

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D0958906	<b>(X3) Date Survey Completed</b>  04/05/2022
<b>Name of Provider or Supplier</b>  Unlv Health	<b>Street Address, City, State</b>  1707 W Charleston Blvd, Ste 140, Las Vegas, NV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>This Statement of Deficiencies was created as a result of an on-site initial CLIA survey conducted at your facility on April 5, 2022. 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.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure entitled "Proficiency Testing," a review of the College of American Pathologists (CAP) Proficiency Testing (PT) Original Evaluation Report for the 2021 SARS-CoV-2 Serology test event A, a review of the submitted CMS-209 form, and an interview with the laboratory director and testing personnel number 2 listed on the CMS-209 form, the laboratory failed to follow the director approved policy and procedure to ensure that the results of proficiency testing were evaluated for acceptability. Findings include: 1. A review of the CAP PT Original Evaluation Report for the 2021 SARS-CoV-2 Serology test event A revealed that there was no documentation of an evaluation of the proficiency testing results by the laboratory director, and the testing personnel involved with the test event. 2. The director approved policy and procedure entitled "Proficiency Testing" stated in Step III, "All PT results are reviewed and evaluated by the laboratory director or general lab supervisors in a timely manner; the results are also reviewed by testing personnel. All laboratory personnel involved with the PT event will review, sign, and date the evaluation report upon review." 3. The findings were confirmed during an interview conducted on April 5, 2022 at approximately 10:00</p>

AM with the laboratory director and testing personnel number two listed on the CMS-209 form. The laboratory anticipated performing 100,000 SARS CoV-2 Total Antibody tests annually, but none were performed to date.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure entitled "Proficiency Testing," a review of the laboratory records for the College of American Pathologists (CAP) Proficiency Testing (PT) test event B for the 2021 SARS-CoV-2 Serology, a review of the submitted CMS-209 form, and an interview with the laboratory director and testing personnel number 2 listed on the CMS-209 form, the laboratory failed to follow the director approved proficiency testing policy and procedure to document the verification of the accuracy of the SARS-CoV-2 Total Antibody test subsequent to non-participation in the test event. Findings include: 1. The laboratory failed to participate in the CAP PT test event B for the 2021 SARS-CoV-2 Serology due to problems encountered with the reagents for the SARS-CoV-2 Total Antibody test, and the laboratory failed to notify CAP of the inability to test the specimens in order to submit the test results by the established deadline. 2. The laboratory failed to document evaluation of the PT specimen test results obtained after the established deadline by procuring the Participant Summary for the the CAP 2021 SARS-CoV-2 Serology test event B. 3. The director approved policy and procedure entitled "Proficiency Testing" stated in Step IV, "The laboratory will verify the accuracy of any analyte, specialty, or subspecialty that is assigned a PT score that does not reflect the accuracy of the laboratory's actual test performance." The policy and procedure stated in Step V, "When such a situation occurs, the laboratory will perform and document verification for the analyte, specialty, or subspecialty affected. 4. The findings were confirmed during an interview conducted April 5, 2022 at approximately 10:30 AM with the laboratory director and testing personnel number two listed on the CMS-209 form. The laboratory anticipated performing 100,000 SARS CoV-2 Total Antibody tests annually, but none were performed to date

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure entitled "Competency Assessment," a review of the laboratory records of training and competency assessment for the testing personnel, a review of the submitted CMS-209 form, and an interview with the laboratory director and testing personnel number 2

listed on the CMS-209 form, the technical consultant failed to ensure that training and competency assessment was completed semi-annually during the first year of employment. Findings include: 1. A review of the training and competency records for one of one testing personnel revealed that the technical consultant failed to ensure that semi-annual training and competency assessment was completed during the first year in which the testing personnel was performing patient testing. 2. The director approved policy and procedure entitled "Competency Assessment" stated in Step III, "Evaluating and documenting competency of personnel responsible for testing will be performed semi-annually during the first year the individual tests patient specimens." 3. The findings were confirmed during an interview conducted with the laboratory director and testing personnel number two listed on the CMS-209 form. The laboratory anticipated performing 100,000 SARS CoV-2 Total Antibody tests annually, but none were performed to date.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a review of the director approved policy and procedure entitled "Competency Assessment," a review of the laboratory records of training and competency assessment for the testing personnel, a review of the submitted CMS-209 form, and an interview with the laboratory director and testing personnel number 2 listed on the CMS-209 form, the technical consultant failed to ensure that training and competency assessment was completed annually after one year of test performance. Findings include: 1. A review of the training and competency records for one of one testing personnel revealed that the technical consultant failed to ensure that annual training and competency assessment was completed after one year in which the testing personnel was performing testing. 2. The director approved policy and procedure entitled "Competency Assessment" stated in Step III, "Evaluating and documenting competency of personnel responsible for testing will be performed semi-annually during the first year the individual tests patient specimens. Thereafter, competency assessment will be performed at least annually." 3. The findings were confirmed during an interview conducted on April 5, 2022 at approximately 11:45 AM with the laboratory director and testing personnel number two listed on the CMS-209 form. The laboratory anticipated performing 100,000 SARS CoV-2 Total Antibody tests annually, but none were performed to date.