

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2195732	(X3) Date Survey Completed 10/04/2022
Name of Provider or Supplier Beechtree Molecular Lab Llc	Street Address, City, State 301 Calista Court, Suite 102, Anchorage, AK	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, the 2021 and 2022 specimen rejection logs, an interview with the Technical Supervisor (TS) and General Supervisor #1 (GS #1), and a lack of documentation, the laboratory failed to follow its procedure for specimen rejection documentation and provider notification. Findings include: 1. The Patient Sample Handling Procedure BML-302, effective 10/24/2020, includes instructions for notifying providers and cancelling tests in their laboratory information system (LIS) when specimens are rejected. 2. The specimen rejection logs for 1/6/22, 3/1/22, and 5/19/22 were reviewed and no corresponding documentation was found in the LIS indicating the samples were cancelled, the reason for the rejection, the name of the authorized provider or contact person who received the notification, and the date and time of notification. 3. The laboratory TS and GS #1 confirmed by interview on 10/4/2022 at 2:00 pm, the specimen rejection procedure was not followed. 4. The laboratory reports performing 4,000 patient specimens annually.</p>
D5413	<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</p>

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.

This STANDARD is not met as evidenced by:

Based on observation of thermocycler settings, the Osang GeneFinder COVID-19 Fast RealAmp Kit instructions for use, the Osang GeneFinder COVID-19 Fast RealAmp Kit package insert, the laboratory's validation, and interview with the Technical Supervisor (TS) and General Supervisor #1 (GS #1), the laboratory did not ensure the PCR cycling conditions were consistent with the manufacturer's instructions. Findings include: a. The programmed qTower PCR Thermal cycler settings for the Fast kit were set at 45 cycles of 95 C for 1 second then 58 C for 30 seconds. b. The Fast kit package insert indicates the qTower settings should be 45 cycles of 95 C for 1 second then 58 C for 5 seconds. c. The laboratory's procedure BML-306 SARS-CoC-2 RNA Detection by Real-Time PCR lists 45 cycles of 95 C for 15 seconds then 58 C for 60 seconds d. The Validation of the Fast Kit completed on 4/11/2022 did not include or document the qTower PCR Thermal cycler settings. e. The laboratory TS and GS #1 confirmed by interview on 10/4/2022 at 2:00 pm, the thermocycler settings were not set to the manufacturer's instructions. f. The laboratory reports performing 3,000 patient COVID specimens 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 patient record review from November 1, 2022 through March 1, 2022 and interview with the Laboratory Technical Supervisor (TS) and General Supervisor #1 (GS #1), the laboratory failed to ensure the test report indicated the correct address of the laboratory location where the tests are performed. Findings include: 1. Two of two random patient test reports for SARS-CoV-2 from 11/18/2021 and 2/9/2022 revealed the testing laboratory as CLIA # 46D2209724, located at 12351 S. Gateway Pl, Suite D-500, Draper, Utah 84020. 2. The laboratory TS and GS #1 confirmed by interview on 10/4/2022 at 2:00 pm, the testing was performed at the Anchorage Laboratory and the test report was not accurate. 3. The laboratory reports performing 4,000 patient specimens annually.