Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0665695	09/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
City Of Hope National Medical Center	1500 East Duarte Road, Duarte, 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 investigation was conducted on 9/11/2025 to 9/12/2025, the laboratory was found not in compliance with the CLIA regulations with the following CONDITION: 42 C.F.R. 493.1240 Condition: Preanalytic systems;
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, review of the laboratory's policies and procedures, patient testing records, and interview with the Technical Supervisor of Hematopathology, the laboratory failed to evaluate the overall quality of the preanalytic system as evidenced by: 1. The laboratory failed to establish and follow its own policy for a system to differentiate specimens that have similar names or identification information and using two patient unique identifiers for two of two patients (See D5311-I). 2. The laboratory failed to have a procedure manual which included requirements for specimen processing, including step-by-step performance of procedures for pathology slide review (See D5311-II). 3. The laboratory failed to follow its own policy of ensuring accuracy and reliability for diagnostic testing provided (See D5391).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on direct observation, review of the laboratory's policies and procedures, patient test records, and interview with the Testing Personnel (TP-7), according to the Centers for Medicare and Medicaid (CMS)-209, the laboratory failed to establish and follow its own policy for a system to differentiate specimens that have similar names or identification information and using two patient unique identifiers for two of two patients tested on February 17, 2025. Findings Included: 1) In direct observation on 9 /12/2025 at 11:00AM, within the TS's office/slide-viewing room, the TS demonstrated the procedures used for patient slide review using the Beckman Coulter Kaluza Analysis Software and Epic Beaker Systems Electronic Health Records (EHR) programs. The system utilized a slide barcode scanning method, and matched two patient identifiers, to ensure congruency of patient records between the two screens and computer programs in use. An alternative manual method to scanning the barcoded slides was demonstrated using the 'outstanding list of experiments' (OLE) on Epic Beaker. 2) Review of the laboratory's policy titled 'City of Hope National Medical Center GEN 203 Patient Identification and Specimen Labeling' stated the following on page 2 of 2: "3.8 The laboratory must match each individual specimen to the paper or electronic requisition. Specimens collected at City of Hope will have the specimen label barcode scanned, either manually or by an automation line. Specimen labels will be matched visually against the requisition using at least two unique identifiers when they are collected outside of City of Hope, or during City of Hope system downtimes, or when other justifiable circumstances exist where scanning a label is not possible." 3) Review of the laboratory's policy titled 'City of Hope National Medical Center HPB 109 Specimen Identification, Criteria for Acceptance and Accessioning Version 4.0, Effective Date 8/10/2021, Last Approval 9/05/2025' stated the following on page 6 of 24: "4.4.2.2 Slides prepared in the patient setting and brought to the laboratory are considered primary specimen containers and must be labeled with two patient identifiers (first and last name and MRN). 4.4.2.3 Slides prepared from specimens in the laboratory are considered secondary specimen containers. A single, unique identifier may be used to label materials derived from the primary specimen for use in subsequent phases of testing (first and last name) 4.4.2.4 All slides are accessioned and receive an EPIC generated label. These labels contain the case number and patient's first and last names." 3) Review of patient test records on 2/17/2025 revealed an incident where the laboratory did not follow its own policy of visually matching at least two unique identifiers when the slide label was not scanned, for the following patients: a. Patient 1, Case IDs: F25-01192-A-3, F25-01192-A-4 b. Patient 2, Case IDs: F25-01193-A-9, F25-01193-A-10 Flow cytometry results for Patient 1 were for Patient 2, and input incorrectly in Epic Beaker and sent to the provider. 4) In a virtual interview on 9/12/2025 at 1:00PM, in the conference room, TP-7 explained he scanned the barcoded slide. One screen showed the patient, and other was the 'Outstanding List of Experiments' (OLE). He manually clicked on the name of the patient with the same last name, as they were listed in order next to one another on the OLE. Two identifiers were not accurately matched as per the policies and procedures. In addition, the previous policy failed to define the Epic-generated Case ID number as a viable patient identifier to fulfill the criteria. Word

