

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2231269	<b>(X3) Date Survey Completed</b>  09/13/2022
<b>Name of Provider or Supplier</b>  Inti Fernandez Md At Mia, Inc	<b>Street Address, City, State</b>  2100 Nw 42nd Ave, 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 initial certification survey conducted at INTI FERNANDEZ MD AT MIA, INC from 09/07/2022 to 09/13/2022 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<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 supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure that the real time isothermal ID NOW COVID-19 test kit was not expired before using it for patient testing. The laboratory tested 39 patients with the expired test kit. Findings Include: During laboratory tour on 09/07/2022 at 01:30 PM, the surveyor found in the testing area two boxes in use of an expired ID NOW COVID-19 test kit from abbot for the detection of SARS-CoV-2, with lot number 1049071 an expiration date of 07/18/2022. Record review of patients tested from 07/19/2022 to 09/07/2022 revealed the following tests performed: -One test on 07/19/2022, 07/25/2022, 07/27/2022, 08/06/2022, 08/07/2022, 08/11/2022, 08/12/2022, 08/14/2022, 08/16/2022, 08/21/2022, 08/29/2022, 08/31/2022. -two tests on 08/01/2022. -three tests on 07/23/2022, 09/02/2022. -four tests on 08/28/2022. -five tests on 07/31/2022. -ten tests on 07/24/2022. For a total of 39 test. During a telephone call on 09/13/2022 at 3:00 PM with laboratory director, he confirmed that the laboratory performed the 39 tests with the expired kits.</p>