Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1065370	06/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pahrump Dermatology & Skin Cancer	1470 E Calvada Blvd Suite #600, Pahrump, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on June 14, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 a random patient audit between the dates of November 29, 2019 and March 30, 2021, a review of the director approved policy and procedure entitled "Post Analytical Mohs Audit" and the policy and procedure entitled "Policy & Procedure Quality Assurance," subtitled, "Quality Assurance Procedures During Mohs," and an interview with the Laboratory Regional Manager, the laboratory failed to ensure that positive patient specimen identification was maintained throughout the testing process for four of ten patients reviewed. Findings include: 1. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that for the March 18, 2019 Mohs case number DAC18-12590A records reviewed, the surgical site for the Mohs surgery performed was not included on the label of one of one patient slides. The site was identified on the Mohs surgery log, Mohs Map, and the patient report as the left anterior medial lower leg. The director approved policy entitled Policy & Procedure Quality Assurance," subtitled, "Quality Assurance Procedures During Mohs," stated, "The patient's name is written on the slide, as well as the patient's date

	of birth, surgery site, surgery date, site of surgery, and biopsy specimen number." The Laboratory Regional Manager confirmed the finding during an interview conducted on June 14, 2021 at approximately 10:45 AM. 2. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that on September 17, 2019 for Mohs case number DAC19-19043A records reviewed, the surgical site for the Mohs surgery identified on the Mohs log did not match the site identified on the patient report and on the label of one of one patient slides. The Mohs surgical site was identified on the Mohs log as the right parietal scalp. The Mohs map, the slide label, and the patient report identified the surgical site as the left posterior ear. The director approved policy entitled, ""Post Analytical Mohs Audit" stated, "The Office Manager will be responsible for verifying the Mohs map card, Mohs Log, patient electronic record, Mohs technician log and slides. This is to ensure that the information that is input on all these records is correct and true." The Laboratory Regional Manager confirmed the finding during an interview conducted on June 14, 2021 at approximately 10:45 AM. 3. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that for the November 19, 2019 Mohs case number DAC19-27153B records reviewed, the number of slides listed on the Mohs log did not match the number of slides made and read by the dermatologist. The Mohs log indicated that there were two slides associated with the Mohs case. The Mohs operative note, and the Mohs map revealed that the patient's Mohs procedure consisted of three stages, and that three slides were made and read by the dermatologist. Three slides associated with the Mohs case were observed and reviewed during the patient audit. The director approved policy entitled, "Post Analytical Mohs Audit" stated, "The Office Manager will be responsible for verifying the Mohs map card, Mohs Log, patient electronic record, Mohs technician log and slides. This is to ensure that the information that is input on all these records is correct and true." The Laboratory Regional Manager confirmed the finding during an interview conducted on June 14, 2021 at approximately 10:45 AM. 4. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that for the February 4, 2020 Mohs case number DAC19-31174A records reviewed, the Mohs case number on one of one patient slides did not match the case number identified on the Mohs log, the Mohs map, and the Mohs operative note. The case number written on the slide was identified as DAC19-3117A. The case number entered into the Mohs log, written on the Mohs map, and entered into the patient chart operative note was identified as DAC19-31174A. The director approved policy entitled, ""Post Analytical Mohs Audit" stated, "The Office Manager will be responsible for verifying the Mohs map card, Mohs Log, patient electronic record, Mohs technician log and slides. This is to ensure that the information that is input on all these records is correct and true." The Laboratory Regional Manager confirmed the finding during an interview conducted on June 14, 2021 at approximately 10:45 AM. The laboratory performs approximately 360 histopathology tests annually.
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 a review of laboratory records of documentation of twice per year verification of accuracy, a review of the director approved policy entitled, "Proficiency Testing," and an interview with the Laboratory Regional Manager, the

