

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2144525	<b>(X3) Date Survey Completed</b>  03/05/2025
<b>Name of Provider or Supplier</b>  Marian Davis Dpm Pa	<b>Street Address, City, State</b>  1190 Nw 95th St Ste 401, Miami, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA validation survey was conducted at Marian Davis DPM PA from February 27, 2025 to March 5, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of equipment temperature records and General Laboratory Supervisor interview, the laboratory failed to review temperature records for freezer log in 2024 (January to April) and 2023 (August to October) and failed to review room temperature and humidity log for 2024 (January to March). The findings included: 1- Review of Daily Danby Freezer Temperature log in 2024 (01/05/2024 to 04/02/2024) and 2023 (08/28/2023 to 10/21/2023) showed it was not signed for review by the General Supervisor or Laboratory Director. 2- Review of Term Pro Room Daily Temperature/Humidity log from 01/05/2024 to 03/18/2024 was not signed for review by the General Supervisor or Laboratory Director. 3-Review of the 2025 Quality Assessment Plan, signed by the Laboratory Director, revealed there is no schedule for reviews of temperature logs. 4-Interview on 02/27/2025 at approximately 1:49 PM with the laboratory General Supervisor, admitted that there is no procedure for temperature recording and monitoring reviews.</p>
<b>D5311</b>	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

(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.

This STANDARD is not met as evidenced by:

1- Based on observation, record review and interview, the laboratory failed to test 7 out of 15 patients reviewed within the acceptable timeframe for wound ABX panel. Findings included: -During the laboratory tour on 02/27/2025 at 10:30 AM it was observed that the laboratory had two boxes for sample storage at the entrance of the molecular testing room. The samples collected were stored at room temperature on those boxes and remain there until testing. -Review of the "STANDARD OPERATING PROCEDURE. Molecular Designs Wound Infection Panels-General Information Testing Policies" signed by the current Laboratory Director on 12/20/2024; revealed that the laboratory is testing the presence of the following organisms: *Acinetobacter baumannii*, *Bacteroides fragilis*, *Citrobacter braakii/freundii*, *Citrobacter koseri*, *Enterobacter cloacae*, *Enterococcus* spp, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca / michiganensis*, *Klebsiella pneumoniae*, *Morganella morganii*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia marscescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, *Streptococcus pyogenes* (Group A). And Antibiotic Resistance Markets as follows: -?-lactamase (blaKPC), ?-lactamase (CTX-M-Group 1), metallo-?-lactamase (blaNDN), Sulfonamides, Trimethoprim, Vancomycin (VanA, VanB). - Review of the sample stability study signed by the previous Laboratory Director on 04/25/2023, revealed that the study confirmed that the samples resulted were not compromised up to five days. -Review of random testing dates during 2023 and 2024, revealed that the laboratory tested the following samples outside of the stability range approved by the laboratory: a) 07/07/2023 tested the 3 samples collected on 06/15/2023. 17 days outside of the timeframe. b) 10/21/2023 tested 1 sample collected on 10/13/2023. Three days outside of the timeframe. c) 01/08/2024 tested 2 samples collected on 01/02/2024 out of 4. One day outside of the timeframe. d) 07/25/2024 tested 1 sample collected on 07/19/2024. One day outside of the timeframe. During an interview on 02/27/2025 at 04:30 PM, the laboratory testing person confirmed that the patients listed above were tested outside of the acceptability stability criteria for wound samples.