Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2048835	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Las Vegas Dermatology Pc	**Street Address, City, State** 653 N Town Center Dr Ste 414, Las Vegas, 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 November 10, 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.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of the 2021 American Proficiency Testing (API) Proficiency Testing (PT) Microbiology KOH preparation program attestation documents for test event numbers one, two, and three, a review of the director approved procedure entitled, "Proficiency Testing," and an interview with the laboratory director, the laboratory failed to ensure that the PT samples were tested the same number of times that it routinely tests patients. Findings include: 1. The API Program attestation documents for the 2021 test event numbers one, two and three completed for each test event indicated that two of two providers performed the testing of two of two samples for each event. One provider signed the attestation form for test event one, and the samples tested were designated as "Catalog #333-21, Bin # 86." The second provider did not sign the attestation form, although the form indicated that the samples tested were identified as "Catalog #333-21, Bin # 86." The attestation form for test event two was signed by two providers, and each indicated that the samples tested were sample numbers KOH-3, and KOH-4. The attestation form for test event three was signed by two providers, and each indicated that the samples tested were sample numbers KOH-5, and KOH-6. 2. The director approved policy entitled, "Proficiency Testing" did not

	include instructions for the performance of the proficiency testing for the API Microbiology KOH specimens to specify that the specimens must be tested in the same manner as patient specimens, including the number of times that the specimens are to be tested. 3. The director confirmed that the KOH proficiency testing samples were read by both provider for each event, and confirmed that patient samples are not routinely tested by both providers during an interview conducted on November 10, 2021 at approximately 12:00 PM. The laboratory performs approximately 30 microbiology tests, and 230 histopathology tests annually.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory records for the American Proficiency Institute (API) Proficiency Testing 2020 Microbiology KOH test event numbers one, two and three, a review of the director approved policy entitled, "Proficiency Testing," and an interview with the Mohs technician, the laboratory failed to maintain a copy of the proficiency testing report forms, and attestation statements signed by the providers and the laboratory director for a minimum of two years from the date of the testing events. Findings include: 1. There were no proficiency testing reporting forms, and signed attestations stating that the specimens were tested in the same manner as patient specimens for the 2020 API Microbiology KOH test event numbers one, two and three available for review at the time of the survey. 2. The director approved policy entitled, "Proficiency Testing" did not include instructions for the performance of the proficiency testing for the API Microbiology KOH specimens to specify that the records of the proficiency testing reporting and attestations were to be maintained for a minimum of two years after the date of the testing events. 3. The Mohs technician confirmed the finding during an interview conducted on November 11, 2021 at approximately 10:00 AM. The laboratory performs approximately 30 microbiology tests, and 230 histopathology tests annually.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory American Proficiency Institute (API) Proficiency Testing (PT) records for the Microbiology KOH 2020, and 2021 test event numbers

	one, two and three, a review of the director approved policy entitled, "Proficiency Testing," and an interview with the laboratory director, the laboratory failed to ensure that the results obtained for the proficiency testing events were reviewed, evaluated, and that documentation of the review was completed. Findings include: 1. There was no documentation of review for the API KOH proficiency testing results for 2020 test event numbers one, two and three, and for the 2021 test event numbers one, two and three. 2. The director approved policy entitled, "Proficiency Testing" did not include instructions for the performance of the proficiency testing for the API Microbiology KOH specimens to specify that the results of the proficiency testing events were to be reviewed, evaluated, and documentation of the review was to be maintained. 3. The laboratory director confirmed the finding during an interview conducted on November 10, 2021 at approximately 12:00 PM. The laboratory performs approximately 30 microbiology tests, and 230 histopathology tests annually.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the 2020 and 2021 American Proficiency Institute (API) Microbiology KOH Proficiency Testing (PT) laboratory records, a review of the director approved policy entitled, "Proficiency Testing," and an interview with the Mohs Technician and the Laboratory Director, the director failed to ensure that the proficiency testing samples were tested in the same manner as patient samples, and to ensure that the proficiency testing program reporting forms and attestations were completed and retained for a minimum of two years after the testing events. Findings include: 1. The API 2021 proficiency testing program attestation documents for test event numbers one, two and three completed for each event listed indicated that two of two providers performed the testing of two of two samples for each event. One provider signed the attestation form for test event one, and the samples tested were designated as "Catalog #333-21, Bin # 86." The second provider did not sign the attestation form, although for form indicated that the samples tested were identified as "Catalog #333-21, Bin # 86." The attestation form for test event two was signed by two providers, and each indicated that the samples tested were sample numbers KOH-3, and KOH-4. The attestation form for test event three was signed by two providers, and each indicated that the samples tested were sample numbers KOH-5, and KOH-6. 2. There were no proficiency test reporting forms, and signed attestations stating that the specimens were tested in the same manner as patient specimens for the 2020 API Microbiology KOH test event numbers one, two and three available for review at the time of the survey. 3. The director approved policy entitled, "Proficiency Testing" did not include instructions for the performance of the proficiency testing for the API Microbiology KOH specimens to specify that specimens must be tested in the same manner as patient specimens, including the number of times the specimens were to be tested, and that the records of the proficiency testing reporting and attestations were to be maintained for a minimum of two years after the date of the testing events. The laboratory performs approximately 30 microbiology tests, and 230 histopathology tests annually.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)

	The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of the laboratory American Proficiency Institute (API) Proficiency Testing (PT) records for the Microbiology KOH 2020, and 2021 test event numbers one, two and three, a review of the director approved policy entitled, "Proficiency Testing," and an interview with the laboratory director, the director failed to ensure that the results obtained for the proficiency testing events were reviewed, and evaluated, and that the documentation of the review was completed. Findings include: 1. There was no documentation of review for the API KOH proficiency testing results for 2020 test event numbers one, two and three, and for the 2021 test event numbers one, two and three. 2. The director approved policy entitled, "Proficiency Testing" did not include instructions for the performance of the proficiency testing for the API Microbiology KOH specimens to specify that the results of the proficiency testing events were to be reviewed, evaluated, and documentation of the review was to be maintained. 3. The laboratory director confirmed the finding during an interview conducted on November 10, 2021 at approximately 12:00 PM. The laboratory performs approximately 30 microbiology tests, and 230 histopathology tests annually.