

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2234830	(X3) Date Survey Completed 08/12/2026
Name of Provider or Supplier Los Angeles Hematology / Oncology	Street Address, City, State 3808 W Riverside Dr Ste 302, Burbank, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the lack of a written and approved laboratory Safety Plan for the laboratory based on a risk assessment, the surveyor's direct observation during the laboratory tour, and interviews with the laboratory's testing personnel (TP) the laboratory failed to have and follow written laboratory safety procedures to ensure protection from physical, chemical, and biohazardous materials. The findings include: 1. The laboratory failed to have and follow a current and approved written general laboratory Safety Plan (policies and procedures) based on a risk assessment to provide protection from physical and biohazardous materials as needed. There were no written policies and procedures for biological or chemical spills cleanup, spill kit, earthquake preparedness, training of TP, safety check records, or laboratory coats available for TP. 2. No policies and procedures were available for decontamination of working surfaces. 3. TP affirmed by interview on August 12, 2026, at approximately 3:00 p.m., that the laboratory lacked a current written general laboratory Safety Plan based on a risk assessment that is approved, signed, and dated by the laboratory director. 4. The safety of laboratory personnel cannot be assured at this time. 4. The annual testing declaration form submitted at the time of the survey stated 10,200 patient samples were processed and reported during the time when the laboratory failed to have and follow written safety procedures.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality assurance plan (QAP) and interview with the laboratory's testing personnel (TP); the laboratory failed to perform quality assessment that included a review of the effectiveness of corrective actions taken to resolve problems, and/or revision of policies and procedures necessary to prevent recurrence of problems and failed to document all general laboratory systems quality assessment activities. The findings included: 1. The laboratory had a QAP to follow and document quality control for all phases of testing (preanalytic, analytic, and postanalytic), including self-audits, and incidents and actions taken that affected the quality of the patient testing. However, no documentation regarding quality assurance activities was performed and documented. 2. The laboratory did not have any records of quality assessment, self-audits, or an incident log or other means of documentation of incidents. 3. TP confirmed this deficiency by interview on August 12, 2026, at approximately 1:30 p.m. 4. The laboratory reported in Form CMS 116 performing approximately 10,200 patient specimens annually for which quality assurance of the preanalytic, analytic, and post-analytic phases of testing was not performed or documented.

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:

Based on the lack of laboratory's policies and procedures for hematology subspecialty, review of eight (8) randomly selected patient test results, and interviews with the laboratory's testing personnel) on August 12 ,2026; the laboratory failed to have CLIA compliant written policies and procedures manuals for hematology tests performed and reported by the laboratory available and followed by laboratory personnel. The findings included: 1. The laboratory lacked CLIA compliant written and LD approved, dated, and signed policies and procedures for: hematology including sample processing , preventive maintenance, document retention, test quality control, storage of samples, and laboratory safety policies. 2. Reliability of the laboratory tests' performance based on complete laboratory procedures to follow by testing personnel to ensure compliance with federal CLIA regulations could not be assured during this survey. 3. TP affirmed by an interview on August 12, 2026, at approximately 12:30 p.m. that the laboratory failed to provide LD signed, dated, and approved laboratory policies and procedures for all the current tests and examinations performed in the laboratory. 4. According to the testing declaration form (CMS-116) submitted and signed the laboratory director; the laboratory processed, tested, and reported approximately a total of 10,200 patient tests annually for hematology, when the laboratory lacked written and approved manuals.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of lack laboratory policies, the lack of laboratory written standard operating procedures, and interview with testing personnel (TP); the laboratory failed to have written requirements for specimen management, process for documenting failures and noncompliance, appropriate corrective actions, and monitoring for recurrence. Findings included: 1. The laboratory subspecialty is hematology. The laboratory uses the Cell Dyn 1800 to test for cell blood counts (CBC) including platelets. 2. TP presented a copy of the Cell Dyn manual as the only standard operating procedure available in the laboratory. 3. The laboratory failed to have CLIA compliant standard operating procedure for the Cell Dyn 1800 and written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage, preservation, transportation, referral specimen, and criteria for specimen acceptability and rejection for hematology. 4. TP confirmed by interview on August 12, 2026, at approximately 12:30 p.m. findings stated above. 5. For eight (8) out of eight (8) patients' records reviewed no CLIA compliant written standard operating procedures for the Cell Dyn 1800 CBC were found.

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 during the laboratory tour, review of laboratory temperature records, and interviews with the testing personnel (TP); the laboratory failed to define a criteria for the refrigerator where quality controls are stored and room temperature for the laboratory. The finding included: 1. During the laboratory tour on August 12, 2026 at approximately 1:30 p.m., the surveyor observed the lack of a room temperature log. 2. Review of the laboratory's temperature records for the refrigerator revealed no acceptable temperature range. 3. Based on interview, the TP confirmed that the temperature ranges were missing for the refrigerator daily temperature log and the lack of a room temperature log. 4. Review of the laboratory's test volume declaration by the laboratory director, the annual test volume was 10,200 hematology tests processed and reported when temperature dependent reagents and test samples accuracy cannot be confirmed.
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:
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation, review of the laboratory records, and interview with the laboratory's testing personnel; the laboratory director failed to be responsible for the overall operation, including, but are not limited to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: D5293, D5401, D5403, D5413, and D5415
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on direct observation during the tour of the laboratory, lack of a laboratory

safety plan based on a risk assessment, and interviews with the laboratory's personnel; it was determined that the laboratory director failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. See D3011.