

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2086564	<b>(X3) Date Survey Completed</b>  10/03/2022
<b>Name of Provider or Supplier</b>  Denise Maria Negron Dpm Pa	<b>Street Address, City, State</b>  267 E 49th St, Hialeah, 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>	A recertification survey conducted on 10/03/2022 found the DENISE MARIA NEGRON DPM PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to follow manufacturer instructions for temperature storage of Dermatophyte Test Medium (DTM) Agar flasks from 10/15/2020 to present. Findings include: During the laboratory tour on 10/03/2022 at 10:26 AM, the surveyor found one box of Hardy Diagnostics DTM Agar stored at 24 Celsius degrees in the facility storage room. Review of Hardy DTM Agar manufacturer instructions revealed that stated: "storage 2 - 8 degrees C on receipt". During an interview on 10/03/2022 at 11:00 AM, the Laboratory Director confirmed that the laboratory failed to store the DTM Agar as per manufacturer instructions for the period of reference.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure that the Dermatophyte Test Medium (DTM) Agar flasks were not expired before using it for patient testing from 05/12/2022 to 08/08/2022 in 33 patients. Findings include: - Review of DTM Agar lot records for 2021 and 2022 revealed that, the lot number 495893 with expiration date 05/11/2022 was used from 03/03/2022 to 08/08/2022 and lot number 504247 with expiration date 10/01/2022 was used from 08/15/2022 to 09/30/2022. -Patient log review revealed that the laboratory tested 33 patients with the expired lot 495893 in the following dates: -One patient tested: 05/17/2022, 05/24/2022, 06/01/2022, 06/03/2022, 06/07/2022, 06/13/2022, 06/17/2022, 06/28/2022, 07/07/2022, 07/19/2022, 07/20/2022, 07/21/2022, 07/27/2022, 07/29/2022, 08/01/2022, 08/03/2022, 08/05/2022 and 08/09/2022. -Two patients tested: 05/16/2022, 05/19/2022, 05/31/2022, 07/25/2022, 07/26/2022 and 08/02/2022. -Three patients tested: 05/12/2022. During an interview on 10/03/2022 at 11:05 AM, the Laboratory Director confirmed that the laboratory tested 33 patients with the expired DTM Agar media.