

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D2213097	<b>(X3) Date Survey Completed</b>  05/19/2022
<b>Name of Provider or Supplier</b>  Lighthouse Lab Ventures I Llc	<b>Street Address, City, State</b>  3131 Las Vegas Blvd S, 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 CLIA initial survey conducted at your facility on May 19, 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>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the patient final laboratory test reports from 1/01/2022 through 5/19/2022 and an interview with the laboratory general supervisor, the laboratory failed to indicate on the patient final test report, the correct name of the laboratory and the correct address of the laboratory that is performing the laboratory testing. Findings include: 1. A review of five random patient test reports between 1/10/2022 and 5/04/2022 found the name of the laboratory on the final test reports to be "Mirimus Laboratory". The name of the laboratory indicated on the federal Clinical Laboratory Improvement Amendments (CLIA) certificate indicates the name of the laboratory as "Lighthouse Lab Ventures I, LLC". 2. A review of the same random patient test reports also revealed that the address of the laboratory was not correct on the final test</p>

reports. The laboratory test reports indicated the address of the laboratory to be "131 S Las Vegas Boulevard Las Vegas, NV 89109". The actual address of the laboratory is "3131 S Las Vegas Boulevard Las Vegas, NV 89109". This was confirmed with the laboratory general supervisor at approximately 11:30 AM on May 19, 2022. The laboratory performs approximately 10,000 Virology laboratory 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 director approved policy and procedure for quality assessment and an interview with the laboratory general supervisor, the laboratory failed to follow the director approved policy and procedure for performing and documenting the monthly quality assessment of the laboratory. Findings include:  
1. The director approved policy and procedure for quality assessment states under number 1, "Review the monitor(s) assigned for each month. Document the review on the appropriate form and attach all supporting data and information." 2. The items to be reviewed and documented for each month according to the laboratory policy are: a. Jan.- Personnel Checklist. b. Feb.- Analytical Checklist. c. March- Patient Test Management Checklist. d. April- Procedure Manual Checklist. 3. There was no documented evidence that the monthly items listed for testing months of January, February, March and April 2022 were reviewed and documented to effectively evaluate the quality of the laboratory. This was confirmed with the laboratory general supervisor at approximately 11:00 AM on May 19, 2022. The laboratory performs approximately 10,000 Virology laboratory tests annually.