

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0956602	<b>(X3) Date Survey Completed</b>  02/03/2022
<b>Name of Provider or Supplier</b>  Alamitos Dermatological Medical Clinic, Inc	<b>Street Address, City, State</b>  27725 Santa Margarita Pkwy Ste 110, Mission Viejo, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance (Eval) records, and interview with the laboratory staff, it was determined that the laboratory failed to perform the evaluation of proficiency testing performance at least twice annually to assure the accuracy of the histopathology diagnosis. The findings included: a. This survey was performed virtually on 2/3/2022 started at 10 am with ML, an Office Manager. b. This office had requested the laboratory emailed records pertaining Eval for the years of 2020 and 2021. c. Reviewed the documents the laboratory submitted before the starting of the virtual survey. d. The laboratory had failed to perform the Eval according to CLIA rules and regs, at least twice annually to verify the accuracy of the test system performed. e. The records indicated that the peer review was performed on the same date of 12/1/2021 by ML for 4 patient cases dated in 2020 and 2021. f. The four cases randomly pulled were: 1) 4/30/20 case # RM 982-20 thru RM 986-20. 2) 10/15/20 case #RM 2827-20 thru 2831-20. 3) 1/14/21 case # 204-21 thru 208-21; and 4) 4/8/21 case #1075-21 thru 1079-21.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Quality Assurance (QA) Procedure, and interview with the laboratory staff (LS), it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess in the analytic systems. The findings included: a. This survey was performed virtually on 2/3/2022 started at 10 am with ML, an Office Manager. b. This office had requested the laboratory emailed records pertaining to Eval for the years of 2020 and 2021 prior to the virtual survey. c. Reviewed the Eval documents and the interview with the LS for the laboratory's QA procedure. d. The QA procedure states that "We will randomly pull 5 slides to check the accuracy of our work twice a year." as well as "When you have check all the items date and sign the notes", and "The peer will also need to date and sign the charts as well" e. Based on interview virtually and review the "QA" procedure, the laboratory failed to follow its written QA Procedure. f. The laboratory failed to perform Eval twice annually, with different dates, not on one date for two years' Eval. g. The laboratory failed to "date" all for their QA taken. h. The laboratory affirmed 2/3/2022 @10:25 am that the laboratory failed to follow its written QA Procedure.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 evaluation of proficiency testing performance (Eval) records, Quality Assurance (QA) Procedure, and interview with the laboratory staff (LS), it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: a. This survey was performed virtually on 2/3/2022 started at 10 am with ML, an Office Manager. b. This office had requested the laboratory emailed records pertaining to Eval for the years of 2020 and 2021, and written QA procedure. c. Reviewed the Eval documents and the interview with the LS for the laboratory's QA procedure, the laboratory failed to perform Eval twice annually, see D-5217, and failed to follow its written policy and procedure, see D-5791.