Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2243207	12/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Juniper Dermatology	3801 N. Capital Of Texas Hwy Ste J225, Austin, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Mohs patient reports and interview, the laboratory failed to include the Mohs case number on the Mohs report for four out of four cases reviewed over the period of six months. Findings follow. A. Review of the laboratory's policies and procedures showed no procedure for ensuring the Mohs case was in the patient chart. B. Review of the laboratory's Mohs patient reports showed the Mohs case number was missing for cases 1. 22-003 05/06/22 2. 22-018 07/15/22 3. 22-029 09/09/22 4. 22-039 11/18/22. B. Interview with the Office Manager on December 8, 2022, at 1140 hours in the office confirmed the findings.
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 review of accuracy assessments, patient testing logs, and interview, the laboratory failed to verify the accuracy of KOH (potassium hydroxide) for fungal elements and Scabies at least twice annually for 1 of 1 event reviewed in 2022. Findings follow. A. Review of accuracy assessments from 2022 for KOH for fungal elements showed a duplicate reading by the same testing personnel (testing personnel #1) was performed for KOH to demonstrate accuracy assessments for six of six specimens tested: Date of testing ID# 1. 8/16/22 255 2. 9/06/22 288 3. 9/29/22 322 4. 10/03/22 330 5. 10/05/22 288 6. 10/24/22 352. B. Review of the KOH Test Accession Logs from 2022 showed 6 patients were tested for fungal elements beginning 8/16/22. C. Interview with the Office Manager on December 8, 2022, at 1140 hours in the office confirmed the findings
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, quality control (QC) records, test reports, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain used in dermatopathology interpretations stained predictably for six of six cases reviewed over a period of five months. Findings follow. A. Review of the Thermo Scientific Richard-Allan Scientific Histology Signature Series Stains, revision 12 /2015 (from the laboratory performing the technical component) showed the following characteristics of the stain: "reddish blue to a crisp blue-purple" "chromatin stain" and "muscle, red blood cells, and connective tissue all stain various shades of red and pink". B. Quality control records were requested at 1120 hours on December 8, 2022, but not provided. C. The following test reports/cases using the H&E stain were reviewed from 05/13/22 to 10/18/22: Case # Date Reported 1. 22-0058 05/13/22 2, 22-0136-A 07/21/22 3. 22-0164-A 08/17/22 4. 22-0182-B 09/08/22 5. 22-0198-A 09/20 /22 6. 22-0224-E 10/18/22 D. Interview with the Office Manager on December 8, 2022, at 1140 hours in the office confirmed there was no documentation of the QC for the H&E stain for dermatopathology interpretations. II. Based on review of manufacturer's instructions, quality control (QC) records, and interview, the laboratory failed to include the intended reactivity of the Mercedes Scientific Platinum Line Hematoxylin Gill III and Eosin Y stain to ensure predictable staining characteristics on their quality control log used to document H&E stain quality for Mohs testing for six out of six months reviewed. Findings follow. A. Review of the Mercedes Scientific manufacturer's package insert EKI, Revision 0, 11/12/15, for the Hematoxylin Gill III and Eosin Y stain under Expected Results stated, "Nuclei - Blue (from the Hematoxylin) Cytoplasm - Various shades of pink which identifies different tissue components Erythrocytes - Shades of pink to red". B. Review of the Mohs Quality Control log: H&E Stain showed from 05/06/22 - 11/18/22 the QC was recorded as either Pass or Fail with no definition of what Passing was: 1. 5/06/22 2. 6 /21/22 3. 7/01/22 4. 7/15/22 5. 8/25/22 6. 9/09/22 7. 10/07/22 8. 10/25/22 9. 11/18/22. C. Interview with the Office Manager on December 8, 2022, at 1035 hours in the

	office confirmed the staining characteristics were not included on the quality control log.
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 review of the Mohs test report and interview, the laboratory failed to include the name and address of the facility on the Mohs map for four of four cases reviewed over a period of six months reviewed. A. Review of the Mohs maps showed no name and address of the facility. The following reports were reviewed as listed by case number and date of service: 1. 22-003 05/06/22 2. 22-018 07/15/22 3. 22-029 09/09 /22 4. 22-039 11/18/22. B. Interview with the Office Manager on December 8, 2022, at 1140 hours in the office confirmed the name and address of the facility were not on the Mohs maps. II. Based on review of the KOH (potassium hydroxide) test report and interview, the laboratory failed to include the address of the facility on the patient's chart for two of two cases reviewed over a period of one month. A. Review of the KOH report located in the Office Visit showed no address of the facility. The following reports were reviewed as listed by ID number and date of service: 1. 322 09 /29/22 2. 330 10/03/22. B. Interview with the Office Manager on December 8, 2022, at 1145 hours in the office confirmed the address of the facility were not on the patient's chart for KOH results.