Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1091083	02/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	779 Bielenberg Drive, Suite 108, Woodbury, MN	

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 document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of Microbiology test procedures at least twice annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Microscopic Examinations for parasites and fungus under the specialty of Microbiology as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 02/15/19 at 10:10 a.m. 2. The Scabies Scraping Procedure and KOH Procedure (fungus), located in the CLIA Policies and Procedures Manual, included a twice annual verification of accuracy requirement for these microscopic examinations. 3. Documentation of the 2017 and 2018 microscopic examination verifications for Scabies and KOH testing indicated the laboratory had not verified these tests at least twice annually. The laboratory was unable to provide additional verification documentation upon request. See below for verification and patient testing data. Test Verifications 2017 2018 Scabies 1 0 KOH 1 1 Test Patients tested 2017 2018 Scabies 2 0 KOH 4 5 4. In an interview on 02/15/19 at 11:20 a.m., the TC confirmed the above finding. *This is a repeat finding. D5217 was cited during the 06 /27/17 survey*
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to document all information required for Histopathology quality control (QC) records. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 02/15/19 at 10:10 a.m. 2. QC was performed using the first patient slide for each testing day as established in the Hematoxylin and Eosin Staining Protocol located in the CLIA Policies and Procedures Manual. Documentation of staining quality and surgeon acceptance was required on the Staining Quality Control Log 3. Staining quality and surgeon acceptance was not documented on patient testing day 01/07/19; one occasion in the timeframe reviewed, July 2017 through date of survey. 4. In an interview on 01/11/18 at 11:45 a.m., the TC confirmed the QC records for 01/07/19 were incomplete.
D5983	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359 The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. This STANDARD is not met as evidenced by: . Based on review of laboratory policies and procedures, testing logs, and interview with laboratory personnel, the Laboratory Director failed to ensure previously cited deficiencies were corrected. Findings are as follows: The following deficiencies were cited during the 06/27/17 survey and were also out of compliance on 02/15/19. 1. D5217 - the laboratory failed to perform and document activities used to verify the accuracy of Microbiology test procedures at least twice annually in 2017 and 2018.