

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0279395	(X3) Date Survey Completed 12/11/2024
Name of Provider or Supplier Uhealth Pathology At Mailman	Street Address, City, State 1601 Nw 12th Ave Room 7002, Miami, 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 was conducted from 12/09/2024 to 12/11/2024. UHEALTH PATHOLOGY AT MAILMAN clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on random patient reports review and staff interview, the laboratory failed to ensure that the patient report listed the name and address of the laboratory that performed the technical component (TC) for the test to detect level of O6-methylguanine-DNA methyl-transferase (MGMT) Methylation Promoter for two out of two patients reviewed. Findings included: 1--Review of validation method for MGMT Methylation Promoter level test revealed that was signed by the Laboratory Director on 01/16/2024. 2-Review of two final patient reports: P#1(dated 04/04/2024), and P#2 (dated 11/22/2024), revealed that the reports of the MGMT Methylation Promoter test failed to list the name and address of the laboratory that performed the TC for the test of reference. 3-During an interview on 12/11/2024 at 01:30 PM, with the laboratory manager, he confirmed that the final reports reviewed did not include the name and address of the laboratory that performed the TC for MGMT Methylation Promoter test and that the laboratory had reported 75 tests since the test was validated.</p>