

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2313642	(X3) Date Survey Completed 05/19/2025
Name of Provider or Supplier Moleculab Llc	Street Address, City, State 13027 Hwy 155, Suite 400, Tyler, TX	
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
D0000	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of an initial survey completed on May 19, 2025.
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on interview, review of laboratory instructions, laboratory establishment studies, and confirmed in interview, the laboratory failed to include instructions to clients for the storage and preservation of the specimen, conditions for specimen transportation, and specimen acceptability and rejection for receipt to the laboratory for PCR testing with the WND 4-Plex Molecular Panel. The findings included: 1. In an interview on 5/19/2025 at 10:40 hours, in the laboratory, the technical supervisor (TS) stated all specimens received for PCR testing are received from client collection sites. 2. Surveyor asked for documentation of the instructions provided to clients for the collection, labeling and submission of specimens for testing and was provided with a double sided, single page, instruction sheet titled "Collection & Shipping Instructions for Wound Pathogens: PCR & Culture". Review of the document did not include instructions for the following submission and handling instructions: Specimen storage and preservation Conditions for specimen transportation Specimen acceptability and rejection criteria 3. Review of laboratory temperature stability studies, approved by the laboratory director on 1/21/2025, included the following summary of results: "Procedure: Eight identical samples were evaluated at four different storage temperatures; -20C, refrigerated, room temperature, and initially at greater than or equal to 55C. Each sample was extracted initially and every 24 hours for seven days. ... Results: Samples tested using the WND 4-plex panel are stable for</p>

at frozen temperatures for four days. A significant shift in result was observed after 96 hours. Samples are stable at refrigerated temperatures and elevated temperatures (greater than 55C) for five days. Significant shift was observed after 120 hours. Sample stored at room temperature are stable for three days. Significant shift was observed after 72 hours." 4. Review of patient testing for April 2025 included the following six patients received for wound PCR testing with the WND 4-Plex Panel: Date Received - Patient ID 04/14/2025 - MOL1234592 04/16/2025 - MOL1234593 04/17/2025 - MOL1234594, MOL1234595 04/21/2025 - MOL1234597, MOL1234596 5. In an interview on 5/19/2025 at 11:30 hours, in the laboratory, TS confirmed the instructions provided to the clients did not include instructions for the storage and preservation of specimens, conditions for specimen transportation, and specimen acceptability and rejection criteria.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on review of laboratory establishment studies, laboratory policy, patient testing, and confirmed in interview, the laboratory failed to have a mechanism in place to ensure acceptable specimen integrity for six of six patient specimens received for PCR testing for records reviewed in April 2025. The findings included: 1. Review of laboratory temperature stability studies for the WND 4-Plex Molecular Panel, PCR test, included the following summary of results: "Procedure: Eight identical samples were evaluated at four different storage temperatures; -20C, refrigerated, room temperature, and initially at greater than or equal to 55C. Each sample was extracted initially and every 24 hours for seven days. ... Results: Samples tested using the WND 4-plex panel are stable for at frozen temperatures for four days. A significant shift in result was observed after 96 hours. Samples are stable at refrigerated temperatures and elevated temperatures (greater than 55C) for five days. Significant shift was observed after 120 hours. Sample stored at room temperature are stable for three days. Significant shift was observed after 72 hours." Review of the laboratory policy titled "Specimen Shipping and Collection", section 6.1.6 "Wound Specimens for PCR" included the following statement: "6.1.6.4 Samples should be shipped to the laboratory as soon as possible to avoid sample deterioration." Surveyor asked for documentation that the specimens received for testing were received under the appropriate storage conditions through shipping, and none could be provided. 2. Review of patient testing for April 2025 included the following six patients received for wound PCR testing with the WND 4-Plex Panel, with no documentation that they were received within the laboratory established acceptability criteria: Date Collected - Date Received - Patient ID 04/11/2025 - 04/14/2025 - MOL1234592 04/14/2025 - 04/16/2025 - MOL1234593 04/14/2025 - 04/17/2025 - MOL1234594 04/15/2025 - 04/17/2025 - MOL1234595 04/15/2025 - 04/21/2025 - MOL1234597 04/16/2025 - 04/21/2025 - MOL1234596 3. In an interview on 5/19/2025 at 11:15 hours, in the laboratory, the technical supervisor (TS) confirmed the laboratory did not have a mechanism in place for the documentation of specimen acceptability for the above wound specimens.