Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0955875	10/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology Grand Blanc	8245 N Holly Road, Suite 101, Grand Blanc, MI	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the office manager, the laboratory failed to establish a written procedure for the use of Chlorazol Black E Fungal Stain for 1 (September 2019) of 24 months reviewed. Findings include: 1. An observation on 10/7/19 at 9:09 am by the surveyor revealed a bottle of Healthlink Chlorazol Black E Fungal Stain dated September 2019. 2. A record review of the laboratory's established procedures revealed a lack of a procedure for the use of Chlorazol Black E Fungal Stain. 3. An interview on 10/7/19 at 9:39 am with the office manager revealed the laboratory purchased the Healthlink Chlorazol Black E Fungal Stain in September 2019. 4. An interview on 10/7/19 at 9:39 am with the office manager confirmed the laboratory had not established a procedure for the use of Chlorazol Black E Fungal stain.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the office manager, the laboratory failed to label Histoclear reagents with the expiration date for the current bottle in use. Findings include: 1. An observation on 10/7/19 at 9:09 am by the surveyor revealed an open bottle of Histoclear reagent without an expiration date. 2. A record review of the laboratory's established "Reagent Labeling" procedure revealed a section stating, "Labels must include: Name of reagent, expiration date, preparation date, warning if reagent is hazardous, strength, concentration or dilution of reagent, and storage requirements." 3. An interview on 10/7/19 at 9:09 am with the office manager confirmed an expiration date was missing from the current bottle of Histoclear reagent in use.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to include the address of the facility where testing was performed for 8 (patients #3, #4, #5, #6, #7, #10, #11, #12) of 10 patient charts reviewed. Findings include: 1. A patient chart review revealed MOHS maps did not include the address of the facility where testing was performed for the following patients: a. Patient #3 performed on 2 /12/19 b. Patient #4 performed on 4/23/19 c. Patient #5 performed on 6/18/19 d. Patient #6 performed on 8/27/19 e. Patient #7 performed on 10/2/19 f. Patient #10 performed on 5/9/18 g. Patient #11 performed on 8/28/18 h. Patient #12 performed on 11/8/18 2. An interview on 10/7/19 at 10:15 am with the office manager confirmed the MOHS maps for the patients above did not include the address of the facility.