

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2115497	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 16115 St Vincent Way Suite 300, Little Rock, AR	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Through a review of Histology patient staining logs, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to document staining quality for Hematoxylin and Eosin (HE) stain on each day of patient testing. As evidenced by: A. A review of patient logs for December 29, 2017 thru July 12, 2018 revealed that HE stains were performed on sixty-eight patients without documentation of HE stain quality controls. Patients tested include patient # 17-001 and patient # 17-002 tested on 12/29/2017: patient # 18-005, patient # 18-006 and patient #18-007 tested on 2/9/18; patient #18--018, patient #18-019 and patient #18-020 tested on 03/23/18; patient #18-024, patient #18-025, patient #18-026, and patient #18-027 tested on 04/13/18: patient #18-039, patient #18-040, patient #18-041, patient #18-042 and patient #18-043 tested on 05/11/18: patient # 18-059, patient #18-060, patient #18-061, patient #18-062, patient #18-063 and patient #18-064 tested on 06/22/18. B. In an interview on 7/12/2018 at 11:30, the technical consultant (as listed on form CMS 209) confirmed the laboratory did not document HE stain quality on the days patients were tested.</p>