

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2224368	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Pro Diametrics Corp DbA Prodi Lab	Street Address, City, State 9627 S Dixie Hwy, Pinecrest, FL	
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	A recertification survey conducted from 01/23/2024 to 02/06/2024 found PRO DIAMETRICS CORP DBA PRODI LAB clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: - D5300 Preanalytic Systems
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to monitor the transport temperature of specimens delivered to the laboratory for BIOFIRE FILMARRAY Pneumonia Panel and failed to define and monitor the transport temperature for Scienetix PCR Respiratory Panel (RPP), Scienetix PCR Urinary Panel (UTI), Scienetix PCR Wound Panel and Scienetix PCR SARS-CoV-2 (COVID). Refer D5311.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions</p>

for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

1-Based on observation, lack of records and interview, the laboratory failed to monitor the transport temperature of specimens delivered to the laboratory for BIOFIRE FILMARRAY Pneumonia Panel testing for six out of six patients reviewed. 2- Based on observation, lack of records and interview, the laboratory failed to define and monitor the transport temperature for specimens delivered to the laboratory for testing with the following tests: Scienetix PCR Respiratory Panel (RPP), Scienetix PCR Urinary Panel (UTI), Scienetix PCR Wound Panel and Scienetix PCR SARS-CoV-2 (COVID) since their implementation on 09/15/2023. Findings included: During the laboratory tour on 01/23/2024 at 10:00 AM, the surveyor found that there was no temperature gauge to monitor specimens arriving in the laboratory via courier at the accessioning area for BIOFIRE FILMARRAY Pneumonia panel, Scienetix PCR: RPP, UTI, Wound and COVID testing. 1-Review of BIOFIRE FILMARRAY Pneumonia Panel manufacturer instructions on page 13 under SAMPLE REQUIREMENTS, it stated on Transport and Storage: "Specimens should be tested with the BIOFIRE Pneumonia Panel as soon as possible. If storage is required, specimens can be held Refrigerated for up to 1 day (2-8C)." -Review of Policy number 22: Specimen Transportation. Implemented on 06/21/2021 and signed by the current Laboratory Director (LD) on 04/15/2022; it stated that samples need to be transported on ice and temperature monitored on reception. -Review of patients reports revealed the following: Patient #1 (collected on 02/18/2022), Patient #2, #3 and #4 (collected on 03/21/2022), Patient #5 and #6 (collected on 03/28/2022) were delivered via courier from Las Vegas. The laboratory failed to have documentation that monitored the temperature of the samples when they were received in the laboratory for testing with BIOFIRE FILMARRAY Pneumonia Panel. 2-Review of Policy number 44: Scienetix Q Tower UTI, RPP, ABR, Wound assay. Implemented on 09/15/2023 and signed by LD on 09/15/223, it stated on section "All Specimens ... the specimens should be transported in an environment that will not exceed room temperature". The policy failed to define the range for "room temperature". Review of "Policy number 24 Specimen Criteria and Rejection" implemented on 09/15/2023 revealed that on Section III "Procedure" it stated that " Urine, Respiratory, Sputum /Sputum-like, Buccal samples, Wound samples, and Fecal samples must arrive at room temperature or below." The policy failed to define the range for room temperature and failed to define how it will monitor the temperature of the samples on arrival. -The laboratory failed to have documentation that monitored the temperature of the samples delivered via courier. The laboratory tested the following number of samples since tests implementation on 09/15/2023: Scienetix PCR: RPP (156 samples), UTI (112 samples), Wound (7 samples) and COVID (1830 samples). During a telephone interview on 02/06/2024 at 09:30 AM, the laboratory manager confirmed that the laboratory failed to document the temperature of samples delivered to the laboratory during transportation and reception in the laboratory for BIOFIRE FILMARRAY Pneumonia Panel and for the Scienetix PCR: RPP, UTI, Wound and COVID.