Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2115497	02/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined the laboratory failed to monitor room temperature in one of two rooms in which supplies with storage temperature requirement were stored. Findings follow: A) During a tour of the laboratory on 02/24/20 at approximately 10:30 AM, 250 BD SST Blood Collection Tubes Lot # 8274451, expiration date 2020-9-30, 350 BD EDTA Blood Collection Tubes Lot # 9260566 expiration date 2021-1-31 and 300 BD Red Top blood collection tubes lot # 8278809 expiration date 2020-9-30, all with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed stored in a storage room separate from the laboratory . B) Upon request, the laboratory was unable to provide records of room temperature in the separate storage room. C) In an interview on 02/24/20 at approximately 11:00 AM, the technical consultant, identified as number three on the CMS 209 form, stated that the laboratory did not monitor the room temperature in the storage room identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observation, interview and review of the "MOHS Surgery" log it was determined that the laboratory utilized expired staining supplies for five months during which 72 MOHS surgery procedures were performed. Findings follow: A) During a tour of the laboratory on 2/24/20 at approximately 10:30 AM, one of one bottle of Avantic UltraClear lot # 1708164 with an expiration date of 8/19 was observed in the flammable storage cabinet in the laboratory. B) In an interview on 2/24 /20 at approximately 10:30 AM, the laboratory staff member, identified as number 1 on the separate staff identification list, confirmed that the Avantik UltrClear identified above was currently in use and had been in use before August 2019 and since. C) Review of the MOHS Surgery log revealed that 72 MOHS surgery procedures had been performed including slide staining since August 2019 to date. D) In an interview on 2/24/20 at approximately 11:00 AM, the technical consultant, identified as number 3 on the CMS 209 form, confirmed that the laboratory had been using Avantik UltraClear in their staining process after its date of expiration and staining was performed on 72 patients after the product expired.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through review of the stain quality control log book, the technical consultant's "Consultation Report", lack of documentation, obeservation and interview it was determined that corrective action taken to document staining supply log numbers was not effective in preventing recurrence in the lack of documentation of staining supply lot numbers on the stain quality control log book. Findings follow: A) Review of the stain quality control log book reveals that staining supply lot numbers were only documented in September 2019, which represented one of twenty-four months reveiwed. Lot numbers documented in September 2019 were: * Hematoxylin - 082238 * Eosin -H262-14 * Histoclear- A08164 B) Review of the technical consultant's "Consultation Report" dated September 2019 revealed "Need to know lot numbers and when stain changed". C) During a tour of the laboratory on 2/24/20 at approximately 10:30 AM, one of one bottle of hematoxylin stain lot # 073130, a different lot number than was documented on September 2019 in the stain quality control log book, was observed in the flammable storage cabinet in the laboratory. D) In an interview on 2/24/20 at approximately 10:30 AM, the laboratory staff member, identified as number 1 on a separate staff identification list, confirmed that hematoxylin lot # 0731330 was currently in use and there was no documentation when the hematoxylin lot # was changed. E) In an interview on 2/24/20 at approximately 11:00 AM, the technical consultant, identified as number 3 on the CMS

	209 form, confirmed that the corrective action specified on the "Consultation Report" on September 2019 did not prevent recurrence of the problem of lack of documentation of staining supply lot #'s on the stain quality control log book.