Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0642889	10/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Foundation Laboratory	1716 W Holt Ave, Pomona, 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 review of the laboratory's proficiency testing (PT) records and interview with the laboratory personnel, it was determined that the laboratory failed to perform successfully in a CAP (College of American Pathologists) PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: a. The laboratory failed to achieve satisfactory performance in CAP PT events for T3 Uptake two out of two consecutive PT testing events in the specialty of Endocrinology constituting unsuccessful PT performance. (See D-2107)
D2098	ENDOCRINOLOGY

	CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each PT testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed serum beta HCG by Siemen Atellia analyzer and enrolled with CAP (College of American Pathologists) PT program to verify the accuracy of the testing system and ensure accuracy of patient test results. b. The laboratory attained a score of 60% for serum beta HCG in Q2 2021 CAP PT event which was unsatisfactory analyte performance. c. The laboratory performed serum beta HCG in approximately 1177 patient samples monthly. d. The laboratory affirmed (10'26/2022 @ 3:15 pm) that the laboratory attained a score of 60% for serum beta HCG in Q2 2021 CAP PT event was unsatisfactory analyte performance.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events was unsuccessful performance. The findings included: a. The laboratory performed endocrinology testing including but not limited to T3 Uptake by Siemens Atellia analyzer. b. The laboratory enrolled with CAP (College of American Pathologists) PT program to ensure accuracy, and reliability of the patient test results. c. The laboratory failed to achieve satisfactory performance for T3 Uptake in two consecutive CAP PT testing events as follows: Events Scores Q1 2021 20 % Q2 2021 0% Q1 - first PT event Q2 - second PT event d. The laboratory performed T3 Uptake in approximately 1565 monthly. e. The laboratory affirmed (10/26/2022 @ 3:15 PM) that the laboratory failed to achieve satisfactory performance of T3 Uptake in both Q1 2021 and Q2 2021 CAP PT events which was unsuccessful performance for T3 Uptake.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports and

	interview with the laboratory personnel, it was determined that the laboratory failed to verify accuracy and reliability of patient test at least twice annually for the analyte which is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed a wide spectrum of analyte including but are not limited to the followings: Absolute CD+4 (CD4), Estradiol (E2), FSH, HIV viral load (HIV), and Troponin I (Trop) quant, which are not listed in subpart I of 42 CFR part 493. b. The laboratory elected to enroll with CAP (College of American Pathologists) PT programs for analyte listed in item (a) to verify the accuracy of test systems at least twice annually to ensure accuracy and reliability of the patient test results. c. The laboratory attained PT scores less than 80 % for the following analyte with each estimated monthly testing volume: Event = PT challenge, Volm = estimated test volume per month Qx, PT where x =1, 2, or 3 Event Analyte Score % Volm Q1 2022 CD4 0 125 Q1 2022 E2 33 601 Q1 2022 FSH 33 634 Q2 2020 HIV 60 150 Q3 2021 Trop 40 57 d. The laboratory affirmed (10/26/2022 @ 3:15 pm) that the laboratory attained scores less than 80% of PT events listed above (c) with approximately test volume monthly.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance (EPTP) for histopathology records, the laboratory's Quality Assessment Manual Policies and Procedures (P&P), and interview with the laboratory director and the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to assess, monitor, perform and document evaluation of proficiency testing performance for biopsy testing system. The findings included: a. The laboratory performs histopathology/biopsy and elected to perform evaluation of proficiency testing performance (EPTP) by peer review/split sample to ensure accuracy and reliability of the patient test results. b. The laboratory had established written P&P in "Quality Assessment (QA) Manual, Policy Number 55 with Policy Title: Biopsy QC" approved and signed by the current laboratory director on 8/5/2018. c. The laboratory's "QA Manual Procedure, Biopsy QC" states: "Once a month a referral processor will pull a completed biopsy report and slide, this is sent to the director who reviews the slide and comments on the report in agreement or disagreement. ...." d. The laboratory failed to follow written policies and procedures to perform EPTP "Once a month" to ensure accuracy and reliability of patient test results. e. The laboratory affirmed (10/26/22 @3:25 pm) that the laboratory failed to follow written P&P and perform "Biopsy QC" "Once a month". e. Review of the laboratory Biopsy QC records for 2021, it showed a total of 4 biopsy reports were performed as follows: ID = Specimen Order No, RD = Report Issue Date/time by a board-certified pathologist RV = Reviewed Date by a qualified peer/the lab director ID RD RV 210043360 01/12/2021 13:49 1/14/21 210331826 02/04/2021 15:53 2/12 /21 211303984 05/20/2021 08:32 5/21/21 211562266 06/11/2021 09:58 6/18/21 f. The laboratory failed to follow written P&P "Once a month" for Biopsy QC for an ongoing mechanism to assess, monitor, perform and document for EPTP and to ensure accuracy and reliability of patient test results.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, and observing the temperature controlling /monitoring devices, and interview with the laboratory staff, it was determined that the laboratory failed to perform and follow the manufacturer's instructions for a digital thermometer (DT) and in a manner that provides test results within the laboratory's stated performance specifications for the test system the laboratory selected. The findings included: a. The laboratory used many refrigerators and freezers (storage devices) to store and maintain required quality of the laboratory supplies including reagents, controls, calibrators, and patient samples, etc. b. The laboratory used digital thermometers (DT) to monitor all storage devices to monitor and maintain the required temperatures within the established acceptable temperature ranges. c. The laboratory personnel failed to follow the manufacturer's instructions and in a manner that maintain the storage temperature within acceptable temperature ranges to assure good quality of all stored materials. d. Observed a #9 DT by ThermPro at time of survey (10/26/22 @ 10:30 am), the DT showed current temperature at 3 oC and "low" at - 0 oC and "high" at 24 oC. e. The laboratory staff stated "low" and "high" were setting for the acceptable temperature range. f. The laboratory established acceptable temperature range for its refrigerator was 2 to 8 oC. g. The laboratory could not interpretate the observed DT record showing "low" at -0 oC and "high" at 24 oC. h. The laboratory failed to take corrective action for the temperature at low - 0 oC and high 24 oC.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory director failed to ensure that the PT samples were tested and attained at least 80% of acceptable scores in each PT event. b. The laboratory performed a wild spectrum of analyte which are listed and are not listed in subpart I of 42 CFR part 493. c. The laboratory elected to enroll with CAP (College of American Pathologist) PT programs for its analyte listed in subpart I and not listed in

	subpart I to verify the accuracy of testing systems and to ensure accuracy and reliability of patient test results. d. The laboratory failed to attain at least 80% of acceptable scores for analyte (see D- 2016, D-2098, D-2107, and D-5217)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's Biopsy QC records, written QA Policies and Procedures (P&P), and interview with the laboratory director and the laboratory personnel, it was determined that the laboratory director failed to ensure that the laboratory maintained and followed written P&P to assure the quality laboratory services. The findings included: a. The laboratory performed biopsy examinations and elected to perform evaluation of proficiency testing performance by split sample/peer review to verify the accuracy of the test system, and to ensure accuracy and reliability of patient test results. b. The laboratory failed to follow written Biopsy QC P&P to perform "Once a month" peer review for patient test results (see D-5291) to ensure accuracy, reliability and timely of the patient test results.