	laboratory failed to ensure that the twice per year verification of accuracy was performed for one of two dermatologists performing Mohs testing for the years of 2019 and 2020. Findings include: 1. There was no documentation of the twice per year verification of accuracy during 2019, and 2020 for one of two dermatologists performing Mohs procedures in the laboratory. 2. The director approved policy entitled "Proficiency Testing" stated, "Twice a year, an assigned medical assistant is to go through the patient surgery lists and randomly choose one patient to have the Mohs surgery slide(s) sent out to be reviewed by another Board Certified Dermatologist in our company to check the performing Doctor's accuracy." 3. The Laboratory Regional Manager confirmed the finding during an interview conducted on June 14, 2021 at approximately 10:45 AM. The laboratory performs approximately 360 histopathology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assessment records, a review of the director approved policy entitled "Post Analytical Mohs audit," and an interview with the Laboratory Regional Manager, the director failed to ensure that the established quality assessment program was maintained to identify failures in quality when they occur. Findings include: 1. The laboratory failed to document corrective action for failures in quality for each day of Mohs testing. The director approved policy entitled, "Post Analytical Mohs Audit" stated, "If there are any discrepancies in any of the above named patient information, there will be corrective action taken by the office manager who is auditing the patient information." The Laboratory Regional Manager indicated that one patient is selected on each day of Mohs testing for review for the quality assessment program. The Laboratory Regional Manager confirmed during an interview conducted on June 14, 2021 at approximately 11:15 AM that if errors are identified with the one patient that is reviewed, corrective action is taken but the corrective action is not documented. 2. The laboratory quality assessment program did not detect and correct the failure to ensure that twice per year verification of accuracy was performed for one of two dermatologists performing Mohs testing during the years of 2019, and 2020. 3. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that on March 18, 2019, the established quality assessment program did not detect and correct the failure of the laboratory to identify the Mohs surgical site on the patient slide for Mohs case number DAC18-12590A. The site was not identified on the patient slide. The site was identified on the Mohs surgery log, Mohs Map, and the patient report as the left anterior medial lower leg. The director approved policy entitled, "Post Analytical Mohs Audit" stated, "The office manager will be responsible for verifying the Mohs Map Card, the Mohs log, patient electronic record, Mohs technician log, and slides. This is to ensure that the information that is input on all these records is correct and true." 4. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that on September 17, 2019, the established quality assessment program did not detect and correct the failure of the laboratory to ensure that the Mohs surgical site was correctly identified on the Mohs log for Mohs case number DAC19-19043A. The Mohs surgical site was identified on the Mohs log as the right parietal scalp. The Mohs map,

	and the patient report identified the surgical site as the left posterior ear. The director approved policy entitled, "Post Analytical Mohs Audit" stated, "The office manager will be responsible for verifying the Mohs Map Card, the Mohs log, patient electronic record, Mohs technician log, and slides. This is to ensure that the information that is input on all these records is correct and true." 5. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that on November 19, 2019, the established quality assessment program did not detect and correct the failure of the laboratory to ensure that the number of slides listed on the Mohs log was consistent with the number of slides made and read by the dermatologist for Mohs case number DAC19-27153B. The Mohs log stated that there were two slides made and read for the case. The Mohs operative note, and the Mohs map stated that three slides were made and read. Three slides were observed and reviewed during the patient audit. The director approved policy entitled, "Post Analytical Mohs Audit" stated, "The office manager will be responsible for verifying the Mohs Map Card, the Mohs log, patient electronic record, Mohs technician log, and slides. This is to ensure that the information that is input on all these records is correct and true." 6. A random patient audit between the dates of November 29, 2019 and March 30, 2021 revealed that on February 4, 2020, the established quality assessment program did not detect and correct the failure of the laboratory to ensure that the Mohs case number DAC19-31174A was consistent on the Mohs log, the Mohs map, the slide label for one of one slides, and the Mohs operative note. The case number written on the slide was identified as DAC19-3117A. The director approved policy entitled, "Post Analytical Mohs Audit" stated, "The office manager will be responsible for verifying the Mohs Map Card, the Mohs log, patient electronic record, Mohs technician log, and slides. This is to ensure that the information that is input on all these records is correct and true." 7. The Laboratory Regional Manager confirmed the findings during an interview conducted on June 14, 2021 at approximately 11:15 AM. The laboratory performs approximately 360 histopathology tests annually.