Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0668322	04/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	400 West Green Meadows Lane, #110, Greenfield, IN	

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 record review and interview, the laboratory failed to follow their policy for twice annual verification of one of one test procedure (Mohs Surgery) in 2018. Finding (s): 1. "Protocol for Proficiency Testing", revised 2/2016, read: "The referring physician selects their own 10 slides for read-out and records the diagnoses in the first Diagnosis column on the PT form. A pathologist will review the 10 slides and record their diagnoses in the Diagnosis column, including any comments, and sign the form. It is suggested that proficiency testing be performed biannually." 2. Review of twice annual verification documents indicated the following: a. Twice annual verification documents were labeled "Dermatology Proficiency Testing" and there were two documents marked with the date 2018. The first document marked 2018 had "1st HALF" circled with the completed date 2/20/19. The second document marked 2018 had "2nd HALF" circled and also had a completion date of 2/20/2019. Both documents marked 2018, "1st HALF" and "2nd HALF" were dated sent by the referring physician on 2/20/2019. Both documents had been reviewed by the dermatopathologist for agreement on 4/22/2019. b. Each of these referrals contained only six slides for review instead of ten slides as required by policy. c. There was nothing marked on the documents to indicate a reason for the delay of completion or delay in submission to reviewing pathologist. 3. Review of Mohs testing records for 2018 indicated the following patients had been seen in 2018: Patients #1 on 10/18, #2 on 11/26/18, and #3 on 12/10/18. 4. On 4/24/19 at 9:40 a.m. staff member (SM) #1

	(Regional Clinic Director) confirmed that biannual proficiency testing had not been documented during 2018, and there was no remedial action or documentation on the reason for the delay or for the change in the number of slides submitted for review.
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 lack of documentation and staff interview, the laboratory director failed to establish and maintain a quality assessment program for one of one test (Mohs Surgery) performed from 2017 to 2019. Finding(s) included: 1. On request for quality assessment reviews of the Mohs Surgery testing from 2017 to 2019 on 4/24/19 at 12: 10 p.m., SM #1 (Regional Clinic Director) indicated that none were available for review. 2. On request for for policy or procedure for quality assessment reviews on 4 /24/19 at 12:10 p.m., SM #1 confirmed there were none available for review.