09/2025 to 9/11/2025, the laboratory was found not in compliance with the CLIA regulations with the following CONDITION: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory temperature records, laboratory policy, test volumes, and interview with the Technical Supervisor (TS) of Chemistry, the laboratory failed to follow it's own policy for defined acceptable room temperature range for 1 of 1 room. Findings Included: 1. In direct observation on 9/11/2025 at 08: 50 AM, the chemistry section temperature range in accordance to the 'Community Hospital of Huntington Park' log sheet was set to an acceptable limit of 17 to 25 degrees Celsius. 2. Review of the laboratory's policy titled 'Community Hospital of Huntington Park Chemistry Policy and Procedure Eff. 11/01/2024' stated the following under 'Specimen Handling and Storage' of serum and plasma specimens: "Mix samples by gentle inversion and bring to room temperature, 18-28 degrees Celsius (54-82 degrees Fahrenheit), prior to analysis." 3. Review of the laboratory's chemistry test volume revealed 640,342 tests run annually. 4. In an interview on 9/11 /2025 at 09:00 AM in the laboratory, the TS of Chemistry confirmed the temperature range of the lab did not adhere to their policy. II. Based on review of the laboratory's policy, laboratory transfusion records, and interview with the Technical Supervisor

	(TS) of Blood Bank, the laboratory failed to follow its own policy for recording temperatures of blood units returned back to the laboratory for 1 of 1 returned units. Findings Included: 1. Review of the laboratory's policy titled 'Community Hospital of Huntington Park Return and Reissue of Blood Products Policy & Procedure', stated the following on page 2 of 3: "Upon return check the unit bag temperature using the laser thermometer should be 2 to 5 degrees Celsius. Document temperature at the time of return. If the Blood unit bag temperature is greater than 5 degrees Celsius on return, the unit is quarantined and discarded. It should not be returned to inventory. Document in the discard/wasted unit log ..." 2. Review of the laboratory's transfusion records (January 2024 to June 2025) revealed no location on the transfusion record forms for temperature recording, and the following blood product returned with no documentation of temperature checks performed and recorded: a. 4/07/2024 - Med Rec #0092651493, Accession #241315776, Unit No: W125624032153 3. In an interview on 9/10/2025 at 1:01 PM, the TS of Blood Bank confirmed that for returned blood units, the laboratory performed the temperature checks but did not record the temperature checks on the transfusion record forms, as per the policy. III. Based on direct observation, review of the laboratory's policy and interview with the Technical Supervisor (TS) of Blood Bank, the laboratory failed to follow its own policy for maintaining minimum inventory of uncrossmatched blood for five of eight blood types. Findings Included: 1. In direct observation on 9/10/2025 at 10:04 AM, one Jewett T100-1 Surveillance Module/Refrigerator (CHP #404801257) was in use with the following uncrossmatched blood products stored inside: a. 1 O Negative units, 6 Required b. 6 O Positive units, 6 Required b. 0 A Negative units, 4 Required c. 4 A Positive units, 4 Required c. 2 B Negative units, 2 Required d. 1 B Positive units, 4 Required e. 0 AB Positive units, 4 Required f. 0 AB Negative units, 2 Required 2. Review of the laboratory's policy titled 'Community Hospital at Huntington Park Daily Inventory of Blood Policy & Procedure' stated the following minimum uncrossmatched unit inventory requirements on page 1 of 3: "1- Each day the blood bank technologist or designee takes a blood product inventory. At the same time a visual inspection of each unit is performed. 2- The minimum daily inventory of blood products which need to be maintained at all times are as follows (uncrossmatched blood) O Positive = 6 units O Negative = 6 units A Positive = 4 units A Negative = 2 units B Positive = 4 units B Negative = 2 units AB Positive = 4 units AB Negative = 2 units" 3. In an interview on 9/10/2025 at 10:04 AM, the TS of Blood Bank confirmed the minimum inventory requirements were not met. 27814 IV. Based on review of the laboratory's procedures, thromboplastin lot worksheet, and interview with Technical Supervisor #2 , the laboratory failed to have a procedure on how to perform the mean of the normal patient range (MNPT) for the Sysmex CA-600 coagulation instrument for the last two years of thromboplastin lot changes as evidenced by: 1. The laboratory could not produce a step-by-step procedure on how to perform a MNPT study for each time a thromboplastin lot was change. The laboratory did not specify the following: How many total patients they required for the study, if an equal distribution of male or females were needed, or definition of a normal patient to be used in the study. 2. In review of the thromboplastin lot worksheet titled Coagulation Parallel testing for the new lot# 564631 documented the following two patients' test results used for the change of lot study: 244276503 = 17.8 seconds 246277352 = 15.9 seconds 3. In interview with technical supervisor #2 at 1212 on 09-09-2025 confirmed they didn't have a step-by-step procedure.
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, manufacturer's instructions, laboratory temperature records, test volumes, and interview with the Technical Supervisor (TS) of Blood Bank, the laboratory failed to define room temperature ranges consistent with the manufacturer's instructions for eight of eight boxes of Ortho-Clinical Diagnostics Anti-IgG (Rabbit) gel cards. Findings Included: 1. In direct observation on 9/10/2025 at 1: 09 PM, eight boxes of Ortho-Clinical Diagnostics Anti-IgG (Rabbit) gel cards (Lot # 040325001-06) were found in storage within the blood bank room, with manufacturer temperature requirements of 2 to 25 degrees C. 2. Review of the laboratory's temperature records labeled 'Community Hospital of Huntington Park Blood Bank Room Temperature Log' revealed an acceptable temperature range of 20 to 30 degrees Celsius in Blood Bank. 3. Review of the laboratory's test volume revealed an annual test volume of 7,270 tests performed in Immunohematology. 4. In an interview on 9/10 /2025 at 1:10 PM in the blood bank, the TS of Blood Bank confirmed the temperature ranges were based on a form that needed to be updated to reflect a newly defined range in accordance with a manufacturer accepted range for reagents stored within.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions and interview with Technical Supervisor #2, the laboratory failed to document the revised expiration date on the Nerl water for one of one reagent seen as evidenced by: 1. In direct observation on 09-09-2025 during a tour of the laboratory at 1223 the Nerl High Purity water lot#253158 did not have the revised expiration date indicated on the reagent box. 2. In review of the Nerl water manufacturer's instructions on the reagent packaging states, "Use water within 30 days." 3. In interview with Technical supervisor on 09-09-2025 at 1224 confirmed that the open date should be indicated box and new revised expiration date, however they use the water within 7 days.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate.

