Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0559170	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Los Angeles Heart Specialists	**Street Address, City, State** 18370 Burbank Blvd, Ste 401, Tarzana, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interview with the laboratory consultant on November 16, 2023, at 2:30 pm, the laboratory failed to successfully participate in the proficiency testing program for the hematocrit test. The findings include: 1. The laboratory participated in the AAB-MLE PT testing program for the specialty of hematology in the year 2023. However, it received an unsatisfactory score of 60% at the M1 and M2 events in 2023 for the hematocrit test which resulted in an unsuccessful PT participation. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot

	be assured. 2. The laboratory consultant on November 16, 2023, at 2:30 pm, affirmed that the laboratory did not receive a satisfactory score for the hematocrit test at the M1 and M2 events in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 11/17/2023, stated that the laboratory performs approximately 33,800 tests in hematology, annually.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interview with the laboratory consultant on November 16, 2023, at 2:30 pm, the laboratory failed to achieve satisfactory performance for the hematocrit test in two consecutive events. The findings include: 1. The laboratory participated in in the AAB-MLE PT testing program for the specialty of hematology in the year 2023. However, it received an unsatisfactory score of 60% at the M1 and M2 events in 2023 for the hematocrit test that resulted in an unsatisfactory analyte performance. Laboratory's failure to achieve satisfactory performance for the same analyte in two consecutive events resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory consultant on November 16, 2023, at 2:30 pm, affirmed that the laboratory did not receive a satisfactory score the hematocrit test at the M1 and M2 events in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 11/17/2023, stated that the laboratory performs approximately 33,800 tests in hematology, annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory consultant during an onsite survey of the laboratory on November 16, 2023, at 2:30 pm, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing moderate complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: The laboratory director failed to ensure the maintenance of an acceptable levels of analytical performance for the hematocrit test. (See D6023)
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interview with the laboratory consultant on November 16, 2023, at 2:30 pm, the laboratory failed to achieve satisfactory performance for hematocrit test in two consecutive PT events. The findings include: See D2130.