Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0597475	11/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Noel T D Chiu Md, A M C	3436 Hillcrest Ave Ste 150, Antioch, 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
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 testing performance for histopathology testing, and interview with the testing personnel/the laboratory director (TD), it was determined that the laboratory failed to perform, at least twice annually of the proficiency testing performance to verify the accuracy of histopathology testing the laboratory performed, which is not included in the subpart I of 42 CFR part 493. The findings included: a. This laboratory performs Mohs surgery and biopsy procedures and examine the skin tissues histopathology. b. At the time of survey, 11/17/2020 @ 10:55 AM, the laboratory failed to provide the documents of evaluation of histopathologic proficiency testing performances for years of 2019 and 2020 as of 11/17/2020. c. The histopathology testing is not included in subpart I of 42 CFR part 493, the laboratory must verify, at least twice annually, the accuracy of histopathology testing system. d. The TD affirmed (11/17/2020 @ 10:55 AM) that no documents were available for the evaluation of proficiency testing of histopathology performance for 2019 and 2020 as of 11/17/2020. e. The laboratory performed histopathology in approximately 1,350 patient specimens 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 testing performance for histopathology testing, and interview with the testing personnel/the laboratory director (TD), it was determined that the laboratory failed to document all proficiency testing evaluation and verification activities. The findings included: a. This laboratory performs Mohs surgery and biopsy procedures and examine the skin tissues histopathology. b. The laboratory failed to document all activities of the laboratory's evaluation of proficiency testing performance for histopathology testing in 2019 and 2020 as of 11/17/2020.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of the laboratory testing records, interview with the testing personnel /the laboratory director (TD), it was determined that the laboratory failed to provide the laboratory established written procedures manual or a manufacturer instruction for DTM testing performed by the laboratory at the time of the survey. The findings included: a. The laboratory performs DTM fungal culture using Hardy Media, lot # 469463 with an expiration date of 3/15/2021. b. At the time of survey, 11/17/2020 @ 11:10 AM, the laboratory was not able to provide the laboratory established written procedures manual for DTM using Hardy Media materials, neither a manufacture instruction. c. There were no written procedures available for the acceptable incubation temperature range to perform the DTM testing, neither when to examine the result (incubation time). c. The TD affirmed verbally that the DTM incubation temperature was under the laboratory's room temperature, but unable to provide the acceptable room temperature range verbally or in written. d. There were no temperature records available for 1) room temperature or 2) acceptable incubation temperature range for DTM testing procedure, and 3) temperature records for the refrigerator storing DTM media. e. The TD affirmed that final examine the DTM results at the 14th days. f. The TD affirmed (11/17/2020 @ 11:10 AM) that he had performed this DTM procedure for 15 years, Based on review of the laboratory testing records, interview with the testing personnel/the laboratory director (TD), it was determined that the laboratory failed to provide the laboratory established written procedures manual or a manufacturer instruction for DTM testing performed by the laboratory at the time of the survey. The findings included: g. The TD affirmed (11/17 /2020 @ 11:10 AM) that he had performed this DTM procedure for 15 years. h. The laboratory performed DTM in approximately 21 patient samples annually.
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 review lack of the laboratory DTM procedure manual, the laboratory testing records, and interview with the laboratory testing personnel/the laboratory director (TD), it was determined that the laboratory failed to follow the manufacturer's instructions or the laboratory established written procedure manual, and examine the results in a manner that provides accurate results. The findings included: a. The laboratory failed to select a written DTM fungal culture procedure manual and/or manufacturer's instructions for Hardy Media DTM procedure, to ensure the accuracy of the DTM test results. b. The TD affirmed (11/17/2020 @ 11:20). that he examines the DTM result at the 14 days. c. Review one of the DTM worksheets from 01/25 /2019 thru 08/13/2019, there were two DTM testing indicated inconsistency with the 14 days. d. Patient J. C date of birth 04/24/64 collected from the left 4th nail was inoculated on 2/5/2019, result was examined on 2/28/2019, 23 days. e. Patient G.J #35596 collected from the right big toenail was inoculated on 2/14/2019 and final resulted on 02/14/2019, the same day. f. The laboratory performed DTM in approximately 21 patient samples annually.
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 review lack of the laboratory DTM fungal culture procedure manual, the testing records, and interview with the testing personnel/the laboratory director (TD) it was determined that the laboratory director failed to be responsible for overall operation and administration of the laboratory to ensure and maintain the quality of the laboratory testing results, and to assure compliance with the applicable regulations. The findings included: a. The laboratory performs DTM fungal culture using Hardy Media, lot # 469463 with an expiration date of 3/15/2021. b. At the time of survey, 11/17/2020 @ 11:10 AM, the laboratory was not able to provide the laboratory established DTM fungal culture procedures manual, or a manufacturer' instruction for DTM fungal culture using Hardy Media, see D-5401, D-5409 and D-5411.
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: Based on review lack of the laboratory's records for evaluation of proficiency testing

	performance for the histopathology testing, and interview with the testing personnel /the laboratory director, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for skin histopathology testing. The findings included: a. This laboratory performs Mohs surgery and biopsy procedures and examine the skin histopathology. b. At the time of survey, 11/17/2020 @ 10:55 AM, the laboratory failed to provide documents for the evaluation of histopathology proficiency testing performances in 2019 and 2020 as of 11/17/2020, see D-5217 and D-5221.