

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0650367	<b>(X3) Date Survey Completed</b>  03/25/2022
<b>Name of Provider or Supplier</b>  Oncolab Inc	<b>Street Address, City, State</b>  36 The Fenway, Boston, MA	
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>	A CLIA recertification survey was conducted for the Oncolab, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS) on 03/25 /2022, the laboratory failed to monitor and document temperature conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting as evidenced by the following: The surveyor reviewed refrigerator, freezer, incubator, and room temperature records for calendar years 2019 and 2020. This record review revealed that the laboratory was missing temperature records for October 2019, November 2019, December 2019, and January 2020. The TS confirmed through interview on 3/25/2022 at 1:00 PM that the laboratory failed to maintain documentation of the laboratory's refrigerator, freezer, incubator, and room temperatures for the last four months before the laboratory suspended patient testing due to COVID. The laboratory performs 100 tests annually.</p>
<b>D5481</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p>

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS) on 3/25/2022, the laboratory failed to retain quality control (QC) records for the one immunology test performed. The surveyor reviewed eighteen (18) patient test runs performed between 10/3/2019 to 1/31/2020. The record review revealed that the laboratory failed to maintain the QC records for seventeen (17) of the eighteen (18) patient test runs performed between 10/3/19 to 1/31/2020. The TS confirmed in the interview on 3/25/2022 at 11:45 AM that QC was performed for each of the patient runs but the worksheets could not be found for the requested dates. The laboratory performs 100 tests annually.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS) on 3/25/2022, the laboratory failed to indicate on the final test report either the patient's name and identification number, or a unique patient identifier and identification number. The surveyor reviewed twenty-nine (29) patient final test reports from October 2019 through January 2020. The record review revealed that the laboratory failed to indicate the patient's name and identification number on sixteen (16) out of the twenty-nine (29) patient final test reports. The sixteen (16) patient final test reports only indicated the patient's name and no identification number. The TS confirmed on 3/25/2022 at 12:18 PM that the sixteen (16) patient final test reports did not indicate both the patient's name and identification number. The laboratory performs 100 tests annually.