

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2273601	(X3) Date Survey Completed 04/01/2026
Name of Provider or Supplier Mokan Labs, Llc	Street Address, City, State 14215 Metcalf Ave, Overland Park, KS	
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 Moken Labs, LLC was found in compliance with 42 CFR Part 493 condition-level requirements for laboratories as a result of a validation survey on 04/01/26. Standard level deficiencies cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's specimen stability study, lack of received specimen documentation, and interview with General Supervisor #1 (GS #1, as listed on the CMS 209 form), the laboratory failed to document specimen acceptability for nine of nine patients. Findings included: 1. During the laboratory tour on 04/01/26 at 11:30 am, GS #1 confirmed the laboratory performed the following: a. Molecular Urinary Track Infection (UTI) with Antibiotic Susceptibility Testing performed on the Genepoint. b. Molecular Sexually Transmitted Infection (STI) panel testing performed on the BioPathogenix. 2. A review of the laboratory's "Validation Summary Performance Report" (approved by the laboratory director on 08/12/2025) and "Stability Study" revealed the following: a. Urine for UTI testing - stable up to seven days at temperatures from 2 -8C, 20-25C, and -20C and colder. b. Swabs for STI testing - stable up to five days at temperatures from 2 -8C, 20-25C, and -20C and colder. 3. Review of nine patient "Comprehensive Molecular Test Requisition Forms" and final patient reports revealed no documentation of the specimen temperature upon receipt into the laboratory. a. Patient UTI1025956 - collected on 01/13/26, received</p>

into the laboratory on 01/14/26, and reported on 01/16/26. b. Patient UTI026595 - collected on 01/29/26, received into the laboratory on 01/31/26, and reported on 01/31/26. c. Patient VGN026598 - collected on 01/30/26, received into the laboratory on 01/31/26, and reported 01/31/26. d. Patient UTI026628 - collected on 02/02/26, received into the laboratory on 02/03/26, and reported on 02/03/26. e. Patient UTI1026988 - collected on 02/11/26, received into the laboratory on 02/12/26, and reported on 02/12/26. f. Patient UTI026995 - collected on 02/12/26, received into the laboratory on 02/12/26, and reported on 02/12/26. g. Patient STI027047 - collected on 01/12/26, received into the laboratory on 02/13/26, and reported on 02/13/26. h. Patient UTI027196 - collected on 02/17/26, received into the laboratory on 02/18/26, and reported on 02/18/26. i. Patient RCT027769 - collected on 03/03/26, received into the laboratory on 03/04/26, and reported on 03/04/26 4. Interview on 04/01/2026 at 12:25 pm with GS #1 confirmed the findings.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)**

(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 manufacturer's instructions, laboratory environmental records, and interview with General Supervisor #1 (GS #1, as listed on the CMS 209 form), the laboratory failed to ensure room temperature followed manufacturer's requirements for one of one month. Findings included: 1. During the laboratory tour on 04/01/26 at 11:30 am, GS #1 confirmed the laboratory performed the following: a. Molecular Urinary Tract Infection (UTI) with Antibiotic Susceptibility Testing performed on the Genepoint. b. Molecular Sexually Transmitted Infection (STI) panel testing performed on the BioPathogenix. c. BPX (BioPathogenix) DNA/RNA Extraction kit for enzymatic digestion of bacteria and fungi. 2. A review of the "BPX Extract-User Guide Section 4.0 to 5.1" section, "4.2 General Guidelines for Nucleic Acid Extraction" stated, "Perform all steps at room temperature (20-25C)". 3. A review of the January 2026 "MANUAL ROOM TEMPERATURE AND HUMIDITY MONITORING LOG: INSTRUMENTATION" revealed an acceptable temperature range of 15C - 25C, exceeding the lower limits of the manufacturer's requirements. 4. In an interview on 04/01/26 at 12:25 pm, GS #1 confirmed the findings above.