	Key: MRN (Medical Records Number) II. Based on direct observation, review of the laboratory's policy and procedures, patient test records, and interview with the Technical Supervisor (TS) of Hematopathology, the laboratory failed to have a procedure manual which included requirements for specimen processing, including step-by-step procedures for pathology slide review through case sign-out for 8 of 8 months reviewed (February to September 2025). Findings Included: 1) In direct observation on 9/12/2025 at 11:00AM, within the TS's office/slide-viewing room, the TS demonstrated the procedures used for patient slide review using the Beckman Coulter Kaluza Analysis Software and Epic Beaker Systems Electronic Health Records (EHR) programs. The system utilized a slide barcode scanning method, and matched two patient identifiers, to ensure congruency of patient records between the two screens and computer programs in use. An alternative manual method to scanning the barcoded slides was demonstrated using the 'outstanding list of experiments' (OLE) on Epic Beaker. 2) Review of the laboratory's policies and procedures 'Shared Policies and Procedures (CLIA #05D0665695)' revealed no policy/sub-policy for specimen processing of histopathology or hematopathology slides associated with barcoding accessioned samples in the Beckman Coulter Kaluza Analysis Software and Epic Beaker Systems EHR program through case sign-out. 3) Review of patient test records on 2/17/2025 revealed an error at the point of case sign-out where results were reported incorrectly for the following patients due to usage of the manual method of the OLE on Epic Beaker: a. Patient 1, Case IDs: F25-01192-A-3, F25-01192-A-4 b. Patient 2, Case IDs: F25-01193-A-9, F25-01193-A-10 4) In an interview on 9/12 /2025 at 11:05 AM in the TS's office/slide-viewing room, the TS confirmed the laboratory's lack of procedures for pathologists to process specimens slides and step-by-step procedures for performing a barcode-scanned pathology slide review with the Epic Beaker and Beckman Coulter Kaluza programs.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's test records, non-conforming events (NCE) log, policies, and interview with the Technical Supervisor (TS) of Hematopathology, the laboratory failed to follow its own policy for ensuring accuracy and reliability of diagnostic testing performed on February 17, 2025 for 1 of 2 patients. Findings Included: 1. Review of patient test records on 2/17/2025 revealed an incident where laboratory Flow Cytometry results were incorrectly reported for the following patient (s): a. Patient 1, Case IDs: F25-01192-A-3, F25-01192-A-4 "Original interpretation: Markedly increased immature B cell population identified, consistent with B lymphoblastic leukemia. Amended Report interpretation: No definite immature B cell population identified Comment: The interpretation is originally entered mistakenly from another patient data analysis which showed increased B-lymphoblast population (~70%). The correct interpretation is entered after discussion ..." b. Patient 2, Case IDs: F25-01193-A-9, F25-01193-A-10; Results reported accurately 2. Review of the laboratory's NCE log (Form Number: 2025HPF003) showed an event logged on 2/18 /2025, which occurred on 2/17/2025. The following was stated: "MRN: 11681465, Sample ID: F25-01192, Incorrect result reported Brief Description of the event: (The provider) noticed a discrepancy on the Flow Cytometry result interpretation as

	compared to previous results and patient history i.e. markedly increased immature B-Cell population, consistent with B lymphoblastic leukemia lymphoblast population vs. no abnormal immature B cell population identified. Immediate action taken: Correct report issued Investigation Details: On 2/18/2025, the clinicial reached out to the pathologist on record to recheck the results. Upon investigation by the performing pathologist who signed out the flyw cytometry case, flow cytometry results from (Patient 2) were accidentally reported out on (Patient 1). The two patients' flow cytometry results appears in consecutive order and their corresponding accession numbers were off by one digit. Results for patient 2 were unaffected and reported correctly." 3. Review of the laboratory's policy titled "PolicyStat ID: 16023128, City of Hope Plan for the Provision of Care in Division of Hematopathology, Duarte Campus" stated the following on page 2 of 5: "III. Scope of Care: B. Patient and their families can expect to receive: 1. Diagnostic testing provided according to the established policies, procedures, and protocols that can been developed to verify accuracy and reliability." 4. In an interview on 9/12/2025 at 2:00 PM, the TS confirmed the mix-up between patient slide resulting, and that the laboratory failed to follow its own policies to ensure accuracy and reliability of diagnostic testing.