Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0969686	12/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Long Phi Dang Md Inc	7891 Westminster Blvd, Westminster, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on touring and observation of the laboratory facility, and interview with the laboratory histotech personnel, it was determined that the laboratory failed to constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the histopathology testing process. The findings included: a. The laboratory includes a histology laboratory and performs grossing, cutting, enbedding, staining, tissue processing, and reagent storage, etc. b. The space for the entire histopathology laboratory appears to be insufficient, difficuty in traffic flow, too crowded and difficult to maintain and ensure quality of tissue slide processing and staining and may be harmful for the personnel working under that environment.
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 lack of the laboratory's evaluation of proficiency histopathology testing performance for the years of 2019 and 2020, and interview with the laboratory staff, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of histopathology test the laboratory performed that is not included in

	subpart I of 42 CFR part 493. The findings included: a. The laboratory performed biopsy tissue histopathology testing on site., which is not incliuded in subpart I of 42 CFR part 493. b. The laboratory failed to perform, at least twice annually, proficiency testing to verify the accuracy of its histopathology testing performance in the years of 2019 and 2020. c. Thge laboratory staff affirmed (12/01/2020 @ 11:10 AM) that the laboratory failed to perform, at least twice annually, the proficiecncy of histopathology testing in the years of 2019 and 2020. d. The laboratory performed histopathology testing in approximately 2,400 annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of lack of the laboratory's evaluation of proficiency histopathology testing performance for the years of 2019 and 2020, and interview with the laboratory staff, it was determined that the laboratory failed to document all proficiency testing evaluation and verification activities. The findings included: a. The laboratory performed biopsy tissue histopathology testing on site., which is not incliuded in subpart I of 42 CFR part 493. b. The laboratory failed to perform, at least twice annually, proficiency testing to verify the accuracy of its histopathology testing performance in the years of 2019 and 2020. c. The laboratory failed to document all proficiency histopathology testing evaluation and verification, see D-5217.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, and interview with the laboratory staff, it was determined that the current laboratory director failed to approve, sign and date the procedures. The findings included: a. A new laboratory director took the responsibility of the laboratory directorship in April 2019, as verified in "Director Attestation" LAB Form 183. b. There is no evidence to indicate the current laboratory director approved, signed, and dated of the laboratory policies and procedures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on observation and touring the histology laboratory, and interview with the histotech, it was determined that the laboratory failed to label the reagents, solutions, or laboratory supplies to indicate its preparation and expiration dates, when opened, to ensure the stabilities of the reagents, solutions, or supplies. The findings included: a. The histology laboratory is located inside the laboratory. b. The laboratory uses solutions, such as xylene, reagent alcohol 95% v/v in the tissue processing procedures. c. No open dates and expiration dates were labeled for these reagents or soluttions.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation and toruing the laboratory, review of the laboratory records, and inteview with the laborator ystaff, it was determined that the laboratory director failed to be responsible for the overall operation including the competencies of the personnel, ensurence of the proficiency testing evaluation, and assuring compliance with applicable regulations. The findings included: a. The laboratory failed to construct, to arrange, to maintain, and to ensure the space, ventilation, and utilities necessary for conducting all phases of the histology testing process, see D-3001. b. The laboratory failerd to perform and document the evaluation of histopathology testing proficiency performance for the years of 2019 and 2020, see D-5217 and D-5221. c. The laboratory director failed to be res[posible for ensuring the procuedures aor changes in procedures to be approvesd, signed and dated, see D-5407 and failed to maintain and assure the stability of reagents or solution and to ensure quality operation of the histology laboratory, see D-5415.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Base on observation adn touring the laboratory facility, review lack of the histopathology proficiency testing records for the years of 2019 and 2020 , and interview with the laboratory staff, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the histology test system. The dfindings included: a The laboratory failed to perform, at least twice annually, proficiency testing to verify the accuracy of

	its histopathology testing performance in the years of 2019 and 2020, see D-5217 b. The laboratory failed to document all proficiency histopathology testing evaluation and verification, see D-5221.