

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D2232333	<b>(X3) Date Survey Completed</b>  07/21/2022
<b>Name of Provider or Supplier</b>  Rapid Lab	<b>Street Address, City, State</b>  2465 Reynolds Ave Ste 101, N 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 certification survey conducted at your facility on July 21, 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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of October 28, 2021 and March 31, 2022, a review of the laboratory maintenance records for the Beckman Coulter Access 2, a review of the Beckman Coulter Access 2 instrument test records between the dates of December 8, 2021 and December 23, 2021, a review of the Beckman Coulter Access 2 operator's guide, and an interview with the laboratory director and the medical technician, the laboratory failed to ensure that the weekly maintenance was performed in accordance with the manufacturer's instructions prior to performing patient testing between the dates of December 8, 2021 and December 23, 2021. Findings include: 1. A random audit of six patients tested between the dates of October 28, 2021 and March 31, 2022 revealed that the laboratory failed to perform weekly maintenance on the Beckman Coulter Access 2 immunoassay instrument between the dates of December 8, 2021 and December 23, 2021 prior to performing patient testing for Thyroid Stimulating Hormone (TSH) on the date of December 22, 2021. 2. A review of the December, 2021 maintenance log for the Beckman Coulter Access 2 immunoassay analyzer revealed that the weekly maintenance was performed</p>

on the dates of December 2, December 8, and December 23, 2021. 3. A review of the Beckman Coulter Access 2 instrument test records between the dates of December 8, 2021 and December 23, 2021 revealed that the laboratory performed TSH testing prior to performing the weekly maintenance on three patients on December 20, 2021, and five patients on December 22, 2021. 4. A review of the Beckman Coulter Access 2 immunoassay instrument operator's manual Chapter 8, entitled, "Routine Maintenance", in section 8.3 entitled, "Weekly Maintenance," it stated, "In order to keep the Access 2 system running properly, perform weekly maintenance once every seven days." 5. The finding was confirmed during an interview with the laboratory director and the medical technician on July 21, 2022 at approximately 1:00 PM. The laboratory performs approximately 75,000 chemistry tests annually.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure entitled, "Calibration /Calibration Verification", the manufacturer's instructions for the Beckman Coulter Lyophilized Chemistry Calibrator, and an interview with the laboratory director and the medical technician, the laboratory failed to ensure that calibration verification was performed for the following tests performed on the Beckman Coulter AU480: Sodium, Potassium, Chloride, Bicarbonate, Blood Urea Nitrogen (BUN), Creatinine, Glucose, Calcium, Total Protein, Albumin, Total and Direct Bilirubin, Cholesterol, and Triglycerides. Findings include: 1. The director approved policy and procedure entitled, "Calibration/Calibration Verification," in the section entitled, "Calibration Verification" stated, "For analyzers and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint and high end of the reportable range, calibration verification must be performed minimally every 6 months to substantiate the continued accuracy of the monitors throughout the reportable range, after initial validation studies are performed with the setup of the analyzer." 2. A review of the manufacturer's instructions for use for the Beckman Coulter Lyophilized Chemistry Calibrator revealed that there are two levels of

calibrator in the kit. 3. The laboratory director and the medical technician confirmed during an interview conducted on July 21, 2022 at approximately 11:30 AM that a third level of calibrator is not available from the manufacturer for the Beckman Coulter AU480 analytes, and that the calibration verification had not been performed every six months as required. The laboratory performs approximately 75,000 chemistry tests annually.

