

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2313828	(X3) Date Survey Completed 05/27/2026
Name of Provider or Supplier Unique Biosciences Llc	Street Address, City, State 3055 Hunter Rd, San Marcos, 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 unique Biosciences LLC laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a initial survey on 05/27/2026 and certification is recommended. Standard level deficiency was cited.
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, laboratory information management system (LIMS), test report, and interview, the laboratory failed to ensure the date format was accurately transmitted from the LIMS to the test report for the lab developed test UniquePerioSignature Panel for the detection of Porphyromonas gingivalis (Pg), Aggregatibacter actinomycetemcomitans (Aa), Treponema denticola (td), Tannerella forsythia (Tf), and Prevotella intermedia (Pi) for four of four test reports reviewed from February 2026 - April 2026. Findings follow. A. Review of the laboratory's policy and procedure titled Quantitative detection of UPS - Panel (Pg, Aa, Td, Tf, and Pi) effective 05/22/2026, under 5.4 Specimen transport stated, "If specimens cannot be delivered or shipped on the day of collection, store specimens at 2 to 8 degrees Celsius (C) or room temperature until specimen delivery or transport. Saliva is stable for 15 days at 4 C to 35 C. Specimens must arrive at Unique</p>

Biosciences laboratory within the 15 days of specimen collection." B. Observation of the Audit Trail section of the LIMS in the laboratory on May 27, 2026 at 1130 hours showed the following patients' samples were collected on the following dates: Patient ID Date Collected 1. #54 02/23/2026 2. #55 04/01/2026 3. #56 04/08/2026 4. #57 04/10/2026 C. Review of the test reports from the LIMS showed the date format was day/month/year instead of month/day/year in one case giving the appearance the sample stability had been exceeded as listed by patient ID, date collected, and date reported: 1. Patient ID: 55 Date Collected: 01/04/2026 Date Reported: 03/04/2026. The additional reports were reported as the following as listed by patient ID, date collected, and date reported: 2. Patient ID: 54 Date Collected: 23/02/2026 Date Reported: 25/02/2026 3. Patient ID: 56 Date Collected: 08/04/2026 Date Reported: 10/04/2026 4. Patient ID: 57 Date Collected: 10/04/2026 Date Reported: 16/04/2026 D. Interview with the Lab Director on May 27, 2026 at 1205 in the conference room confirmed the date format was in the European format and they had not caught that.