	This STANDARD is not met as evidenced by: Based on review of the laboratory procedure, the laboratory's quality control records, and interview with Technical supervisor #3 the laboratory failed to document quality control count in duplicate and record their average calculation for Body Fluid/ Cerebral Spinal Fluid (CSF) Red blood cell (RBC) counts from January 2025 to May 2025 as evidenced by: 1. In review of the laboratory's procedure, "CSF and Other Body Fluids Cell Hem-03", states under quality control: "Use the controls as you would a patient sample ... Count the cells in the 9 squares on both sides of the hemocytometer. Average the number of cells counted on both sides. Calculate the total number of red cells and total number of white cells per ul as follows: Average No. of cells counted = total cells/ul 0.9." 2. In review of the laboratory's quality control records form January 2025 to May 2025, the laboratory did not document the second quality control count or their average number of cells calculation. 3. In interview with technical supervisor #3 on 9-10-2025 at 1341 confirmed that they failed to document the quality control duplicate (2nd) count and show their average calculation.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 Form, personnel records, and interview with the Quality Control (QC) director, the laboratory failed to ensure individuals performing testing met the required qualifications. The laboratory failed to ensure 10 of 17 testing personnel (TP) met requirements to perform high complexity testing. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory

	training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS) 209 Form, personnel records, and confirmed in an interview with the Quality Control (QC) director, the laboratory failed to meet testing personnel (TP) qualifications for 10 of 17 individuals performing high complexity testing. Findings Included: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report (CLIA), provided by the laboratory on 9/09/2025, identified 19 TPs performing high complexity testing. 2. Review of the laboratory's TP educational credential records revealed no education and/or foreign degree equivalency for the following TPs: a. TP-2, TP-3, TP-6, TP-9, TP-10, TP-11, TP-12, TP-14, TP-15, TP-17 3. In an interview on 9/11/2025 at 11:00 AM in the conference room, the QC director confirmed the aforementioned TPs did not have record of education and/or foreign degree equivalency, in order to qualify for high complexity testing.