**D5801**

**TEST REPORT**  
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
Based on a random audit of the laboratory's patient final test reports from October 28, 2021 through March 31, 2022, a review of patient tests that were submitted to a reference laboratory and a review of the subsequent reports from the same time period, and an interview with the laboratory manager, the laboratory failed to ensure that patient laboratory results were accurate and reliable from the point of data entry to the final report destination. Findings include: 1. The laboratory failed to ensure that patient test result information performed by a reference laboratory was correctly transcribed into the laboratory's own information system to reflect accurate patient test results including the same reference laboratory's reference ranges and units of measure for each analyte. 2. A random audit of six patients tested between the dates of October 28, 2021 and March 31, 2022 revealed that one of six patient test results that had been performed at a reference laboratory included information on the laboratory's final report that did not match the reference laboratory's information. 3. A review of the final comprehensive metabolic panel reported on December 23, 2021 for a random patient identified by a date of birth of 12/30/96 revealed that the laboratory failed to accurately reflect the reference laboratory's reference ranges for alkaline phosphatase and carbon dioxide when transcribing the results into the laboratory information system. 4. The reference laboratory report from December 23, 2021 revealed that the reference range for alkaline phosphatase was 40-120 U/L. The final report result reported by the laboratory reflected a reference range for alkaline phosphatase of 35-144 U/L. 5. The reference laboratory report from December 23, 2021 revealed that the reference range for carbon dioxide was 19-31 meq/L. The final result reported by the laboratory reflected a reference range for carbon dioxide of 20-32 mmol/L. 6. The findings were confirmed during an interview with the laboratory director and the medical technician conducted on July 21, 2022 at approximately 3:00 PM. The laboratory performs approximately 75,000 chemistry tests annually.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure entitled, "Calibration /Calibration Verification," a review of the laboratory quality assessment records, and an interview with the laboratory director and the medical technician, the director failed to ensure that the program of quality assessment was maintained to ensure the quality of the laboratory services and to detect failures of quality when they occurred. Findings include: 1. A review of the laboratory Quality Assessment records between the months of September, 2021 and June, 2022 revealed that for the months of September 2021, November 2021, December 2021 and March 2022, there is no documentation regarding whether calibration verification was up to date for the Beckman Coulter AU480. For the months of October 2021, April 2022, May 2022, and June 2022, the calibration verification up to date documentation was designated by a checkmark. For the months of January 2022 and February 2022, the documentation for the calibration verification up to date is designated as "yes." 2. The director approved policy and procedure entitled, "Calibration/Calibration Verification," in the section entitled, "Calibration Verification" states, "For analyzers and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint and high end of the reportable range, calibration verification must be performed minimally every 6 months to substantiate the continued accuracy of the monitors throughout the reportable range, after initial validation studies are performed with the setup of the analyzer." 3. The laboratory director and the medical technician confirmed during an interview conducted on July 21, 2022 at approximately 11:30 AM that the calibration verification had not been performed every six months, and that the quality assessment documentation failed to detect the failure to perform the calibration verification. The laboratory performs approximately 75,000 chemistry tests annually.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure entitled, "Staff Orientation, Training and Competency," personnel training and competency assessment records, a random patient audit between the dates of October 28, 2021 and March 31, 2022, and an interview with the laboratory director and the medical technician, the director failed to ensure that all personnel completed initial training and competency assessment in this laboratory prior to performance of patient testing.

Findings include: 1. A review of the personnel training and competency assessment records revealed that one of three testing personnel failed to complete initial training and competency assessment in this laboratory prior to the performance of patient testing. 2. The documents labeled as the initial training and competency assessment for the personnel were dated April 21, 2021. The personnel did not begin working in the laboratory until October 8, 2021. It was revealed during an interview with the medical technician on July 21, 2022 at approximately 10:00 AM that the documents dated April 21, 2021 were from a different laboratory where the personnel was previously employed. 3. The documents labeled as the six month training and competency assessment for the personnel were dated November 8, 2021. 4. A random patient audit of six patients tested between the dates of October 28, 2021 and March 31, 2022 revealed that the patient identified by the date of birth of 9/8/50 had testing performed for a CBC on October 28, 2021, and for a Basic Metabolic Panel and TSH on October 29, 2021 by the personnel prior to the completion of the initial training and competency assessment performed in this laboratory. 5. The findings were confirmed during an interview with the laboratory director and the on July 21, 2022 at approximately 10:30 AM. The laboratory performs approximately 75,000 chemistry tests and 20,000 hematology tests annually.