

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2228917	(X3) Date Survey Completed 01/18/2023
Name of Provider or Supplier Dna Molecular Sciences	Street Address, City, State 4310 Cameron St Ste 9/10, 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 initial CLIA certification survey conducted at your facility on January 18, 2023. 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.
D2004	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the November, 2022 laboratory quality assessment records, a review of the 2022 College of American Pathologists (CAP) Proficiency Testing (PT) order confirmation, a review of the 2022 American Proficiency Institute (API) PT order confirmation, and an interview with the general supervisor, the laboratory failed to ensure that the laboratory was enrolled in one proficiency testing program for 2022 for one year before switching to a different proficiency testing program. Findings include: 1. A review of the November, 2022 monthly quality assessment records revealed that the laboratory received the 2022 SARS-CoV-2 molecular survey CAP proficiency testing specimens on November 23, 2022. The documentation in the quality assessment record stated, "CAP SARS-CoV2 (sic) Molecular Survey received 11/22/23. Not performed. Moved PT Provider to API not CAP." 2. A review of the CAP order confirmation located during the survey revealed that the laboratory enrolled in the CAP SARS-CoV-2 Molecular PT program on June 16, 2022. The laboratory enrolled after the first test event of the year was completed. 3. A review of the API order confirmation provided at the time of the survey revealed that the</p>

laboratory enrolled in the 2022 API SARS-CoV-2 Molecular PT program on August 30, 2022. 4. The findings were confirmed during an interview with the general supervisor on January 18, 2023 at approximately 10:45 AM. The laboratory performs approximately 25,000 Microbiology 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 the November, 2022 laboratory quality assessment records, a review of the 2022 College of American Pathologists (CAP) Proficiency Testing (PT) records, a review of the 2022 American Proficiency Institute (API) PT records, and an interview with the general supervisor, the laboratory failed to ensure that twice per year verification of accuracy was performed and documented for SARS-CoV-2.

Findings include: 1. A review of the November, 2022 monthly quality assessment records revealed that the laboratory received the 2022 SARS-CoV-2 molecular survey CAP proficiency testing specimens on November 23, 2022. The documentation in the quality assessment record stated, "CAP SARS-CoV2 (sic) Molecular Survey received 11/22/23. Not performed." 2. A review of the CAP order confirmation located during the survey revealed that the laboratory enrolled in the CAP SARS-CoV-2 Molecular PT program on June 16, 2022. The laboratory enrolled after the first test event of the year was completed. 3. A review of the 2022 API Microbiology test event three revealed that the laboratory participated in one test event for SARS-CoV-2 during 2022. The laboratory obtained a score of 100% on event three. 4. The findings were confirmed during an interview with the general supervisor on January 18, 2023 at approximately 10:45 AM. The laboratory performs approximately 25,000 Microbiology tests annually.