Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0982884	08/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Christine Lee, Md, A Prof Medical Corp	370 N Wiget Ln Ste 125, Walnut Creek, 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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory staff on 08 /22, 2019, the laboratory failed for those tests performed by the laboratory that are not included in subpart I of this part, to maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). The findings included: a. The laboratory performs dermatopathology/MOH's testing. b. Upon record review of the testing years January 1, 2018 through August 22, 2019, the laboratory did not have records of twice annual verification of the MOH's dermatopathology slide reviews. c. The laboratory staff confirmed by interview on August 22, 2019 at approximately 2:30 p.m. that the laboratory did not maintain documentation of twice annual verification of the testing accuracy for the MOH's testing procedures. d. The laboratory reports on the CMS-116 to performing approximately 250 MOH's patient slide reviews annually.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on laboratory personnel interview and dermatopathology/MOH's patient log and staining procedure on 08/22/2019, the laboratory failed for for differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. . The findings included: a. For ten (10) out of ten (10) randomly selected patient dermatopathology/MOH's specimens from January 1, 2018 to August 22, 2019, the laboratory maintained no documentation to indicate that the reagents used to stain these patient specimens were reviewed for intended stain reactivity. b. The laboratory had a log titled "Quality Control Assessment of MOH's Staining procedure", on the log there were three dates in which the stains had been assessed: May 8, 2018, May 15, 2018 and September 11, 2018. For the (10) random patient sampling review, (10) out of (10) had no Quality Assessment documented. Random sample patient dates were: 01/09/2018 03/06/2018 05/22/2018 08/21/2018 12/18/2018 02/05/2019 04/16/2019 06/11/2019 07/23/2019 08/13/2019 c. The laboratory staff confirmed by interview that the laboratory had not documented the stains quality assessment for the dates reviewed. d. The laboratory documented on the CMS-116, performing 250 patient dematopathology/MOH's patient samples annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory MOH's patient logs and interview with the laboratory staff on August 22, 2019, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. The Findings included: a. The laboratory contracts the postion of Histotech for performing and documenting MOH's procedures in the MOH's patient log manual. The MOH's patient log did not contain the information regarding the quality of the stains for each day of patient testing. as required in C.F.R. 493.1252(d). See D5601. b. The laboratory failed to have documentation of performing twice annual verifiation of accuracy for the survey years 2018 and 2019. See D2003 c. The laboratory staff confirmed by interview on August 22, 2019 at approximately 1:30 p.m. the lack of documentation for the reagents and the quality of the stains each day of patient use, and twice annual verification of accuracy. d.. According to the laboratory CMS-116, the laboratory performs approximately 250 MOH's patient tests annually.